



Food Safety Code: Dietary Supplement Manufacturing

Edition 9



About SQFI

SQFI is a division of FMI, established to administer the SQF Program, a leading, global food safety, and quality certification and management system. Our mission is to deliver consistent, globally-recognized food safety and quality certification programs based on sound scientific principles, applied across all industry sectors and valued by all stakeholders. www.sqfi.com

About FMI

As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain – from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services – to amplify the collective work of the industry. www.fmi.org

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FMI

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For permission contact FMI at www.fmi.org, or 2345 Crystal Drive, Suite 800, Arlington, VA, 22202, USA. Care should be taken to ensure current edition of the Code is used and that material be updated whenever the Code is amended or revised. The date of the Code should be clearly identified in materials.

First Printed May 1995.

SQF Code, Edition 9 improvement suggestions are encouraged from all parties. Written comments should be sent to SQFI at 2345 Crystal Drive, Suite 800, Arlington, VA, 22202, USA.

SQFI

One World. One Standard.

Globalization has revolutionized the food supply chain. This globalization has brought many companies a whole world of opportunities but also more risks. Consumers and retailers are demanding the highest levels of safety, quality, and responsibility from companies. They expect companies to follow all the stringent industry and regulatory standards. The SQF (Safe Quality Food) Institute is your trusted partner to achieve universal recognition of the safety and quality of your products, services, and processes.

At SQFI, our goal is always food safety and quality – and we are dedicated to writing a rigorous standard and developing comprehensive training, cohesive guidance materials, and free educational resources to help you along the way. Success does not happen in a vacuum, and neither does food safety. Together, we can help to build a safer supply chain, one food producer at a time.

SQF Code Edition 9

SQFI has updated the SQF Code from Edition 8.1 to Edition 9 to:

1. Consolidate requirements to create a simpler, more streamlined experience without a negative impact on standard integrity.
2. Meet updated GFSI requirements for implementation beyond 2020.

SQF Edition 9 comes with several enhancements and improvements to the Code structure, methodology, and technical requirements. From dietary supplements to pet food, several primary and manufacturing industries now have dedicated Codes to provide a more specific set of requirements and risk assessment for each.

All enhancements made to the SQF Codes are to build a better overall audit experience that adds even more value to SQF certification.

The SQFI Commitment

SQF certification assesses and assures the implementation of a site's food safety and quality plan and confirms the site has the necessary tools and training to manage food safety and quality.

A site's achievement of SQF food safety certification indicates a commitment to:

1. Produce safe, quality food.
2. Comply with the requirements of the SQF Code.
3. Comply with applicable food legislation.

By implementing an SQF Food Safety Management System, sites become equipped to address a buyer's food safety and quality requirements. The SQF Code provides a solution for businesses supplying local and global food markets. Products produced and manufactured via the SQF Code certification process retain a high degree of acceptance in global markets, benefiting both certified sites and their customers.

About the SQF Program

The SQF Program was first developed in Australia in 1995 and has been owned and managed by FMI, The Food Industry Association, since 2003. In 2004, GFSI first recognized our standard as one that meets its benchmark requirements.

SQFI Vision

To be the single most trusted source for global food safety and quality certification.

SQFI Mission

Our mission is to deliver consistent, globally-recognized food safety and quality certification programs based on sound scientific principles, applied across all industry sectors and valued by all stakeholders.

Contact SQFI

At SQFI, we incorporate retailer and stakeholder feedback to address the many global food safety, and quality issues society faces every day. We recognize pursuing a certification program for your business is a big commitment – regardless of your food safety and quality experience levels.

Visit www.sqfi.com for the SQF certified site directory, SQF guidance, tip sheets and checklists, training opportunities, tools to find a certification body and to register in the SQFI assessment database.

The SQFI assessment database is an audit management and data capture solution developed to contain costs and improve the efficiency and effectiveness of food safety audits. This innovative technology represents significant progress in how audit data is captured, managed and made available, and sets the SQF program apart from other similar GFSI programs.

Customer Service – info@sqfi.com | 202-220-0635 | 1-877-277-2635

Database Assistance – info@sqfi.com

Compliance – compliance@sqfi.com

Disclaimers

Certification of a site's SQF System by a Safe Quality Food Institute licensed certifying body does not guarantee a site's product safety or constant adherence to all food safety regulations.

This reference document is published in English and is available in several other languages. If the translated content differs, the original English version is to be referenced for final interpretation.

Feel free to use the Glossary included in the Appendix for further context and clarification of terminology used in this document.

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Part



Implementing and Maintaining the SQF Food Safety Code: Dietary Supplements Manufacturing

A1: Food Sector Categories in This Code

FOOD SECTOR CATEGORY	APPLICABLE GMP MODULES
 31 Dietary Supplements Manufacturing	Module 17: GMP for Processing of Dietary Supplements

The Safe Quality Food Institute (SQFI) publishes a suite of globally recognized food safety and quality codes that cover all aspects of the food supply chain from primary production through to retail and foodservice. All standards are available free of charge at www.sqfi.com.

Before embarking on the SQF journey, sites are encouraged to download and review the SQF code that best fits their needs.

Food Safety Fundamentals

SQF Fundamentals for Primary Production – Basic	All Primary food sector categories (FSCs)
SQF Fundamentals for Primary Production – Intermediate	All Primary food sector categories (FSCs)
SQF Fundamentals for Manufacturing – Basic	All Manufacturing and Storage and Distribution food sector categories (FSCs)
SQF Fundamentals for Manufacturing – Intermediate	All Manufacturing and Storage and Distribution food sector categories (FSCs)

HACCP-based Food Safety Codes

*Denotes SQF Food Safety Codes that are GFSI benchmarked

Primary Production	
The SQF Food Safety Code: Primary Animal Production*	FSC 1: Production, Capture, and Harvesting of Livestock and Game Animals, and Apiculture
The SQF Food Safety Code: Primary Plant Production*	FSC 2: Indoor Growing and Harvesting of Fresh Produce and Sprouted Seed Crops (NEW!) FSC 3: Growing and Production of Fresh Produce and Nuts FSC 4: Fresh Produce, Grain, and Nut Packhouse Operations FSC 5: Extensive Broad Acre Agricultural Operations
The SQF Food Safety Code: Aquaculture	FSC 6: Intensive Farming of Seafood

PART A: Implementing and Maintaining the SQF Food Safety Code: Dietary Supplements Manufacturing

Manufacturing	
The SQF Food Safety Code: Food Manufacturing*	FSC 10: Dairy Food Processing FSC 11: Honey Processing FSC 12: Egg Processing FSC 13: Bakery and Snack Food Processing FSC 14: Fruit, Vegetable, and Nut Processing, and Fruit Juices FSC 15: Canning, UHT, and Aseptic Operations FSC 16: Ice, Drink, and Beverage Processing FSC 17: Confectionery Manufacturing FSC 18: Preserved Foods Manufacturing FSC 19: Food Ingredient Manufacturing FSC 20: Recipe Meals Manufacturing FSC 21: Oils, Fats, and the Manufacturing of Oil or Fat-based Spreads FSC 22: Processing of Cereal Grains FSC 25: Repackaging of Product Not Manufactured On-site FSC 33: Food Processing Aides Manufacturing
The SQF Food Safety Code: Animal Product Manufacturing*	FSC 7: Slaughtering, Boning, and Butchery FSC 8: Manufactured Meats and Poultry FSC 9: Seafood Processing
The SQF Food Safety Code: Dietary Supplements Manufacturing*	FSC 31: Dietary Supplements Manufacturing
The SQF Food Safety Code: Pet Food Manufacturing*	FSC 32: Pet Food Manufacturing
The SQF Food Safety Code: Animal Feed Manufacturing*	FSC 34: Animal Feed Manufacturing
Food Packaging	
The SQF Food Safety Code: Manufacture of Food Packaging*	FSC 27: Manufacture of Food Packaging
Storage and Distribution	
The SQF Food Safety Code: Storage and Distribution*	FSC 26: Storage and Distribution
Retail	
The SQF Food Safety Code: Food Retail	FSC 24: Food Retailing
Foodservice	
The SQF Food Safety Code: Foodservice	FSC 23: Food Catering and Foodservice

HACCP-based Food Quality

Quality	
The SQF Quality Code	Applies to all GFSI-recognized and equivalent standards and other Food Safety Management Standards including HACCP certification and ISO 22000

A2: Steps to Achieving SQF Certification (steps 1 – 10)

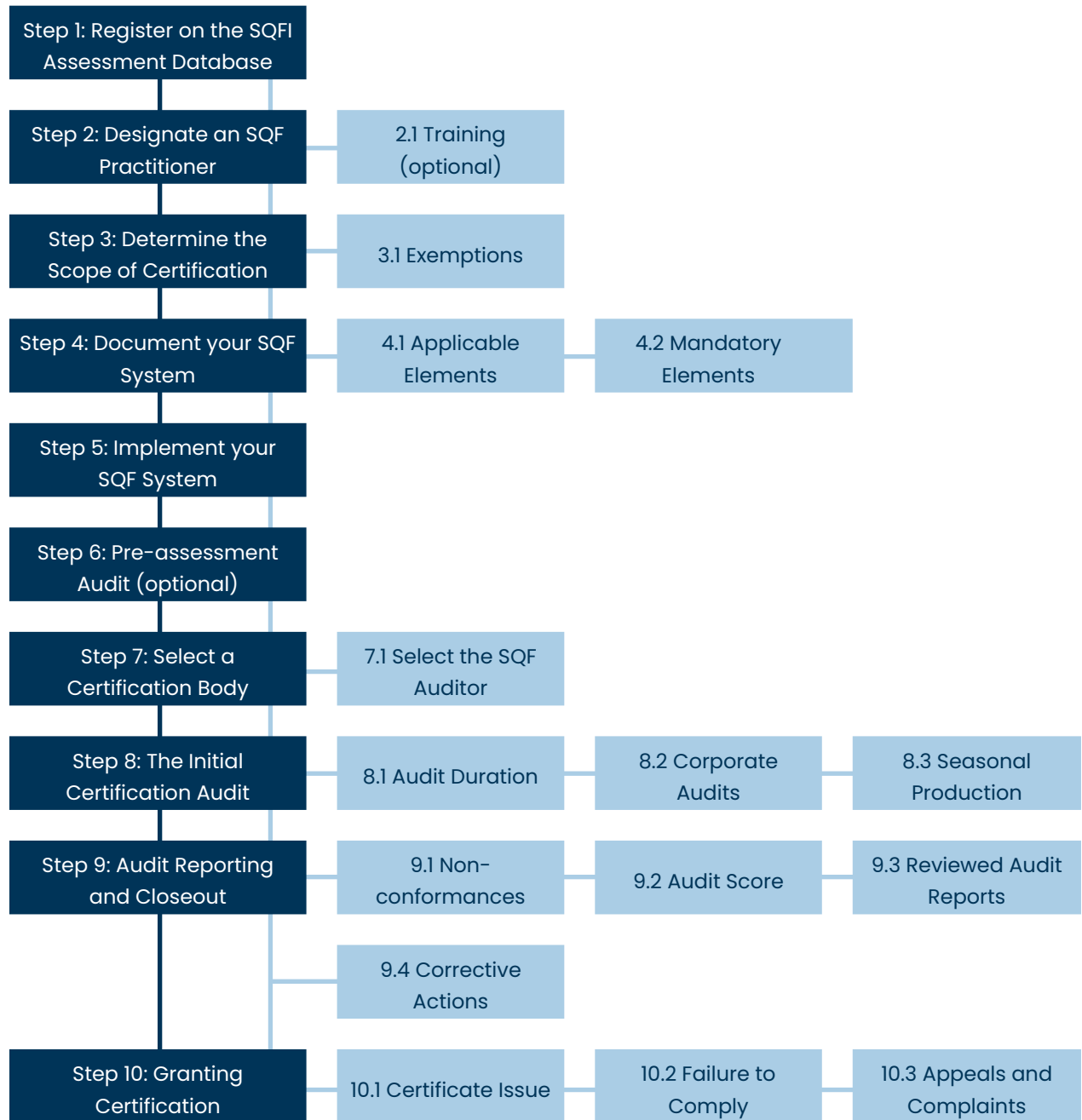
The SQF Food Safety Code: Dietary Supplements Manufacturing sets out the implementation, maintenance, and technical requirements for sites involved in the manufacture, blending, transport, and storage of dietary supplements including vitamins, probiotics, and label supplements.

- Part A (this part) sets out the steps you need to take to implement and maintain certification to the SQF Food Safety Code: Dietary Supplements Manufacturing, and
- Part B is the auditable standard. It details the SQF System elements that must be met (module 2) and the relevant Good Manufacturing Practices (GMP) for the manufacture of dietary supplements (module 17).

If you are in a site management or technical role and are responsible for implementing the requirements of the SQF Food Safety Code: Dietary Supplements Manufacturing, you can learn how to get started and implement your SQF System in several ways.

- SQFI has an online “Implementing SQF Systems” training course, which can be accessed from sqfi.com. It is a web-based education tool where you can enroll and complete SQF Systems training in your own time and at your own pace.
- An “Implementing SQF Systems” training course is available through the SQFI network of licensed training centers. Details about the training centers and the countries in which they operate are available at sqfi.com.
- Although training is recommended, you can train yourself by downloading the SQF Food Safety Code: Dietary Supplements Manufacturing from sqfi.com free of charge and applying it to your industry sector, site, and processes.
- Your management may choose to utilize the services of a registered SQF consultant. All SQF consultants are registered by SQFI to work in specific food sector categories (FSCs) and are issued with an identification card indicating the FSCs in which they are registered. The criteria outlining the requirements necessary to qualify as an SQF consultant and the application forms are available at sqfi.com. The SQF Consultant Code of Conduct outlines the practices expected of SQF consultants.
- Guidance documents are available for some SQF Codes and FSCs from sqfi.com. These documents can help you interpret the requirements of the SQF Codes and assist with documenting and implementing an SQF System. The documents are developed with the assistance of food sector technical experts. The guidance documents are available to assist you but are not auditable documents. Where there is a divergence between the guidance document and the SQF Food Safety Code: Dietary Supplements Manufacturing, the SQF Code prevails.

The steps in achieving SQF certification are as follows:



Step 1: Register on the SQFI Assessment Database

To be considered for SQF certification, you are required to register your site on the SQFI assessment database. The database can be accessed at sqfi.com.

There is a fee for each site, payable at registration and annual renewal. The fee scale is dependent on the size of the site, as determined by gross annual sales revenue and by industry sector. The fee scale is available at sqfi.com.

You need to register your site with SQFI prior to the start of the initial certification audit and remain registered at all times to retain your site certification. If you do not maintain registration, the site certificate will be invalid until the site is properly registered on the SQFI assessment database.

Step 2: Designate an SQF Practitioner

The SQF Food Safety Code: Dietary Supplements Manufacturing requires that every certified site has a suitably qualified SQF practitioner to oversee the development, implementation, review, and maintenance of the SQF System, including the system elements, Good Manufacturing Practices (GMPs), and food safety plans. The requirements for an SQF practitioner are described in the system elements, Part B: 2.1.1.4 and 2.1.1.5.

You may choose to have more than one SQF practitioner to meet shift and operational requirements.

An alternative staff member should also be identified to manage the SQF System in the absence of the designated SQF practitioner.

2.1 Training (optional)

An “Implementing SQF Systems” training course is available online and through the SQFI network of licensed training centers. SQF practitioners who are responsible for designing, implementing, and maintaining the requirements of the SQF Food Safety Code: Dietary Supplements Manufacturing are encouraged to participate in a training course. The “Implementing SQF Systems” training course is not mandatory for SQF practitioners but is strongly recommended.

Details of the training courses are available at sqfi.com

SQF practitioners are required to successfully complete HACCP training that is a minimum two-day duration and assessed.

Training in other food industry disciplines, Good Manufacturing Practices (GMP) and Internal Auditing may also be beneficial, and licensed SQF training centers can provide details about the other training courses they provide.

Step 3: Determine the Scope of Certification

Before implementing the SQF Code, you must decide the scope of certification – in other words, the food sector categories, products, and processes to be included in your SQF System.

The scope of certification determines which elements of the SQF Food Safety Code: Dietary Supplements Manufacturing are to be documented and implemented and will be audited by the certification body. The scope needs to be agreed between your site and the certification body before the initial certification audit and cannot be changed during or immediately following a certification or re-certification audit.

The scope of certification specifies:

- **The site.** SQF certification is site specific. The entire site, including all premises, support buildings, silos, tanks, loading and unloading bays, and external grounds are identified and included in the scope of certification.

If activities are carried out in different premises but are overseen by the same senior, operational, and technical management and are covered by the one SQF System, the site can be expanded to include those premises.

- **Food sector categories (FSCs).** SQFI has a list of food sector categories to classify product groups and ensure that the auditor who audits your site has the requisite knowledge and skills. The SQF food sector categories, or FSCs, are aligned with GFSI industry sectors. A full list of food sector categories for all SQF Food Safety Codes is provided in Appendix 1. The FSC that applies to the SQF Food Safety Code: Dietary Supplements Manufacturing is FSC 31 Dietary Supplements Manufacturing.

- **The products.** SQF certification is product specific. Within each applicable food sector category, you need to identify the products that are included in your SQF System. The manufacture of all listed products will be audited for compliance to SQF and will be listed on the certificate of compliance unless you request an exemption (refer to Part A 3.1).

For requirements on changing the scope of certification, refer to Part 4.1

3.1 Exemptions

If you wish to exempt any products processed or handled on-site or part of the premises, the request for exemption needs to be submitted to the certification body in writing prior to the certification audit, detailing the reason for exemption.

If approved by the certification body, exemptions are listed in the site description in the SQFI assessment database and in audit reports. However, all parts of the premises and processes that are involved with the production, processing, and storage of products included in the scope cannot be exempted.

Exempted products and parts of the site cannot be promoted as being covered by the certification. Instances where the promotion of exempted products, equipment, or areas of the site are identified and substantiated (either through the regular audit or by other means) will result in the immediate withdrawal of the SQF certification.

You need to demonstrate that exempted parts of the site, processes, or products do not put certificated products at food safety risk.

Step 4: Document Your SQF System

To achieve SQF food safety certification, you need to document and implement the system elements (module 2) and the relevant GMP requirements (module 17) of the SQF Food Safety Code: Dietary Supplement Manufacturing. This is a two-stage process:

First, you need to prepare the policies, procedures, work instructions, and specifications that meet the system elements and GMP modules of the SQF Food Safety Code for Food Manufacturing. In other words, “Say what you do.”

4.1 Applicable Elements

The auditable requirements of the SQF Food Safety Code: Dietary Supplements Manufacturing are described in the following hierarchy:

- Module, Module 2 (system elements) and Module 17 (GMP requirements)
- Section, e.g., 2.1, 2.2, 2.3 etc.
- Clause, e.g., 2.1.1, 2.1.2, 2.1.3, etc.
- Element, e.g., 2.1.1.1, 2.1.1.2, 2.1.1.3, etc.

The applicable elements are the elements of the relevant SQF Food Safety Code that must be documented and implemented to assure the safety of products within the scope of certification. Not all elements are applicable. There may be some sections or clauses that do not apply to your site.

All applicable system elements and GMP requirements are assessed during the certification audit.

Where an element is not applicable and this can be appropriately justified, it is stated as “not applicable” or “N/A” by the SQF food safety auditor in the audit report.

4.2 Mandatory Clauses

Mandatory clauses are requirements within module 2 – system elements that must be documented, implemented, and audited for a site to achieve SQF certification; system elements that cannot be exempted during a certification or–certification audit.

Mandatory elements cannot be reported as “not applicable” or “exempt” and must be audited and compliance/non-compliance reported.

Mandatory elements are designated with “Mandatory” in the system elements in the SQF Food Safety Code: Dietary Supplement Manufacturing. They are:

2.1.1	Management Responsibility	2.5.1	Validation and Effectiveness
2.1.2	Management Review	2.5.2	Verification Activities
2.1.3	Complaint Management	2.5.3	Corrective and Preventative Action
2.2.1	Food Safety Management System	2.5.4	Internal Audits and Inspections
2.2.2	Document Control	2.6.1	Product Identification
2.2.3	Records	2.6.2	Product Trace
2.3.4	Approved Supplier Program	2.6.3	Product Withdrawal and Recall
2.4.1	Food Legislation	2.7.1	Food Defense Plan
2.4.2	Good Manufacturing Practices	2.7.2	Food Fraud
2.4.3	Food Safety Plan	2.8.1	Allergen Management
2.4.7	Product Release	2.9.2	Training Program

Step 5: Implement Your SQF System

Once you are satisfied that the policies, procedures, work instructions, and specifications are in place to meet the SQF requirements, you need to make sure that all documents are being followed and records are being kept demonstrating compliance to the relevant modules of the SQF Food Safety Code for Food Manufacturing.

In other words, “Do what you say.” SQFI recommends that a minimum of ninety (90) days of records is available before a site audit is conducted.

Step 6: Pre-assessment Audit (optional)

A pre-assessment audit is not mandatory but is suggested as a way to provide a “health check” of the site’s implemented SQF Food Safety System. A pre-assessment audit may include an on-site or off-site review of your documentation and can assist in identifying gaps in your site’s SQF Food Safety System so that corrective action can occur before engaging the selected certification body for a full certification audit.

The pre-assessment audit can be conducted using a variety of means, such as internal resources, a registered SQF consultant, or a registered SQF food safety auditor.

Step 7: Select a Certification Body

Certification bodies are licensed by SQFI to conduct SQF audits and issue SQF certificates. SQFI-licensed certification bodies are accredited to the international standard ISO/IEC 17065:2012 (or subsequent versions as applicable) and are subject to annual assessments of their certification activities by SQFI-licensed accreditation bodies.

Your site needs to have an agreement with a certification body in place at all times, which outlines the agreed SQF certification services to be provided. At a minimum, these include:

- The scope of certification (refer to step 3) including any approved exemptions;
- The expected audit duration and the reporting requirements;
- The certification body's fees structure, including audit costs, travel time and expenses, report writing, ancillary costs, and costs for close-out of non-conformances;
- The conditions under which the SQF certificate is issued, withdrawn, or suspended;
- The certification body's appeals and complaints process, and
- The availability of auditor(s) for the site's FSC(s).

A list of licensed certification bodies that operate in your region or country is available at sqfi.com. Certification bodies are also listed in the SQFI assessment database, and you can request a quote or select a certification body online once you have registered (refer to Part A, step 1).

7.1 Select the SQF Auditor

The SQF food safety auditor is selected by the certification body. The auditor is required to be employed by or contracted to the certification body and registered with SQFI for the same food sector category(ies) as the site's scope of certification (refer to Part A, step 3). In the event the SQF auditor does not have the required food sector category(ies), a technical expert may be used to assist the registered SQF food safety auditor (refer to Part A, 15.7).

The certification body is required to ensure that no SQF food safety auditor conducts audits of the same site for more than three (3) consecutive certification cycles.

The certification body has to advise you of the name of the SQF food safety auditor at the time that the SQF audit is scheduled (except for unannounced audits). You can check the registration and food sector category(ies) of the SQF food safety auditor at sqfi.com.

An SQF food safety auditor cannot audit a site where he/she has participated in a consulting role or has a conflict of interest with anyone at the site within the last two (2) years. You can refuse the service of an SQF food safety auditor if you think the auditor has a conflict of interest, or for other reasons. In such circumstances, you need to outline the reasons in writing to the certification body.

Step 8: The Initial Certification Audit

An SQF audit of the SQF Food Safety Code: Dietary Supplements Manufacturing is an assessment by a qualified and registered SQF food safety auditor (or audit team) to ensure that your documentation (refer to step 4) complies with the SQF Code and that your food safety, hygiene, and management activities are carried out according with your documented policies, procedures, and specifications. A full definition of the SQF audit is in Appendix 2: Glossary.

Once the audit scope (refer to step 3) is agreed with your certification body, it cannot be changed after the audit has started.

The initial certification audit is conducted by the SQF food safety auditor(s) appointed by the certification body. Part of the audit may be conducted remotely using information and communication technology (ICT), but at least half of the allocated audit duration must be on-site. Remote activities can only be conducted by agreement between you and your certification body and are dependent on your ICT capability and information security requirements.

The off-site and on-site parts are conducted at a time agreed between you and the certification body, and the on-site component only when the main processes are operating.

Activities that may be conducted during the remote part of the audit process include:

- Review of qualifications of the SQF practitioner(s) and the food safety (HACCP) team;
- Review of policies, procedures, food safety plans, work instructions, and registers/listings;
- Interviews with key personnel;
- Food safety plans, HACCP programs, and food safety management personnel;
- Review of internal audits, corrective actions, complaints, recalls;
- Traceability and mock recall exercise;
- Threat and vulnerability assessments for food defense and food fraud programs.

On-site activities may include the following, as appropriate:

- Follow-up on disputed documents and records from the remote activities;
- Follow-up on interviews and observation of work procedures;
- The implementation of the food safety plan(s) and Good Manufacturing Practices; and
- Verification that the food safety management system, including HACCP, addresses all products, processes, and facilities included within the certification scope.

Remote activities do not apply to unannounced audits (refer to 11.4.)

8.1 Audit Duration

The audit duration is the expected total time that is required for the SQF auditor to complete the assessment of the SQF System. It may or may not include the time necessary for report writing. You should confirm with your certification body the fees for the audit, including report writing time.

The minimum duration for a certification or re-certification audit is two days, including both remote and on-site activities (refer to step 8).

The audit duration is calculated by the certification body based on the size of the facility, the number of employees, the complexity of your processes, and the food safety risk. The certification body will discuss and agree on the audit duration with you to ensure complete coverage of your SQF System.

Factors that can impact on the audit duration include:

- The scope of the audit;
- The size of the site and the design of product flow and staff movement;
- The number and complexity of product lines and the overall process;
- Whether the product is high or low-risk;
- The complexity of the SQF System design and documentation;
- The level of mechanization and labor intensiveness;
- The ease of communication with company personnel (e.g., different languages spoken within the site)

The certification body is required to document the justification for the audit duration in their agreement with you.

8.2 Corporate Audits

If your site is part of a larger corporation and some food safety functions are conducted at a corporate head office (i.e., an office that does not process or handle products), an optional corporate audit of the Code elements managed by that office can be conducted by the certification body. This part of the assessment may also be conducted remotely using ICT.

The decision on whether a separate corporate audit should be conducted is made by agreement between the certification body and the corporation and communicated by the corporate office to SQF-certified sites managed by the corporate office.

When a corporate audit is conducted, the audit evidence shall be reviewed and all identified corporate non-conformances must be closed out before the site audits are conducted. Any open non-conformances, which are not closed out, are attributed to the site or sites.

The SQF food safety auditor audits the application of the corporate functions relative to the site's scope of certification during the audit of each site managed by the corporate office. All mandatory and applicable elements of the SQF Food Safety Code: Dietary Supplements Manufacturing are audited at each site regardless of the findings of the corporate audit.

8.3 Seasonal Production

If your site is involved in seasonal production (i.e., the major production activities are conducted over a shorter time duration that does not exceed more than five consecutive months in any calendar year), your initial certification audit will need to be conducted during the peak operational part of the season (i.e., when your processes are operating).

If you are seeking to include products from more than one season within your scope of certification, you need to agree with the certification body that it will conduct the initial certification audit during the highest risk and/or highest volume production operation.

Documentation and records for other seasonal production are reviewed as part of the certification audit.

Step 9: Audit Reporting and Closeout

The SQF food safety auditor(s) reviews your documentation and the effective implementation of your documented policies, procedures, and specifications. The auditor(s) collects evidence of compliance or non-compliance against all mandatory and applicable elements of the SQF code by reviewing documentation and records, interviews with key staff, and observation of operational and cleaning activities.

The on-site activities include the entire site, including the interior and exterior of the buildings, regardless of the scope of certification and agreed exemptions. The site audit includes a review of all operational and cleaning shifts and pre-operational inspections, where applicable.

When remote audit activities are used, SQFI expects that the auditor will spend 80% of on-site audit time making observations and conducting interviews.

9.1 Non-conformances

Where the SQF food safety auditor(s) find deviations from the requirements of relevant modules of the SQF Food Safety Code: Dietary Supplements Manufacturing, the SQF food safety auditor(s) advises you of the number, description, and extent of the non-conformances. Non-conformances are also referred to as non-conformities.

Non-conformances against the SQF Food Safety Code: Dietary Supplements Manufacturing are graded as follows:

- A minor non-conformance is evidence of a random or infrequent failure to maintain compliance with a requirement, but does not indicate a breakdown in the food safety management system or that food safety is compromised. It is evidence of an incomplete or inappropriate implementation of SQF requirements, which, if not corrected, could lead to system element breakdown.

- A major non-conformance is a failure of a system element, a systemic breakdown in the food safety management system, a serious deviation from the requirements, and/or absence of evidence demonstrating compliance to an applicable system element or Good Manufacturing Practices. It is evidence of a food safety risk to products included in the scope of certification.
- A critical non-conformance is a breakdown of control(s) at a critical control point, a prerequisite program, or other process steps and judged likely to cause a significant public health risk and/or product contamination.

A critical non-conformance is also raised if the certification body deems that there is systemic falsification of records relating to food safety controls and the SQF System.

If the SQF food safety auditor considers that a critical non-conformance exists during a certification audit, the SQF food safety auditor is required to immediately advise you and notify the certification body.

A critical non-conformance raised at an initial certification audit results in an automatic failure of the audit, and your site is required to re-apply for certification (refer to 10.2.).

9.2 Audit Score

Based on the evidence collected by the SQF food safety auditor, each applicable clause of the SQF certification food safety audit is automatically scored in the audit report.

The score is based on the following factors:

0 - aspect meets the criteria

1 - aspect does not meet the criteria due to minor variations (minor non-conformance)

5 - aspect does not meet the criteria (major non-conformance)

50 - aspect does not meet the criteria (critical non-conformance)

A single rating is calculated for your site audit as $(100 - N)$ where N is the sum of the individual rating criteria allocated. The rating provides an indication of the overall condition of your site against the SQF Food Safety Code: Dietary Supplements Manufacturing and provides a guideline on the required level of surveillance by the certification body. The audit frequency at each rating level is indicated as follows:

Score	Rating	Certification ¹	Audit Frequency
96 - 100	E - Excellent	Certificate issued	12 monthly re-certification audit
86 - 95	G - Good	Certificate issued	12 monthly re-certification audit
70 - 85	C - Complies	Certificate issued	6 monthly surveillance audit
0 - 69	F - Fails to comply	No certificate issued	Considered to have failed the SQF audit

9.3 Reviewed Audit Report

SQFI provides the certification body with the electronic audit checklist to be used by SQF food safety auditors when conducting your SQF food safety audit. It is available on the SQFI assessment database and is customized by the SQF industry sector. The checklist used for your audit is specific to your site.

The SQF checklist is designed to ensure the uniform application of SQF food safety audit requirements. It is used by SQF food safety auditors to record their findings and determine the extent to which your site operations comply with SQF requirements.

The audit report is in draft form and the audit evidence is only recommended until technically reviewed and approved by the authorized certification manager of the certification body.

SQFI requires that:

- The food safety auditor must report (compliant/non-compliant) on all mandatory elements (refer to 4.2) for the SQF food safety audit report to be submitted.
- Non-conformances (refer to 9.1) identified during the site audit need to be accurately described in the SQF food safety audit report and include the element of the SQF Food Safety Code: Dietary Supplements Manufacturing and the reason for the non-conformance.
- The SQF food safety auditor is required to report all non-conformances to you before the close of the site audit.
- The draft audit report is completed by the SQF auditor and provided to the certification body for technical review.
- The certification body reviews and approves the audit evidence record and makes it available to you within ten (10) calendar days from the last day of the audit.

9.4 Corrective Actions

You need to take appropriate corrective action for every non-conformance identified by the SQF food safety auditor. Corrective action is the action you take to eliminate the cause of a detected non-conformance to prevent its recurrence (a full definition is in Appendix 2: Glossary).

Evidence of your corrective actions is required to be sent to the SQF food safety auditor so that it can be verified and closed out within thirty (30) calendar days of the completion of your site audit.

If you fail to submit corrective actions, or the SQF food safety auditor does not verify your corrective actions within thirty days, the certification body is unable to certify your site, and you are required to re-apply for certification (refer to 10.2).

- **Minor non-conformances** (refer to 9.1) are required to be closed out in the SQFI assessment database within thirty (30) calendar days of the completion of the site audit. The certification body can grant additional time for close-out where there is no immediate threat to product safety and alternative temporary methods of control are initiated. Your site is advised of the extended time frame.

Where additional time is granted, the non-conformance is still closed out in the SQFI assessment database and the SQF food safety auditor documents all details of justification of the extension, how the risk is being controlled, and the agreed completion date.

A documented root cause analysis is required as part of the corrective action evidence for every minor non-conformance.

- **Major non-conformances** (refer to 9.1) are also required to be closed out in the SQFI assessment database within thirty (30) calendar days of the completion of the site audit. A documented root cause analysis is required as part of the corrective action evidence for every major non-conformance.

If the corrective action involves structural change or cannot be corrected due to seasonal conditions or installation lead times, additional time can be granted provided the corrective action time frame is acceptable to the certification body and temporary action is taken by your site to mitigate the risk to product safety.

In such cases, the non-conformance is closed out and the SQF food safety auditor documents all details of justification of the extension, how the risk is being controlled, and the agreed completion date.

Step 10: Granting Certification

The certification body makes the certification decision based on the evidence of compliance and non-compliance recommended by the SQF food safety auditor during the SQF audit. Although SQFI provides guidance on certification, the certification body is responsible for deciding if certification is justified and granted, based on the objective evidence provided by the SQF food safety auditor.

Any certification decisions that are made outside the scope of this clause require the certification body to provide written justification to SQFI.

The final audit report with completed and approved corrective actions is made available to the site before the final certification decision is made. The SQF food safety audit report is the property of the site and cannot be distributed to other parties without your site's permission.

Certification of the SQF System is awarded to sites that achieve a "C - complies" audit rating or greater with no outstanding non-conformances. Your certification body makes the certification decision no more than forty-five (45) calendar days from the last day of the site audit. Once SQF certification is granted, the SQFI issues a unique certification number, which is specific to that site.

10.1 Certificate Issue

Within ten (10) calendar days of granting certification, the certification body provides you with an electronic and/or hard copy of your site's certificate. The certificate is valid for seventy-five (75) days beyond the anniversary of the initial certification audit date.

The certificate remains the property of the certification body and can be in a form designed by the certification body, but it must include the following information:

- The name and address of your site as listed on the SQFI assessment database;
- The name, address, and logo of the certification body;
- The logo of the accreditation body and the certification body's accreditation number;
- The heading "certificate";
- The phrase "(site name) is registered as meeting the requirements of the SQF Food Safety Code: Dietary Supplements Manufacturing, Edition 9";
- The scope of registration – food sector category (FSC 31) and products;
- Dates of audit (last day), date of next re-certification audit, date of certification decision, and date of certificate expiry;
- Indication of unannounced re-certification audit (where applicable);
- Signatures of the authorized officer and issuing officer of the certification body; and
- The SQF logo

Certified site information is posted on sqfi.com.

Certificates are published in English. However, certified sites in non-English-speaking countries may require a certificate in a local language. SQFI allows the certification body to issue local language certificates on request as long as:

- The certificate information listed above is included;
- The certification body has a protocol in place for translation and can verify the translation; and
- An English and a translated copy of the certificate are uploaded to the SQFI assessment database and the accreditation body register.

10.2 Failure to Comply

If your site receives an "F – fails to comply" rating at an initial food safety certification audit or fails to correct identified non-conformances within the required time frame (refer to 9.4), your site is considered to have failed the SQF food safety audit and must then re-apply for another certification audit.

10.3 Appeals and Complaints

Your certification body needs to provide you with its documented procedure for handling and resolving appeals and complaints made by your site or by another party about your site.

Appeals. If you have reason to appeal a decision made by your SQF food safety auditor as a result of an audit or a decision taken by your certification body regarding your certification, you are required to lodge that appeal with your certification body. Your certification body is required to investigate and resolve this matter without delay and keep a record of all appeals and their resolution.

If the appeal cannot be satisfactorily resolved by the certification body, the matter is to be referred to SQFI via email to compliance@sqfi.com; however, this is only after the matter has been referred to the certification body and not satisfactorily resolved.

Appeals regarding decisions on the suspension and/or withdrawal of the SQF certification by a certification body do not delay the decision to suspend or withdraw the certification.

Complaints about the conduct or behavior of an SQF-registered auditor or other certification body personnel are to be lodged with the certification body, which is required to investigate and resolve the complaint without delay and keep a record of the resolution.

If the certification body receives a complaint about your site from other parties, the certification body is required to investigate and resolve the matter without delay and keep a record of the resolution.

If upon the investigation of a complaint, it is determined that there has been a substantiated breakdown of your site's SQF System or any other condition not in compliance with the SQF Food Safety Code: Dietary Supplements Manufacturing and/or other supporting documents, the certification body is required to suspend certification as outlined in step 14.

Complaints about SQFI, the SQF Codes, the SQFI assessment database, SQF training centers, and SQF professionals and unresolved complaints lodged with certification bodies can be referred to SQFI via email to compliance@sqfi.com.

A3: Maintaining Your SQF Certification (steps 11 – 15)

Step 11: Re-certification

To maintain your certification to the SQF Food Safety Code: Dietary Supplements Manufacturing, your site is required to attain a “C - complies” audit rating or greater at your certification and re-certification audits, ensure that surveillance and/or re-certification audits occur within the required time frame, ensure that no critical non-conformances are raised at surveillance or re-certification audits, and that all major and minor non-conformances are corrected within the time frame specified.

11.1 Re-certification Audits

Your site’s re-certification audit is conducted within thirty (30) calendar days either side of the anniversary of the last day of the initial certification audit. It is conducted to verify the continued effectiveness of your site’s SQF System.

As per the initial certification audit, part of the re-certification audit may be conducted remotely using ICT, but a minimum of 50% of the allocated audit duration must be on-site. Remote activities can only be conducted by agreement with your certification body and are dependent on your ICT capability and information security requirements. Examples of off-site and on-site activities are listed under Step 8: The Initial Certification Audit.

The re-certification audit score is calculated in the same way as the initial certification audit, and the same rating system is applied (refer to 9.2).

The purpose of the re-certification audit is to:

- Verify the continued efficacy of corrections and corrective actions closed out at your previous audits;
- Verify that your SQF Food Safety System continues to be implemented as documented;
- Verify that your internal audits, annual reviews of the crisis and food defense plans and recall system, and management reviews have been effectively completed;
- Verify that corrective and preventative actions have been taken on all non-conformities;
- Ensure you have taken appropriate action where changes to your site’s operations have been made that impact the site’s SQF Food Safety System;
- Verify all critical steps and the effective interactions among all elements of your SQF System remain under control;
- Verify the overall effectiveness of the SQF System in its entirety in light of changes within your operations;
- Verify that you continue to demonstrate a commitment to maintaining the effectiveness of your SQF System and to meeting regulatory and customer requirements; and
- Ensure contribution to the continued improvement of your site’s SQF System and business operation.

11.2 Variations from the Initial Certification Process

The requirements for the re-certification audit are the same as those described in step 8 for the initial certification audit, with the following exceptions:

- If your site fails to permit the re-certification audit within the agreed time frame, the certification body is required to immediately suspend your site's certificate.
- If your site receives an "F – fails to comply" rating at the re-certification audit, the certification body is required to immediately suspend your site's certificate.
- If your site fails to closeout non-conformities within thirty (30) days, the certification body is required to immediately suspend your site's certificate.

Refer to 15.1 for temporary or permanent changes of re-certification audit dates and certificate extensions.

11.3 Re-certification Audits – Seasonal Operations

The re-certification audit of seasonal operations follows the requirements of step 11.1. However, where there is a significant change in seasonal operations, whereby your re-certification audit's sixty (60) day window cannot be met, you can agree with your certification body to temporarily reset your re-certification audit date so that it falls during the peak operational part of the season.

If you wish to permanently change the re-certification audit date due to seasonal conditions, the request must be made in writing to the SQF Compliance Manager.

11.4 Unannounced Audits

The certification body is required to conduct an unannounced audit of your site once every three years. Your first three-year cycle commences with your initial certification audit date. Within the first three years of certification, you are required to have one unannounced audit. Thereafter, you will have an unannounced audit every three years.

The protocol for SQF unannounced re-certification audits is as follows:

- The unannounced food safety audit occurs within the sixty (60) day re-certification window (i.e., the anniversary date of the initial certification audit +/- thirty (30) days);
- If you change certification bodies, the site's unannounced re-certification audit schedule does not change;
- The initial unannounced audit year is determined between your site and the certification body. Thereafter, the unannounced audit is every three years;
- The date of the unannounced audit is determined by the certification body within the sixty (60) day re-certification audit window;
- A defined blackout period may be established by negotiation between your site and your certification body to prevent the unannounced re-certification audit from occurring out-of-season or when the site is not operating for legitimate business reasons;

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- Unannounced audits are on-site audits. Remote activities using ICT do not apply to unannounced audits;
- If you refuse entry to an SQF food safety auditor for an unannounced audit, the certification body is required to immediately suspend your certificate; and
- Certificates issued following unannounced re-certification audits indicate that the audit was unannounced (refer to 10.1).

Your site may forgo the three-year certification cycle and voluntarily elect to have annual unannounced re-certification audits. If annual unannounced re-certification audits are conducted at your site, then the protocol outlined for the three-year certification cycle audit is to be followed for each audit.

Sites with annual unannounced re-certification audits are recognized on the SQF certificate as an “SQFI Select Site.”

Step 12: Surveillance Audits

A surveillance audit is conducted if your site attains a “C – complies” rating at a certification audit or re-certification audit.

The surveillance audit is conducted within thirty (30) calendar days on either side of the six (6) month anniversary of the last day of the last certification or re-certification audit.

A new score and rating are issued at the surveillance audit, but the site’s re-certification audit date is not affected.

The surveillance audit is a full SQF System audit. In particular, the surveillance audit is intended to:

- Verify the continued efficacy of corrections and corrective actions closed out at your previous audits;
- Verify that your SQF System continues to be implemented as documented;
- Verify you have taken appropriate action where changes to your site’s operations have been made that impact on the site’s SQF Food Safety System;
- Confirm continued compliance with the requirements of the SQF Food Safety Code: Dietary Supplement Manufacturing;
- Verify all critical steps remain under control; and
- Contribute to continued improvement of your site’s SQF System and business operation.

Major or minor non-conformities raised at the surveillance audit are required to be closed out, as indicated in Part A, 9.4.

12.1 Surveillance Audit – Seasonal Operations

Seasonal operations occur at sites where the major production activities are conducted over a shorter time duration that does not exceed more than five consecutive months in any calendar year.

Seasonal operations that attain a “C – complies” rating at a certification or re-certification audit are required to have a surveillance audit.

Where the surveillance audit date falls within the operational season, your surveillance audit is required within thirty (30) days either side of the six (6) month anniversary of the last day of the previous certification or re-certification audit.

If the due date of your surveillance audit falls outside the operational season, then the certification body is required to conduct a pre-operational audit no less than thirty (30) days prior to the next season. The pre-operational audit comprises a full review of corrective actions from the last audit and preparedness for the next re-certification audit.

Step 13: Suspending Certification

The certification body is required to suspend your SQF certificate if your site:

- Fails to permit the re-certification or surveillance audit within the audit window;
- Fails to take corrective action within the time frame specified in 9.4;
- Fails to permit an unannounced audit or refuses entry to an SQF food safety auditor for an unannounced audit; or
- Receives an “F – fails to comply” rating at a surveillance or re-certification audit.

The certification body may also suspend certification if in the opinion of the food safety auditor and supported by the technical reviewer the site fails to maintain the requirements of the SQF Food Safety Code: Dietary Supplement Manufacturing.

13.1 Reporting Suspension

If your site’s certificate is suspended, the certification body immediately amends the site details on the SQFI assessment database to “suspended” status, indicating the reason for the suspension and the effective date. The certification body also:

- Informs your site in writing of the reasons for the action taken and the effective date. Acknowledgment of receipt of the suspension notification is required; and
- Notifies SQFI about the suspension using the online change and notification form 13.2 Corrective Action Following Suspension.

The following action is required, dependent on the reason for suspension:

IF	THEN
<p>i. Your site does not permit the re-certification or surveillance audit to occur within the audit window:</p>	<p>The certification body requests that within forty-eight (48) hours of receiving notice of the suspension you provide a plan detailing the justification for the delay and the time table for the rescheduled audit (must be no more than thirty (30) days from the audit window).</p> <p>The certification body conducts an announced on-site re-certification or surveillance audit (as applicable) within thirty (30) calendar days of receiving your corrective action plan.</p> <p>If your site successfully completes the SQF audit with an E, G, or C rating, the certification body reinstates your site status on the SQFI assessment database and provides you with written notice that your certificate is no longer suspended.</p> <p>Regardless of the rating and because the site failed to permit the re-certification audit in the designated time frame, the certification body conducts an additional unannounced surveillance audit no more than six (6) months after the suspension to verify continued compliance with the SQF Code.</p>
<p>ii. Your site does not take corrective action within the time frame specified:</p>	<p>The certification body requests that within forty-eight (48) hours of receiving notice of the suspension you provide a detailed plan outlining the corrective actions to be taken to resolve the outstanding non-conformances.</p> <p>The certification body verifies that the corrective action plan has been implemented through an on-site visit within thirty (30) calendar days of receiving your corrective action plan.</p> <p>When the corrective action plan has been successfully implemented, the certification body reinstates your site status on the SQFI assessment database and provides you with written notice that your certificate is no longer suspended.</p>
<p>iii. Your site does not permit an unannounced audit or refuses entry to an SQF food safety auditor for an unannounced audit:</p>	<p>The certification body requests that within forty-eight (48) hours of receiving notice of the suspension you provide a plan detailing the justification for the refusal to permit an unannounced audit and an agreement to proceed with an unannounced audit within the next thirty (30) days.</p> <p>The certification body conducts an on-site re-certification audit within thirty (30) calendar days of receipt of the site confirmation.</p> <p>If your site successfully completes the unannounced audit with an E, G, or C rating, the certification body reinstates your site status on the SQFI assessment database and provides you with written notice that your certificate is no longer suspended.</p> <p>Additionally, an unannounced surveillance audit is conducted no more than six (6) months after the above unannounced re-certification audit to verify continued compliance with the SQF System.</p>
<p>iv. Your site receives an “F – fails to comply” rating at a surveillance or re-certification audit:</p>	<p>The certification body requests that within forty-eight (48) hours of receiving notice of the suspension you provide a detailed plan outlining the corrective actions to be taken to resolve the outstanding non-conformances.</p> <p>The certification body verifies that the corrective actions have been implemented by means of an on-site visit within sixty (60) calendar days of receiving your corrective action plan.</p> <p>When the corrective action plan has been successfully implemented, the certification body reinstates your site status on the SQFI assessment database and provides you with written notice that your certificate is no longer suspended.</p> <p>If the suspension is the result of a re-certification audit, the certification body conducts an unannounced surveillance audit no more than six (6) months after the suspension to verify the effective implementation of the corrective action plan.</p>

v. Your site does not maintain the requirements of the SQF Food Safety Code for Food Manufacturing:	The certification body requests that within forty-eight (48) hours of receiving notice of the suspension you provide a detailed plan outlining the corrective actions to be taken regarding the failure to maintain the SQF Food Safety Code. The certification body verifies the corrective actions have been implemented by means of an on-site visit within thirty (30) calendar days of receiving your corrective action plan. When the corrective action plan has been successfully implemented, the certification body re-instates your site status on the SQFI assessment database and provides you with written notice that your certificate is no longer suspended.
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If your site’s SQF certificate is suspended, your site cannot represent itself as holding an SQF certificate for the duration of the suspension.

Appeals regarding decisions on the suspension and/or withdrawal of your SQF certification by a certification body shall not delay the decision to suspend or withdraw the certification (refer to 10.3).

Step 14: Withdrawing Certification

The certification body withdraws the certificate if your site:

- Has been placed under suspension and fails to follow the suspension protocol, as defined by the certification body in your notice of suspension;
- Fails to take approved corrective action within the time frames specified, as determined by the certification body (refer to step 13.1);
- Has intentionally and systemically falsified its records;
- Fails to maintain the integrity of the SQF certificate; or
- Has an administrator, receiver, receiver and manager, official manager, or provisional liquidator appointed over its assets or where an order is made or a resolution passed for the closure of your site (except for the purposes of amalgamation or reconstruction) or the site ceases to carry on business or becomes bankrupt or applies to take the benefit of any law for the relief of bankrupt or insolvent debtors or makes any arrangement or composition with its creditors.

If your site’s certificate is withdrawn, the certification body immediately amends your site’s details on the SQFI assessment database to a “withdrawn” status, indicating the reason for the withdrawal and the effective date. The certification body also:

- Informs you in writing that the SQF certificate has been withdrawn, the reason for such action, and the effective date. Acknowledgment of receipt of the withdrawal notification is required.
- Notifies SQFI about the withdrawal using the online change and notification form; and
- Instructs you to return the certificate within thirty (30) days of notification.

If your certificate is withdrawn, you are not permitted to re-apply for certification for twelve (12) months from the date the certificate was withdrawn by the certification body. The withdrawn site is posted on sqfi.com for twelve (12) months.

Step 15: Changes to Site SQF Requirements

The SQF Food Safety Code: Dietary Supplements Manufacturing enables you to change your requirements based on your changing business arrangements. These include changes and additions in product scope, changing your certification body, site relocation, and changes in business ownership.

If your site experiences a recall of products included in its scope of certification or has regulatory intervention, SQFI and your certification body are required to be notified.

The SQF requirements are listed here. If you need assistance with any of these changes, you can contact the SQFI customer service team at info@sqfi.com

15.1 Temporary or Permanent Change of Audit Dates

Written approval by the SQF Compliance Manager is required to issue an extension to your site's certificate or a temporary or permanent change to your site's re-certification audit time frame, including changes due to extraordinary events such as acts of nature or extreme weather.

All change requests are required to be sent by the certification body that issued your site's most recent SQF certificate.

All requests regarding temporary or permanent certification changes for legitimate business reasons are to be submitted to SQFI by the certification body using the Change Request and Notification Form (available at sqfi.com). Using this online form enables SQFI to track and manage all incoming requests and respond in a timely manner.

15.2 Changing the Scope of Certification

If you wish to add food sector categories or new products to your scope of certification, you may request the increased scope of certification in writing to the certification body.

If the scope change is a new process or a major change to an existing process, a new product line, or a significant change in personnel, raw materials, packing materials or ingredients, the certification body is required to be advised in writing. The certification body conducts a site audit of the additional process or products and either issues a new certificate or advises you in writing why a new certificate cannot be issued.

An audit for an expansion in scope does not change the re-certification date or certificate expiry date. When a new certificate is issued, the re-certification audit date and certificate expiry date remain the same as on the original certificate.

When the scope of certification has been changed, the certification body makes the appropriate scope changes to your site record in the SQFI assessment database.

If your request is received within thirty (30) days prior to the re-certification audit window, the certification body may defer the scope extension to the upcoming re-certification audit and advise you accordingly. No new certificate is issued until after a successful re-certification audit.

15.3 Changing the Certification Body

If you are not satisfied with the arrangements or performance of your certification body, you can change to another SQF-licensed certification body after one certification cycle and only after closure of all outstanding non-conformances, and as long as the certification is not suspended or under threat of suspension or withdrawal.

If your site requires a surveillance audit, you can change certification bodies only after the surveillance audit is conducted or by written approval from the SQF Compliance Manager (compliance@sqfi.com).

When a site changes certification bodies, the certificate issued by the previous certification body remains valid until the expected expiration date.

Your certification number and re-certification date are transferred with your site to the new certification body.

The new certification body is required to undertake a review of your site's certification before the transfer is complete to:

- Confirm the certificate is current, valid, and relates to the SQF System as certified;
- Confirm your site's food sector category falls within the new certification body's scope of accreditation;
- Confirm any complaints received are actioned;
- Review your site's audit history (where you can demonstrate such history to the satisfaction of the new certification body by way of copies of audit reports completed by any previous certification body(ies) and the impact of any outstanding non-conformances);
- Confirm the stage of the current certification cycle.

If you require to change your certification body, you need to make the last re-certification audit report and surveillance audit report (if applicable) available to the new certification body.

15.4 Relocation of Premises

SQF certification is site specific (refer to step 3), so if you relocate your business premises, your site's certification does not transfer to the new site.

A successful certification of the new premises is required. An initial certification audit must be completed for the new facility.

15.5 Change of Business Ownership

If the ownership of a certified site changes (e.g., the site's business has been sold), within thirty (30) calendar days of the change of ownership the new owner is required to notify the certification body and apply to retain the SQF certification and the existing certification number.

If the staff with major responsibility for the management and oversight of the SQF Food Safety System has been retained, the certification body may retain the existing audit frequency status.

If there are significant changes in site management and personnel, the certification body is required to complete an initial certification audit and issue a new certificate and a new certification number. The audit frequency applicable to a new certification applies.

15.6 Notification of Recalls and Regulatory Infringements

If your site initiates a food safety event that requires public notification, such as a Class I or Class II recall or receives a regulatory warning letter, you must notify your certification body and SQFI in writing at foodsafetycrisis@sqfi.com within twenty-four (24) hours of the event.

Your certification body and SQFI are required to be listed in your essential contacts lists as defined in system element 2.6.3 of the SQF Food Safety Code: Dietary Supplement Manufacturing.

Your certification body is required to notify SQFI within a further forty-eight (48) hours of any action it intends to take to ensure the integrity of the certification.

15.7 Use of a Technical Expert

Technical experts may be used to assist SQF food safety auditors in audits where the auditor is SQF registered but does not possess some or any site's food sector category(ies) or for products/processes where the audit would benefit from expert technical advice.

The use of a technical expert to assist an SQF food safety auditor in the performance of an SQF audit is permitted, provided your site has been notified before the audit and accepts the expert's participation. The technical expert must sign a confidentiality agreement with the certification body.

Before the audit, the certification body must submit the technical qualifications of the technical expert and the justification for use of the technical expert to SQFI. Approval, if granted, is for one site audit only.

Technical experts are required to:

- Hold a university degree in a discipline related to the food sector category for high-risk sectors or a higher education qualification for low-risk categories;
- Have received HACCP training with certificate of attainment issued; and
- Have five years' full-time experience in a technical, professional, or supervisory position related to the food sector category and specific products.

If the audit includes remote activities, the assigned technical expert may make use of ICT during the audit process. The registered SQF auditor is required to be present, either in person or remotely.

15.8 Language Used During the Audit

The certification body is required to ensure that the SQF food safety auditor conducting the audit can competently communicate in the oral and written language of the site being audited.

In circumstances where a translator is required, the translator must be provided by the certification body and have knowledge of the technical terms used during the audit, be independent of the site being audited, and have no conflict of interest. The site is to be notified of any increase in audit duration and cost associated with the use of a translator.

If there is a conflict, the English version of the SQF Food Safety Code: Dietary Supplements Manufacturing prevails.

15.9 The SQFI Compliance and Integrity Program

To meet the requirements of SQFI's Compliance and Integrity Program, SQFI may randomly monitor the activities of the certification bodies and their auditors through techniques that include but are not limited to validation and/or witness audits.

While conducting these additional monitoring activities, your site is required to allow SQFI-authorized representatives into the site during or after the audit has taken place.

The attendance of an SQFI representative does not interfere with the site's operations or result in additional audit time or non-conformances, and it will not increase the cost charged by the certification body for the audit.

B

Part

The SQF Food Safety Code: Dietary Supplements Manufacturing

2.1 Management Commitment

2.1.1 Management Responsibility (Mandatory)

2.1.1.1 Senior site management shall prepare and implement a policy statement that outlines at a minimum the commitment of all site management to:

- i. Supply safe dietary supplements;
- ii. Establish and maintain a food safety culture within the site;
- iii. Establish and continually improve the site's food safety management system; and
- iv. Comply with customer and regulatory requirements to supply safe dietary supplements.

The policy statement shall be:

- v. Signed by the senior site manager and displayed in prominent positions; and
- vi. Effectively communicated to all site personnel in the language(s) understood by all site personnel.

2.1.1.2 Senior site management shall lead and support a food safety culture within the site that ensures at a minimum:

- i. The establishment, documentation, and communication to all relevant staff of food safety objectives and performance measures;
- ii. Adequate resources are available to meet food safety objectives and performance measures and resource allocation and responsibility ensures regulation and any associated licensing is maintained and aligned with the SQF System;
- iii. Food safety practices and all applicable requirements of the SQF System are adopted and maintained;
- iv. Staff are informed and aware of their food safety and regulatory responsibilities;
- v. Staff are aware of their role in meeting the requirements of the SQF Food Safety Code: Dietary Supplements Manufacturing and are held accountable for meeting these requirements;
- vi. Staff are positively encouraged and required to notify management about actual or potential food safety issues; and
- vii. Staff are empowered to act to resolve food safety issues within their scope of work.

2.1.1.3 The reporting structure shall identify and describe site personnel with specific responsibilities for tasks within the food safety management system. It shall clearly indicate the designated quality control person or other resource responsible for regulations.

Job descriptions for key employees shall be documented and include a provision to cover for the absence of key personnel.

Site management shall ensure departments and operations are appropriately staffed and organizationally aligned to meet food safety objectives.

- 2.1.1.4 Senior site management shall designate a primary and substitute SQF practitioner for each site with responsibility and authority to:
- i. Oversee the development, implementation, review, and maintenance of the SQF System;
 - ii. Ensure all regulatory requirements are being met;
 - iii. Take appropriate action to ensure the integrity of the SQF System; and
 - iv. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.
- 2.1.1.5 The primary and substitute SQF practitioner shall:
- i. Be employed by the site;
 - ii. Demonstrate awareness of the regulatory requirements for the designated food safety person;
 - iii. Hold a position of responsibility related to the management of the site's SQF System;
 - iv. Have completed a HACCP training course;
 - v. Be competent to implement and maintain HACCP-based food safety plans; and
 - vi. Have an understanding of the SQF Food Safety Code: Dietary Supplements Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification.
- 2.1.1.6 Senior site management shall ensure the training needs of the site are resourced, implemented, and meet the requirements outlined in system elements 2.9 and that site personnel meet the required competencies to carry out those functions affecting the legality and safety of food products.
- 2.1.1.7 Senior site management shall ensure the integrity and continued operation of the food safety system in the event of organizational or personnel changes within the company or associated facilities.
- 2.1.1.8 Senior site management shall designate defined blackout periods that prevent unannounced re-certification audits from occurring out of season or when the site is not operating for legitimate business reasons. The list of blackout dates and their justification shall be submitted to the certification body a minimum of one (1) month before the sixty (60) day re-certification window for the agreed-upon unannounced audit.

2.1.2 Management Review (Mandatory)

- 2.1.2.1 The SQF System shall be reviewed by senior site management at least annually and include:
- i. Changes to food safety management system documentation (policies, procedures, specifications, food safety plan);
 - ii. Food safety culture performance;
 - iii. Food safety objectives and performance measures;

- iv. Corrective and preventative actions and trends in findings from internal and external audits, customer complaints, and verification and validation activities;
- v. Hazard and risk management system; and
- vi. Follow-up action items from previous management reviews.

Records of all management reviews and updates shall be maintained.

2.1.2.2 The SQF practitioner(s) shall update senior site management on at least a monthly basis on matters impacting the implementation and maintenance of the SQF System. The updates and management responses shall be documented.

2.1.3 Complaint Management (Mandatory)

2.1.3.1 The methods and responsibility for handling and investigating the cause and resolution of complaints that may result in a food safety issue from commercial customers, consumers, and authorities, arising from products manufactured or handled on-site or co-manufactured, shall be documented and implemented. It shall minimally include:

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

2.1.3.2 Adverse trends of customer complaint data shall be investigated and analyzed and the root cause established by personnel knowledgeable about the incidents.

2.1.3.3 Corrective and preventative action shall be implemented based on the seriousness of the incident and the root cause analysis as outlined in 2.5.3. Records of customer complaints, their investigation, and resolution shall be maintained.

2.2 Document Control and Records

2.2.1 Food Safety Management System (Mandatory)

2.2.1.1 The methods and procedures the site uses to meet the requirements of the SQF Food Safety Code: Dietary Supplements Manufacturing shall be maintained in electronic and/or hard copy documentation. They will be made available to relevant staff and include:

- i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard;
- ii. The food safety policy statement and organization chart;
- iii. The processes and products included in the scope of certification;
- iv. Food safety and dietary supplement regulations that apply to the manufacturing site and the country(ies) of sale (if known);
- v. Raw material, ingredient, packaging, and finished product specifications;
- vi. Food safety procedures, prerequisite programs, food safety plans;

- vii. Production and process control procedures and specifications supporting or impacting regulatory limits/claims and food safety; and
- viii. Other documentation necessary to support the development, implementation, maintenance, and control of the SQF System.

2.2.1.2 Food safety plans, Good Manufacturing Practices, and all relevant aspects of the SQF System shall be reviewed, updated, and communicated as needed when any changes implemented have an impact on the site's ability to deliver safe dietary supplements.

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

The reasons for the change shall be documented.

2.2.2 Document Control (Mandatory)

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

Current SQF System documents and amendments to documents shall be maintained.

2.2.3 Records (Mandatory)

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

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

2.2.3.3 Records shall be readily accessible, retrievable, and securely stored to prevent unauthorized access, loss, damage, and deterioration. Retention periods shall be in accordance with customer, legal, and regulatory requirements, at minimum the product shelf life. Software programs and electronic data and records shall be backed-up on hard drives or cloud remote from the site's system.

2.3 Specifications, Formulations, Realization, and Supplier Approval

2.3.1 Product Formulation and Realization

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

2.3.1.2 New product formulations, manufacturing processes, and the fulfillment of product requirements shall be established, validated, and verified by site trials and product testing as required to ensure:

- i. Product safety, regulatory limits (e.g., potency, strength, homogeneity, and purity), and claims are maintained to the end of the shelf life;
- ii. Manufacturing processes and instructions ensure product homogeneity, flushing sequences, special instructions, and cleanout procedures;
- iii. Product formulations are developed by authorized persons;
- iv. Shelf life studies account for pre-consumer handling and storage requirements including the establishment of “use by,” “best before dates,” or equivalent terminology; and
- v. Instructions for consumer preparation, where applicable, and storage and handling requirements.

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

2.3.1.4 Product formulations and manufacturing processes for products included in the scope of certification shall be reviewed when there are changes in materials, ingredients, or equipment.

2.3.1.5 The process flows for all new and existing manufacturing processes shall be designed to ensure that product is manufactured according to approved product formulations and to prevent cross-contamination.

2.3.1.6 Records of product design, formulations, label compliance, process flows, shelf life trials, and approvals for all new and existing products shall be maintained.

2.3.2 Specifications (Raw Material, Packaging, Finished Product, and Services)

2.3.2.1 The methods and responsibility for developing, managing, and approving raw material, finished product, and packaging specifications shall be documented.

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

2.3.2.3 All raw materials, packaging, and ingredients, including those received from other sites under the same corporate ownership, shall comply with specifications and with the relevant legislation, including licensing, in the country of manufacture and country of destination, if known.

The specifications, where applicable, shall ensure that when raw materials are used according to formulation or recipe that the purity, strength, and composition of the finished product meet label declarations and regulatory requirements.

2.3.2.4 Raw materials, packaging, and finished products shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose.

2.3.2.5 Site management shall require approved raw materials suppliers to notify the site of changes in product composition that could have an impact on product formulation (e.g., protein content, moisture, purity, strength, composition, amino acid profiles, contaminant levels, allergens, and/or other parameters that may be variable by season).

2.3.2.6 Verification of packaging shall include certification that all packaging that comes into direct contact with dietary supplements 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.

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.

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

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

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

- i. Microbiological, chemical, and physical limits;
- ii. Purity, strength, and composition supporting regulatory and quality label claims;
- iii. Limits or levels of possible adulterants;
- iv. Labeling and packaging requirements; and
- v. Storage conditions.

2.3.2.10 Specifications for raw materials and packaging, chemicals, processing aids, contract services, and finished products shall be reviewed as changes occur that impact product safety. Records of reviews shall be maintained.

A list of all the above specifications shall be maintained and kept current.

2.3.3 Contract Manufacturers

2.3.3.1 The methods and responsibility for ensuring all agreements with contract manufacturers relating to food safety, customer product requirements, their realization, and delivery shall be documented and implemented.

2.3.3.2 The site shall establish a method to determine the food safety risk level of contract manufactured product and shall document the risk. The site shall ensure that:

- i. Products and processes of co-manufacturers that are considered high-risk have undergone an audit by the site or third-party agency to confirm compliance with the SQF Food Safety Code: Dietary Supplements Manufacturing and regulatory and customer requirements;

- ii. Products and processes of co-manufacturers that are considered low risk meet the requirements of the SQF Food Safety Code: Dietary Supplements Manufacturing, or other GFSI-benchmarked certification programs, and regulatory and customer requirements; and
- iii. Changes to contractual agreements are approved by both parties and communicated to relevant personnel.

2.3.3.3 Contractual agreements with third-party storage and distribution businesses shall include requirements relating to customer product requirements and compliance with clause 2.3.3.2 of the SQF Food Safety Code: Dietary Supplements Manufacturing. Contractual agreements shall be approved by both parties and communicated to relevant personnel. The site shall verify compliance with the SQF Code and ensure that customer and regulatory requirements are being met at all times.

2.3.3.4 Records of audits, contracts, and changes to contractual agreements and their approvals shall be maintained.

2.3.4 Approved Supplier Program (Mandatory)

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

A current record of approved suppliers, receiving inspections, and supplier audits shall be maintained.

2.3.4.2 The approved supplier program shall be based on the past performance of a supplier and the risk level of the raw materials, ingredients, processing aids, packaging, and services supplied, and shall contain at a minimum:

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

2.3.4.3 Verification of raw materials shall include certificates of conformance, certificates of analysis, or sampling, and testing. The verification frequency shall be identified by the site.

2.3.4.4 The receipt of raw materials, ingredients, processing aids, and packaging from non-approved suppliers shall be acceptable only in an emergency situation and provided a receiving inspection or analysis is conducted and recorded before use.

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

2.3.4.6 Supplier audits shall be based on risk (as determined in 2.3.4.2) and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques.

2.4 Food Safety System

2.4.1 Dietary Supplement Legislation (Mandatory)

2.4.1.1 The site shall ensure that, at the time of delivery to its customer, the dietary supplement supplied shall comply with the legislation that applies to the dietary supplement and its production in the country of manufacture, and the country of use or sale (if known). This includes:

- i. Compliance with federal or national legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen, and additive labeling;
- ii. Compliance with regulatory licensing requirements for the site and/or its suppliers and customers;
- iii. Labeling of identity preserved foods;
- iv. Purity, strength, and composition claims; and
- v. Any other criteria listed under dietary supplement legislation and relevant established industry codes of practice.

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

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

2.4.2 Good Manufacturing Practices (Mandatory)

2.4.2.1 The site shall ensure the applicable Good Manufacturing Practices described in module 17 of this Food Safety Code are applied or exempted according to a written risk analysis outlining the justification for exemption or evidence of the effectiveness of alternative control measures that ensure food safety is not compromised.

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

2.4.3 Food Safety Plan (Mandatory)

- 2.4.3.1 A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. The food safety plan shall be effectively implemented and maintained and shall outline how the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.
- 2.4.3.2 The food safety plan or plans shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and engineering knowledge of the relevant raw materials, packaging materials, processing aids, products, and associated processes. Where the relevant expertise is not available on-site, advice may be obtained from other sources to assist the food safety team.
- 2.4.3.3 The scope of each food safety plan shall be developed and documented including the start and end points of the processes under consideration and all relevant inputs and outputs.
- 2.4.3.4 Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. The descriptions shall reference the finished product specifications (refer to 2.3.2.9) plus any additional information relevant to product safety, such as pH, water activity, composition, and/or storage conditions.
- 2.4.3.5 The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing, if applicable, and potential alternative uses of the product.
- 2.4.3.6 The food safety team shall develop and document a flow diagram covering the scope of each food safety plan. The flow diagram shall include every step in the process, all raw materials, packaging materials, service inputs (e.g., water, steam, gasses as applicable), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team to cover all stages and hours of operation.
- 2.4.3.7 The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.
- 2.4.3.8 The food safety team shall conduct a hazard analysis for every identified hazard to determine which hazards are significant, i.e., their elimination or reduction to an acceptable level is necessary to control food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards.
- 2.4.3.9 The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure.

- 2.4.3.10 Based on the results of the hazard analysis (refer to 2.4.3.8), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e., a critical control point or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure.
- 2.4.3.11 For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product (critical limits). The food safety team shall validate all of the critical limits to ensure the level of control of the identified food safety hazard (s) and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1).
- 2.4.3.12 The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.11). Monitoring procedures shall identify the personnel assigned to conduct monitoring, the sampling and test methods, and the test frequency.
- 2.4.3.13 The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure.
- 2.4.3.14 The documented and approved food safety plan(s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs, or other changes affecting product safety occur.
- 2.4.3.15 Procedures shall be in place to verify that critical control points are effectively monitored, and appropriate corrective actions are applied. Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5).
- 2.4.3.16 Critical control point monitoring, corrective action, and verification records shall be maintained and appropriately used.
- 2.4.3.17 Where food safety and/or dietary supplement regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements.

2.4.4 Product Sampling, Inspection, and Analysis

- 2.4.4.1 The methods, responsibility, and criteria for sampling, inspecting, and/or analysis shall be documented and implemented. The methods applied shall ensure:
- i. Inspections and analyses are completed at regular intervals as required and to agreed specification and legal requirements;
 - ii. Inspections and/or testing are conducted to ensure raw materials, packaging, labels, work-in-progress, and finished products comply with the relevant specifications, formulation/recipes, and regulatory requirements, and are true to label;

- iii. Sampling and testing shall be statistically based, representative of the process/batch, and ensure production and process controls are maintained to meet specifications and formulation/recipe; and
- iv. Retention samples, if required by customers or regulations, are stored and maintained for the stated shelf-life of the product.

2.4.4.2 Product analyses shall be conducted to nationally recognized methods or alternative methods that are validated as equivalent to the nationally recognized methods.

Where internal laboratories are used to conduct input, environmental, or product analysis, sampling and testing methods shall be in accordance with the applicable requirements of ISO/IEC 17025 and include annual proficiency testing for staff conducting analyses.

External laboratories shall be accredited to ISO/IEC 17025, or an equivalent international standard, licensed or recognized by a regulatory authority if required, and included on the site's contract service specifications list (refer 2.3.2.11).

2.4.4.3 On-site laboratories conducting chemical and microbiological analyses that may pose a risk to product safety shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel.

Signage shall be displayed identifying the laboratory area as a restricted area, accessible only by authorized personnel.

2.4.4.4 Provisions shall be made to isolate and contain all hazardous laboratory waste held on the premises and manage it separately from food waste. Laboratory waste outlets shall at a minimum be downstream of drains that service dietary supplement processing and handling areas.

2.4.4.5 Retention samples, if required by customers or regulations, shall be stored according to the typical storage conditions for the product and maintained for the stated shelf life of the product.

2.4.4.6 Records of all inspections and analyses shall be maintained.

2.4.5 Non-conforming Materials and Product

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

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

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

2.4.6 Product Rework

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

- i. Reworking operations, including inspection, analysis, and approval for release, are overseen by qualified personnel;
- ii. Reworked product is clearly identified and traceable;
- iii. Reworked product is processed in accordance with the site's food safety plan;
- iv. Each batch of reworked product, including any returned product, is inspected or analyzed as required before release;
- v. Inspections and analyses conform to the requirements outlined in element 2.4.4.1;
- vi. Release of reworked product conforms to element 2.4.7; and
- vii. Reworked product does not affect the safety or integrity of the finished product.

Records of all reworking operations shall be maintained.

2.4.7 Product Release (Mandatory)

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

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

2.4.7.2 Product release shall include a procedure to confirm that product labels comply with the dietary supplement legislation that applies in the country of manufacture and the country(ies) of use or sale if known (refer to 2.4.1.1).

If product is packaged and distributed in bulk or unlabeled, product information shall be made available to inform customers and/or consumers of the requirements for its safe use.

2.4.7.3 In the event that the site uses positive release based on product pathogen or chemical testing, a procedure shall be in place to ensure that product is not released until acceptable results have been received.

In the event that off-site or contract warehouses are used, these requirements shall be effectively communicated and verified as being followed.

2.4.8 Environmental Monitoring

2.4.8.1 A risk-based environmental monitoring program shall be in place for all dietary supplement manufacturing processes and immediate surrounding areas, which impact manufacturing processes.

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

- 2.4.8.2 An environmental sampling and testing schedule shall be prepared. It shall at a minimum:
- i. Detail the applicable pathogens or indicator organisms to test for in that industry;
 - ii. List the number of samples to be taken and the frequency of sampling;
 - iii. Outline the locations in which samples are to be taken and the rotation of locations as needed; and
 - iv. Describe the methods to handle elevated or undesirable results.
- 2.4.8.3 Environmental testing results shall be monitored, tracked, and trended, and preventative actions (refer to 2.5.3.1) shall be implemented where unsatisfactory results or trends are observed.

2.5 SQF System Verification

2.5.1 Validation and Effectiveness (Mandatory)

- 2.5.1.1 The methods, responsibility, and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall ensure that:
- i. Good Manufacturing Practices are confirmed to ensure they achieve the required results;
 - ii. Critical food safety limits are reviewed annually and re-validated or justified by regulatory standards when changes occur; and
 - iii. Changes to the processes or procedures are assessed to ensure the controls are still effective.

Records of all validation activities shall be maintained.

2.5.2 Verification Activities (Mandatory)

- 2.5.2.1 The methods, responsibility, and criteria for verifying monitoring of Good Manufacturing Practices, critical control points, process controls, formulations/recipes, other food safety controls, and the legality of certified products shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each verified record.
- 2.5.2.2 A schedule outlining the verification activities, their frequency of completion, and the person responsible for each activity shall be prepared and implemented.

Records of verification of activities shall be maintained.

2.5.3 Corrective and Preventative Action (Mandatory)

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

Deviations from food safety requirements may include customer complaints, non-conformances raised at internal or external audits and inspections, non-conforming product and equipment, withdrawals and recalls, as appropriate.

2.5.3.2 Records of all investigation, root cause analysis, and resolution of non-conformities, their corrections, and the implementation of preventative actions shall be maintained.

2.5.4 Internal Audits and Inspections (Mandatory)

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

- i. All applicable requirements of the SQF Food Safety Code: Dietary Supplements Manufacturing are audited per the SQF audit checklist or a similar tool;
- ii. Objective evidence is recorded to verify compliance and/or non-compliance;
- iii. Corrective and preventative actions of deficiencies identified during the internal audits are undertaken; and
- iv. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective and preventative actions.

2.5.4.2 Staff conducting internal audits shall be trained and competent in internal audit procedures. Where practical, staff conducting internal audits shall be independent of the function being audited.

2.5.4.3 Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and facility and equipment maintenance are compliant to the SQF Food Safety Code: Dietary Supplements Manufacturing. The site shall:

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

2.5.4.4 Records of internal audits and inspections and any corrective and preventative actions taken as a result of internal audits shall be recorded as per 2.5.3.

Changes implemented from internal audits that have an impact on the site's ability to deliver safe dietary supplements shall require a review of applicable aspects of the SQF System (refer to 2.3.1.3).

2.6 Product Traceability and Crisis Management

2.6.1 Product Identification (Mandatory)

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

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

2.6.1.2 Product start-up, product changeover, and packaging changeover (including labels) procedures during packing shall be documented and implemented. Procedures shall ensure that:

- i. The correct product is in the correct package and with the correct label;
- ii. The changeover is inspected and approved by an authorized person; and
- iii. Label use is reconciled and any inconsistencies investigated and resolved.

Product changeover and label reconciliation records shall be maintained.

2.6.2 Product Trace (Mandatory)

2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure:

- i. Finished product is traceable at least one step forward to the customer and at least one step back from the process to the manufacturing supplier;
- ii. The receipt dates of raw materials, ingredients, food contact packaging and materials, and other inputs are recorded (refer to 2.8.1.8 for traceback of allergen containing food products);
- iii. Traceability is maintained where product is reworked (refer to 2.4.6); and
- iv. The effectiveness of the product trace system is reviewed at least annually as part of the product recall and withdrawal review (refer to 2.6.3.2).

Records of raw and packaging material receipt and use and finished product dispatch and destination shall be maintained.

2.6.3 Product Withdrawal and Recall (Mandatory)

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

- i. Identify those responsible for initiating, managing, and investigating a product withdrawal or recall;
- ii. Describe the management procedures to be implemented, including sources of legal, regulatory, and expert advice, and essential traceability information;

- iii. Outline a communication plan to inform site personnel, customers, consumers, authorities, and other essential bodies in a timely manner appropriate to the nature of the incident; and
- iv. Ensure that SQFI, the certification body, and the appropriate regulatory authority are listed as essential organizations and notified in instances of a food safety incident of a public nature or product recall for any reason.

2.6.3.2 The product withdrawal and recall system shall be reviewed, tested, and verified as effective at least annually. Testing shall include incoming materials (minimum traceability one step back) and finished product (minimum traceability one step forward).

Testing shall be carried out on products from different shifts and for materials (including bulk materials) that are used across a range of products and/or products that are shipped to a wide range of customers.

2.6.3.3 Records shall be maintained of withdrawal and recall tests, root cause investigations into actual withdrawals and recalls, and corrective and preventative actions applied.

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

2.6.4 Crisis Management Planning

2.6.4.1 A crisis management plan based on the understanding of known potential dangers (e.g., flood, drought, fire, tsunami, or other severe weather events, warfare or civil unrest, computer outage, pandemic, loss of electricity or refrigeration, ammonia leak, labor strike) that can impact the site's ability to deliver safe dietary supplements shall be documented by senior management, outlining the methods and responsibility the site shall implement to cope with such a business crisis. The crisis management plan shall include at 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 any responses do not compromise product safety;
- iv. The measures to isolate and identify product affected by a response to a crisis;
- v. The measures taken to verify the acceptability of food prior to release;
- vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers;
- vii. Sources of legal and expert advice; and
- viii. The responsibility for internal communications and communicating with authorities, external organizations, and media.

2.6.4.2 The crisis management plan shall be reviewed, tested, and verified at least annually with gaps and appropriate corrective actions documented. Records of reviews of the crisis management plan shall be maintained.

2.7 Food Defense and Food Fraud

2.7.1 Food Defense Plan (Mandatory)

- 2.7.1.1 A food defense threat assessment shall be conducted to identify potential threats that can be caused by a deliberate act of sabotage or terrorist-like incident.
- 2.7.1.2 A food defense plan shall be documented, implemented, and maintained based on the threat assessment (refer to 2.7.1.1). The food defense plan shall meet legislative requirements as applicable and shall include at a minimum:
- i. The methods, responsibility, and criteria for preventing dietary supplement adulteration caused by a deliberate act of sabotage or terrorist-like incident;
 - ii. The name of the senior site management person responsible for food defense;
 - iii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing, and storage areas through designated access points;
 - iv. The methods implemented to protect sensitive processing points from intentional adulteration. Sites requiring licensing under regulations shall meet regulatory requirements for security;
 - v. The measures taken to ensure the secure receipt and storage of raw materials, ingredients, packaging, equipment, and hazardous chemicals to protect them from deliberate acts of sabotage or terrorist-like incidents;
 - vi. The measures implemented to ensure raw materials, ingredients, packaging (including labels), work-in-progress, process inputs, and finished products are held under secure storage and transportation conditions; and
 - vii. The methods implemented to record and control access to the premises by site personnel, contractors, and visitors.
- 2.7.1.3 Instruction shall be provided to all relevant staff on the effective implementation of the food defense plan (refer to 2.9.2.1).
- 2.7.1.4 The food defense threat assessment and prevention plan shall be reviewed and tested at least annually or when the threat level, as defined in the threat assessment, changes. Records of reviews and tests of the food defense plan shall be maintained.

2.7.2 Food Fraud (Mandatory)

- 2.7.2.1 The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud, including susceptibility to raw material or ingredient substitution, finished product mislabeling, dilution, or counterfeiting, shall be documented, implemented, and maintained.
- 2.7.2.2 A food fraud mitigation plan shall be developed and implemented, that specifies the methods by which the identified food fraud vulnerabilities shall be controlled, including identified food safety vulnerabilities of ingredients and materials.
- 2.7.2.3 Instruction shall be provided to all relevant staff on the effective implementation of the food fraud mitigation plan (refer to 2.9.2.1).

2.7.2.4 The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually with gaps and corrective actions documented. Records of reviews shall be maintained.

2.8 Allergen Management

2.8.1 Allergen Management (Mandatory)

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

- i. A risk analysis of those raw materials, ingredients, and processing aids, including food grade lubricants, that contain food allergens;
- ii. An assessment of workplace-related food allergens that may originate from locker rooms, vending machines, lunchrooms, and visitors;
- iii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination, if known;
- iv. A list of allergens that is accessible to relevant staff;
- v. The control of hazards associated with allergens and incorporated into the food safety plan, and
- vi. Management plans for control of the identified allergens.

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

2.8.1.3 Provisions shall be made to clearly identify and segregate dietary supplements that contain allergens. Segregation procedures shall be implemented and continually monitored.

2.8.1.4 Where allergenic material may be intentionally or unintentionally present, cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact.

Separate handling and production equipment shall be provided, where satisfactory line hygiene and clean-up or segregation are not possible.

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

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

- 2.8.1.7 The product identification system (refer to 2.6.1.1) shall make provision for clear identification and labeling, in accordance with the regulatory requirements, of those products produced on production lines and equipment on which dietary supplements containing allergens are manufactured.
- 2.8.1.8 The product trace system (refer to 2.6.2) shall take into consideration the conditions under which allergen- containing dietary supplements are manufactured and ensure full traceback of all ingredients and processing aids used.
- 2.8.1.9 The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in-progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product changeover procedures.
- 2.8.1.10 Re-working of product (refer to 2.4.6) containing food allergens shall be conducted under conditions that ensure product safety and integrity are maintained. Re-worked product containing allergens shall be clearly identified and traceable.
- 2.8.1.11 Sites that do not handle allergenic materials or produce allergenic products shall document, implement, and maintain an allergen management program addressing at a minimum the mitigation of introduced or unintended allergens through supplier, contract manufacturer, site personnel, and visitor activities.

2.9 Training

2.9.1 Training Requirements

- 2.9.1.1 The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented (refer to 2.1.1.6).
- 2.9.1.2 Appropriate training shall be provided for personnel carrying out the tasks essential to the effective implementation of the SQF System and the maintenance of food safety and regulatory requirements.

2.9.2 Training Program (Mandatory)

- 2.9.2.1 A training program shall be documented and implemented that outlines the necessary competencies for specific duties and the training methods to be applied for personnel carrying our task associated with food safety. The training program shall include at a minimum:
- i. Implementing HACCP for personnel involved in developing and maintaining food safety plans;
 - ii. Monitoring and corrective action procedures for all personnel engaged in monitoring critical control points (CCPs);
 - iii. Personal hygiene for all personnel involved in handling dietary supplement products and food contact surfaces;

- iv. Good Manufacturing Practices and work instructions for all personnel engaged in dietary supplement handling, processes, and equipment;
- v. Sampling and test methods for all personnel involved in sampling and testing of raw materials, packaging, work-in-progress, and finished products;
- vi. Environmental monitoring for relevant personnel;
- vii. Allergen management, food defense, and food fraud for all relevant personnel; and
- viii. Tasks identified as critical to meeting effective implementation and maintenance of the SQF Code.

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

2.9.2.2 Training materials, the delivery of training, and procedures on all tasks critical to meeting regulatory compliance and the maintenance of food safety shall be provided in language(s) understood by staff.

2.9.2.3 Training records shall be maintained and include:

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

Module 17: Good Manufacturing Practices for Processing of Dietary Supplements

17.1 Site Location and Premises

17.1.1 Premises Location and Approval

- 17.1.1.1 The site shall assess local activities and the site environment to identify any risks that may have an adverse impact on product safety and implement controls for any identified risks. The assessment shall be reviewed in response to any changes in the local environment or activities.

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

17.1.2 Building Materials

- 17.1.2.1 Floors shall be constructed of smooth, dense, impact-resistant material that can be effectively graded, drained, impervious to liquid, and easily cleaned. Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions.

Where floor drainage is not available, plumbed options to handle overflow or wastewater shall be in place.

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

- 17.1.2.3 Waste trap system shall be located away from any dietary supplement handling areas or entrances to the premises.

- 17.1.2.4 Walls, partitions, ceilings, and doors shall be of durable construction. Internal surfaces shall have an even and regular surface and be impervious with a light-colored finish and shall be kept clean (refer to 17.2.5).

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

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

A risk analysis shall be conducted to ensure product contamination risks are mitigated.

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

A risk analysis shall be conducted to ensure product contamination risks are mitigated.

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

17.1.2.8 Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products. Drop ceilings, where present, shall be constructed to enable monitoring for pest activity, facilitate cleaning, and provide access to utilities.

17.1.2.9 Stairs, catwalks, and platforms in product processing and handling areas shall be designed and constructed so they do not present a product contamination risk and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 17.2.5).

17.1.3 Lighting and Light Fittings

17.1.3.1 Lighting in product processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively and shall comply with local light intensity regulations or industry standards.

17.1.3.2 Light fixtures in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers, and recessed into or fitted flush with the ceiling.

Where fixtures cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials, and addressed in the cleaning and sanitation program.

17.1.3.3 Light fixtures in the warehouse or other areas where product is covered or otherwise protected shall be designed to prevent breakage and product contamination.

17.1.4 Inspection/Quality Control Area

17.1.4.1 If online inspection is required, a suitable area close to the processing line shall be provided for the inspection of product (refer to 2.4.4). The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall:

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

17.1.5 Dust, Insect, and Pest Proofing

17.1.5.1 All external windows, ventilation openings, doors, and other openings shall be effectively sealed when closed and proofed against dust, vermin, and other pests.

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

17.1.5.2 External doors, including overhead dock doors in product handling areas used for product, pedestrian, or truck access, shall be designed and maintained to prevent pest ingress by at least one or a combination of the following methods:

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

17.1.5.3 Electric insect control devices, pheromone, or other traps and baits shall be located and operated so they do not present a contamination risk to the product, packaging, containers, or processing equipment. Poison rodenticide bait shall not be used inside ingredients or product storage areas or processing areas where ingredients, packaging, and products are handled, processed, or exposed.

17.1.6 Ventilation

17.1.6.1 Adequate ventilation shall be provided in enclosed processing and product handling areas.

Where appropriate, positive air-pressure systems shall be installed to prevent airborne contamination.

17.1.6.2 All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 17.2.5 to prevent unsanitary conditions.

17.1.6.3 Extractor fans and canopies shall be provided in areas where open cooking operations are carried out or a large amount of steam is generated. Capture velocities shall be sufficient to prevent condensation build-up and to evacuate all heat, fumes, and other aerosols to the exterior via an exhaust hood positioned over the cooker(s).

17.1.6.4 Fans and exhaust vents shall be insect-proofed and located so they do not pose a contamination risk and be kept clean.

17.1.7 Equipment and Utensils

17.1.7.1 Specifications for equipment and utensils and procedures for purchasing equipment shall be documented and implemented. The specifications shall ensure that the equipment can consistently produce product that meets specifications and is capable of operating satisfactorily within the operating limits required by the process.

17.1.7.2 Equipment and utensils shall be designed, constructed, installed, operated, and maintained to meet any applicable regulatory requirements and so as not to pose a contamination threat to products.

Equipment shall include those used in automated, mechanical, or electronic systems.

17.1.7.3 Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers. Where possible, product contact equipment shall be segregated from non-contact equipment.

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

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

17.1.7.6 Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious, and readily cleaned as per 17.2.5.1. Bins used for inedible material shall be clearly identified.

17.1.7.7 All equipment and utensils shall be cleaned after use (refer to 17.2.5.1) or at a set and validated frequency to control contamination, and be stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

Single-service articles (e.g., utensils intended for one-time use, paper cups, and paper towels) shall be stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that protects against contamination.

17.1.7.8 Vehicles used in product contact, handling, or processing zones or cold storage rooms shall be designed and operated so as not to present a food safety hazard.

17.1.7.9 Non-conforming equipment shall be identified, tagged, and/or segregated for repair or disposal in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product. Records of the handling, corrective action, and/or disposal of non-conforming equipment shall be maintained.

17.1.8 Grounds and Roadways

17.1.8.1 A suitable external environment shall be established, and the effectiveness of the measures shall be monitored and periodically reviewed. The premises, its surrounding areas, storage facilities, machinery, and equipment shall be kept free of waste or accumulated debris, and vegetation shall be controlled so as not to attract pests and vermin or present a food safety hazard to the sanitary operation of the site.

17.1.8.2 Paths, roadways, and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operations of the premises. They shall be adequately drained to prevent the pooling of water. Drains shall be separate from the site drainage system and regularly cleared of debris.

17.1.8.3 Paths from amenities leading to site entrances shall be effectively sealed.

17.2 Site Operation

17.2.1 Repairs and Maintenance

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

17.2.1.2 Routine maintenance of plant and equipment in any dietary supplement processing, handling, or storage areas shall be performed according to a maintenance control schedule and recorded.

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

17.2.1.3 Failures of plant and equipment in any dietary supplement processing, handling, or storage areas shall be documented and reviewed and their repair(s) incorporated into the maintenance control schedule.

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

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

17.2.1.6 Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and the cleaning program. There shall be a plan in place to address the completion of temporary repairs to ensure they do not become permanent solutions.

17.2.1.7 Product contact equipment and equipment located over product contact equipment shall be lubricated with food-grade lubricant, and its use shall be controlled to minimize the contamination of the product.

17.2.1.8 Paint used in a dietary supplement handling or processing area shall be suitable for use, in good condition, and not be used on any product contact surfaces.

17.2.2 Maintenance Staff and Contractors

17.2.2.1 Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 17.3).

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

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

17.2.3 Calibration

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

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

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

17.2.3.3 Calibration shall be performed:

- i. According to regulatory requirements and/or the equipment manufacturer's recommended schedule;
- ii. Before first use; and
- iii. At routine intervals or as otherwise necessary to ensure the accuracy, precision, and control of the instrument.

17.2.3.4 Procedures shall be documented and implemented to address the resolution of potentially affected products when measuring, test, or inspection equipment is found to be out of calibration.

17.2.3.5 Calibrated measuring, testing, and inspection equipment shall be protected from damage and unauthorized adjustment or use.

17.2.3.6 A directory of measuring, test, and inspection equipment that require calibration and records of the calibration tests shall be maintained.

17.2.4 Pest Prevention

17.2.4.1 A documented pest prevention program shall be effectively implemented. It shall:

- i. Describe the methods and responsibility for the development, implementation, and maintenance of the pest prevention program;
- ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications;
- iii. Outline the methods used to prevent pest problems;
- iv. Outline the pest elimination methods and the appropriate documentation for each inspection;
- v. Outline the frequency with which pest status is to be checked;
- vi. Include the identification, location, number, and type of applied pest control/monitoring devices on a site map;
- vii. List the chemicals used. The chemicals are required to be approved by the relevant authority, and their Safety Data Sheets (SDS) made available;
- viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station;
- ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and
- x. Measure the effectiveness of the program to verify the elimination of applicable pests and to identify trends.

17.2.4.2 Pest contractors and/or internal pest controllers shall:

- i. Be licensed and approved by the local relevant authority;
- ii. Use only trained and qualified operators, who comply with regulatory requirements;
- iii. Use only approved chemicals;
- iv. Provide a pest prevention plan (refer to 2.3.2.8) that includes a site map, indicating the location of bait stations traps, and other applicable pest control/monitoring devices;
- v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments;
- vi. Provide regular inspections for pest activity with appropriate action taken if pests are present, and
- vii. Provide a written report of their findings and the inspections and treatments applied.

17.2.4.3 Pest activity risks shall be analyzed and recorded. Inspections for pest activity shall be conducted on a regular basis by trained site personnel and the appropriate action taken if pests are present. Identified pest activity shall not present a risk of contamination to dietary supplement products, raw materials, or packaging.

Records of all pest control inspections and applications shall be maintained.

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

17.2.4.5 Pesticides shall be clearly labeled and stored per 17.6.4 if kept on-site.

17.2.4.6 No domestic animals shall be permitted on-site in product handling or storage areas.

17.2.5 Cleaning and Sanitation

17.2.5.1 The methods and responsibility for the effective cleaning of the dietary supplement handling and processing equipment and environment and storage areas shall be documented and implemented. Consideration shall be given to:

- i. What is to be cleaned;
- ii. How it is to be cleaned;
- iii. When it is to be cleaned;
- iv. Who is responsible for the cleaning;
- v. Validation of the cleaning procedures for food contact surfaces (including CIP);
- vi. Methods used to confirm the correct concentrations of detergents and sanitizers; and
- vii. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

17.2.5.2 Detergents and sanitizers shall be suitable for use in a dietary supplement manufacturing environment, labeled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure that detergents and sanitizers are stored as outlined in element 17.6.4 and are handled only by trained staff.

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

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

17.2.5.5 Cleaning equipment, tools, racks, and other items used in support of the cleaning and sanitizing program shall be clearly identified, stored, and maintained in a manner that prevents contamination of processing areas, product handling equipment, and storage areas as well as the tools themselves.

17.2.5.6 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards, and other utensils used by staff. The areas for these cleaning operations shall be controlled so they do not interfere with manufacturing operations, equipment, or product. Racks and containers for storing cleaned utensils shall be provided as required.

17.2.5.7 Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure dietary supplement processing areas, product contact surfaces, equipment, staff amenities, sanitary facilities, and other essential areas are clean before the start of production.

If wet washing is in use, a sanitizer shall be applied and dried before the commencement of production.

Pre-operational inspections shall be conducted by qualified personnel.

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

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

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

17.3 Personnel Hygiene and Welfare

17.3.1 Personnel Welfare

17.3.1.1 Personnel who are known to be carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of dietary supplements or enter storage areas where dietary supplement is exposed.

Staff shall be instructed to notify their supervisor(s) if they have, or if there is a reasonable possibility that they have, a health condition that could result in microbial contamination of any raw materials, contact surfaces, or products.

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

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

17.3.1.3 Personnel with exposed cuts, sores, or lesions shall engage in handling or processing exposed products or handling primary (food contact) packaging or touching food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored, metal-detectable bandage or an alternative suitable waterproof and colored dressing.

17.3.2 Handwashing

17.3.2.1 All personnel shall have clean hands, and hands shall be washed by all staff, contractors, and visitors:

- i. On entering product handling or processing areas;
- ii. After each visit to a toilet;
- iii. After using a handkerchief;

- iv. After smoking, eating, or drinking; and
- v. After handling wash down hoses, cleaning materials, dropped product, or contaminated material.

17.3.2.2 Handwashing stations shall be provided adjacent to all personnel access points and in accessible locations throughout product handling and processing areas as required.

17.3.2.3 Handwashing stations shall be constructed of stainless steel or similar non-corrosive material and at a minimum supplied with:

- i. A potable water supply at an appropriate temperature;
- ii. Liquid soap contained within a fixed dispenser;
- iii. Paper towels in a hands-free cleanable dispenser; and
- iv. A means of containing used paper towels to ensure they are handled, dispensed, used, and disposed of in a manner that protects against contamination of raw materials, contact surfaces, and products.

17.3.2.4 The following additional facilities shall be provided in high-risk areas:

- i. Hands-free operated taps; and
- ii. Hand sanitizers.

17.3.2.5 Signage in appropriate languages instructing people to wash their hands before entering the dietary supplement processing areas shall be provided in a prominent position in break rooms, at break room exits, toilet rooms, and in outside eating areas, as applicable.

17.3.2.6 When gloves are used, personnel shall maintain the handwashing practices outlined above.

17.3.3 Clothing and Personal Effects

17.3.3.1 The site shall undertake a risk analysis to ensure that the clothing and hair policy protects materials, dietary supplements, and product contact surfaces from unintentional microbiological or physical contamination.

17.3.3.2 Clothing worn by staff engaged in handling food shall be maintained, stored, laundered, and worn so it does not present a contamination risk to products. Provision shall be made for the laundering and storage of clothing worn by personnel engaged in high-risk processes.

17.3.3.3 Clothing, including shoes, shall be clean at the start of each shift and maintained in a serviceable condition.

17.3.3.4 Excessively soiled uniforms shall be changed or replaced when they present a product contamination risk.

17.3.3.5 Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area, and when damaged.

Non-disposable aprons and gloves shall be cleaned and sanitized as required and, when not in use, stored on racks provided in the processing area or in designated sealed containers in personnel lockers. They should not be placed or stored on packaging, ingredients, product, or equipment.

- 17.3.3.6 Protective clothing shall be manufactured from material that will not pose a food safety threat and is easily cleaned.

All protective clothing shall be cleaned after use, or at a frequency to control contamination, and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

- 17.3.3.7 Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided nearby or adjacent to the personnel access doorways and handwashing facilities.

- 17.3.3.8 Jewelry and other loose objects shall not be worn or taken into a product handling or processing operation or into any area where dietary supplement is exposed.

The wearing of plain bands with no stones, prescribed medical alert bracelets, or jewelry accepted for religious or cultural reasons can be permitted. The site will need to confirm with their customer requirements and applicable legislation.

If hand jewelry cannot be removed, it shall be covered by material that is maintained in an intact, clean, and sanitary condition.

17.3.4 Visitors

- 17.3.4.1 All visitors shall be trained in the site's food safety and hygiene procedures before entering any product processing and handling areas or shall be escorted at all times in product processing, handling, and storage areas.

- 17.3.4.2 All visitors, including management staff, shall be required to remove jewelry and other loose objects in accordance with the facility's Good Manufacturing Practices and 17.3.3.8. All visitors shall wear suitable clothing and footwear when entering any product processing and handling area.

- 17.3.4.3 Visitors exhibiting visible signs of illness shall be prevented from entering areas in which dietary supplement is handled and processed.

- 17.3.4.4 Visitors shall enter and exit product handling areas through the proper staff entrance points and comply with all handwashing and personnel practice requirements.

17.3.5 Staff Amenities (change rooms, toilets, break rooms)

- 17.3.5.1 Staff amenities shall have documented cleaning procedures, be supplied with appropriate lighting and ventilation, and shall be made available for use by all persons engaged in the handling and processing of product.

- 17.3.5.2 Change rooms shall be provided to enable staff and visitors to change into and out of protective clothing as required. Change rooms shall be kept clean.

17.3.5.3 High-risk change areas shall be provided for staff engaged in the processing of high-risk products or processing operations in which clothing can be soiled.

17.3.5.4 Provision shall be made for staff to store their street clothing and personal items separate from clean uniforms, product contact zones, product, and packaging storage areas.

17.3.5.5 Where required, a sufficient number of showers shall be provided for use by staff.

17.3.5.6 Toilet rooms shall be:

- i. Designed and constructed so that they are accessible to staff and separate from any processing and product handling operations;
- ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room;
- iii. Sufficient in number for the maximum number of staff;
- iv. Constructed so that they can be easily cleaned and maintained;
- v. Located inside or nearby areas for storing protective clothing, outer garments, and other items while using the facilities; and
- vi. Kept clean and tidy.

Tools/equipment used for cleaning toilet rooms shall not be used to clean processing areas.

17.3.5.7 Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance with regulations.

17.3.5.8 Handwashing basins shall be provided immediately outside or inside the toilet room and designed as outlined in 17.3.2.3.

17.3.5.9 Separate break rooms shall be provided away from product contact/handling zones. Break rooms shall be:

- i. Ventilated and well lit;
- ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting;
- iii. Equipped with a sink serviced with hot and cold potable water for washing utensils;
- iv. Equipped with refrigeration and heating facilities, enabling staff to store or heat food and to prepare non-alcoholic beverages if required; and
- v. Kept clean and free from waste materials and pests.

17.3.5.10 Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for the introduction of contamination, including pests, to the site.

17.4 Personnel Processing Practices

17.4.1 Staff Engaged in Food Handling and Processing Operations

17.4.1.1 All personnel engaged in any product handling, preparation, or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices:

- i. Personnel entry to processing areas shall be through the personnel access doors only;
- ii. All doors are to be kept closed. Doors shall not be open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging;
- iii. Packaging material, product, and ingredients shall be kept in appropriate containers as required, and off the floor;
- iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; and
- v. All wash down and compressed air hoses shall be stored on hose racks after use and not left on the floor.

17.4.1.2 Personnel working in or visiting product handling or processing operations shall ensure that:

- i. Staff and/or visitors wear outer garments in a manner that protects against contamination;
- ii. Staff and/or visitors maintain personal cleanliness;
- iii. Staff do not eat or taste any product being processed in the food handling/contact zones, except as noted in element 17.4.1.4;
- iv. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails, or fingernail polish is not permitted when handling exposed product;
- v. Hair restraints and beard covers, where applicable, are used in areas where product is exposed;
- vi. Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed; and
- vii. Drinking water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging, tools, or equipment storage.

17.4.1.3 The flow of personnel in processing and handling areas shall be managed such that the potential for contamination is minimized.

17.4.1.4 In circumstances where it is necessary to undertake sensory evaluations in a product handling/contact zone, the site shall implement controls and procedures to ensure:

- i. Food safety is not compromised;
- ii. Sensory evaluations are conducted by authorized personnel only;
- iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations;

- iv. Sensory evaluations are conducted in areas equipped for the purpose; and
- v. Equipment used for sensory evaluations is sanitized, maintained, and stored separately from processing equipment.

17.5 Water, Ice, and Air Supply

17.5.1 Water Supply

- 17.5.1.1 Adequate supplies of potable water drawn from a known clean source shall be provided for water used as an ingredient during processing operations and for cleaning the premises and equipment. The source of potable water shall be identified as well as on-site storage (if applicable) and reticulation within the facility.
- 17.5.1.2 Contingency plans shall be in place for instances when the potable water supply is deemed to be contaminated or otherwise inappropriate for use.
- 17.5.1.3 Supplies of hot and cold water shall be provided, as required, to enable the effective cleaning of the premises and equipment.
- 17.5.1.4 The delivery of water within the premises shall ensure potable water is not contaminated. Testing of the backflow system, where possible, shall be conducted at least annually and records shall be maintained.
- 17.5.1.5 The use of non-potable water shall be controlled such that:
 - i. There is no cross-contamination between potable and non-potable water lines;
 - ii. Non-potable water piping and outlets are clearly identified; and
 - iii. Hoses, taps, and other similar sources of possible contamination are designed to prevent backflow or back-siphonage.
- 17.5.1.6 Where water is stored on-site, storage facilities shall be adequately designed, constructed, and routinely cleaned to prevent contamination.

17.5.2 Water Treatment

- 17.5.2.1 Water treatment methods, equipment, and materials, if required, shall be designed, installed, and operated to ensure water receives effective treatment.

Water treatment equipment shall be monitored regularly to ensure it remains serviceable.
- 17.5.2.2 Water used as an ingredient in processing or for cleaning and sanitizing equipment shall be tested and, if required, treated to maintain potability (refer to 17.5.2.1).
- 17.5.2.3 Treated water shall be regularly monitored to ensure it meets the specified indicators. Water treatment chemicals usage shall be monitored to ensure chemical residues are within acceptable limits. Records of testing results shall be kept.

17.5.3 Water Quality

17.5.3.1 Water shall comply with local, national, or internationally recognized potable water microbiological and quality standards, as required when used for:

- i. Washing, thawing, and treating dietary supplements;
- ii. Handwashing;
- iii. Conveying dietary supplements;
- iv. An ingredient or processing aid;
- v. Cleaning product contact surfaces and equipment;
- vi. The manufacture of ice; or
- vii. The manufacture of steam that will come into contact with product or be used to heat water that will come into contact with product.

17.5.3.2 Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities, and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken at sources supplying water for the process or cleaning or from within the site. The frequency of analysis shall be risk-based and at a minimum annually.

17.5.3.3 Water and ice shall be analyzed using reference standards and methods.

Records of analyses shall be maintained.

17.5.4 Ice Supply

17.5.4.1 Ice provided for use during processing operations, as a processing aid, or an ingredient shall comply with 17.5.3.1.

17.5.4.2 Ice that is purchased shall be from an approved supplier and included in the site's food safety risk assessment. Ice shall be supplied in containers that are appropriate for use, cleanable if reused, and be tested as appropriate.

17.5.4.3 Ice rooms and receptacles shall be constructed of materials as outlined in element 17.1.2 and designed to minimize contamination of the ice during storage, retrieval, and distribution.

17.5.5 Air and Other Gases

17.5.5.1 Compressed air or other gases (e.g., nitrogen or carbon dioxide) that contact dietary supplements or product contact surfaces shall be clean and present no risk to food safety.

17.5.5.2 Compressed air systems and systems used to store or dispense other gases used in the manufacturing process that come into contact with dietary supplements or product contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards.

17.6 Receipt, Storage, and Transport

17.6.1 Receipt, Storage, and Handling of Goods

- 17.6.1.1 The site shall document and implement an effective storage plan that allows for the safe, hygienic receipt and storage of raw materials (i.e. frozen, chilled, and ambient), ingredients, retention samples, packaging, equipment, and chemicals.
- 17.6.1.2 Controls shall be in place to ensure all ingredients, raw materials, processing aids, and packaging are received and stored properly to prevent cross-contamination risks and in a manner that does not affect the purity, strength, homogeneity, and composition of final products.
- Unprocessed raw materials shall be received and stored separately from processed raw materials to avoid cross-contamination risk.
- 17.6.1.3 The responsibility and methods for ensuring effective stock rotation principles shall be documented and implemented.
- 17.6.1.4 Procedures shall be in place to ensure that all ingredients, materials, work-in-progress, rework, and finished product are utilized within their designated shelf life.
- 17.6.1.5 Where raw materials, ingredients, packaging, equipment, and chemicals are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there are no risks to the integrity of those goods, no potential for contamination, or adverse effect on food safety.
- 17.6.1.6 Records shall be available to verify the effectiveness of alternate or temporary control measures for the storage of raw materials, ingredients, packaging, equipment, chemicals, or finished products.

17.6.2 Cold Storage, Freezing, and Chilling of Dietary Supplements

- 17.6.2.1 The site shall provide confirmation of the effective operational performance of freezing, chilling, and cold storage facilities. Chillers, blast freezers, and cold storage rooms shall be designed and constructed to allow for the hygienic and efficient refrigeration of dietary supplements and be easily accessible for inspection and cleaning.
- 17.6.2.2 Sufficient refrigeration capacity shall be available to chill, freeze, store chilled, or store frozen the maximum anticipated throughput of product with allowance for periodic cleaning of refrigerated areas.
- 17.6.2.3 The site shall have a written procedure for monitoring temperatures, including the frequency of checks, and corrective actions if the temperature is out of specification.

Freezing, chilling, and cold storage rooms shall be fitted with temperature monitoring equipment and located to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible.

They shall be fitted with an automated device for regulating temperature or an automated alarm system to indicate a significant temperature change when temperature adjustments are a manual operation.

Records shall be kept of frozen, cold, and chilled storage room temperatures.

17.6.2.4 Discharge from defrost and condensate lines shall be controlled and discharged into the drainage system.

17.6.3 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods

17.6.3.1 Rooms used for the storage of product ingredients, packaging, finished products, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration and to prevent packaging from becoming a harborage for pests or vermin.

Practices shall also ensure adequate separation and identification of the different materials being stored.

17.6.3.2 Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning and inspection of the floors and behind the racks. Storage areas shall be cleaned at a pre-determined frequency.

17.6.4 Storage of Hazardous Chemicals and Toxic Substances

17.6.4.1 Hazardous chemicals and toxic substances with the potential for product contamination shall be:

- i. Clearly labeled, identifying and matching the contents of their containers;
- ii. Included in a current register of all hazardous chemicals and toxic substances that are approved for use and stored on-site; and
- iii. Supported by current Safety Data Sheets (SDS) made available to all staff.

17.6.4.2 Storage of hazardous chemicals and toxic substances shall be:

- i. Located in an area with appropriate signage indicating that area is for hazardous storage;
- ii. Controlled, lockable, and accessible only by personnel trained in the storage and use of chemicals;
- iii. Adequately ventilated;
- iv. Stored where intended and not comingled (e.g., food versus non-food grade);
- v. Designed such that pesticides, rodenticides, fumigants, and insecticides are stored separately from sanitizers and detergents; and
- vi. Stored in a manner that prevents a hazard to finished product or product contact surfaces.

Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

17.6.4.3 Hazardous chemicals and toxic substances shall be correctly labeled and:

- i. Used only according to manufacturers' instructions;

- ii. Controlled to prevent contamination or a hazard to raw and packaging material, work-in-progress, finished product, or product contact surfaces;
- iii. Returned to the appropriate storage areas after use; and
- iv. Be compliant with national and local legislation.

17.6.4.4 Daily supplies of chemicals used for continuous sanitizing of water, as a processing aid, or for emergency cleaning of processing equipment and surfaces in product contact zones may be stored within or in close proximity to a processing area, provided that access to the chemical storage facility is restricted to only authorized personnel.

17.6.4.5 Personnel who handle hazardous chemicals and toxic substances including pesticides and cleaning chemicals:

- i. Shall be fully trained in the purpose of the hazardous chemicals and toxic substances, their storage, handling, and use;
- ii. Be provided with first aid equipment and personnel protective equipment (PPE); and
- iii. Ensure compliance with the proper identification, storage, usage, disposal, and clean-up requirements.

17.6.4.6 The site shall dispose of empty, obsolete, and unused chemicals, pesticides, toxic substances, and containers in accordance with requirements and ensure that primary containers are:

- i. Not reused;
- ii. Segregated and securely stored prior to collection; and
- iii. Disposed through an approved vendor.

17.6.4.7 In the event of a hazardous spill, the site shall:

- i. Have spillage clean-up instructions to ensure that the spill is properly contained; and
- ii. Be equipped with PPE, spillage kits, and cleaning equipment.

17.6.5 Loading, Transport, and Unloading Practices

17.6.5.1 The practices applied during loading, transport, and unloading of dietary supplements shall be documented, implemented, and designed to maintain appropriate storage conditions and product integrity. Dietary supplements shall be loaded, transported, and unloaded under conditions suitable to prevent cross-contamination.

17.6.5.2 Vehicles (e.g., trucks/vans/containers) used for transporting product within the site and from the site shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose, and free from odors or other conditions that may negatively impact the product.

17.6.5.3 Vehicles (e.g., trucks/vans/containers) shall be secured from tampering using seals or other agreed-upon and acceptable devices or systems.

- 17.6.5.4 Loading and unloading docks shall be designed to protect the product during loading and unloading. Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity during loading and transport.
- 17.6.5.5 Refrigerated units shall maintain the product at the required temperature. The unit's temperature settings shall be set, checked, and recorded before loading, and the product temperature shall be recorded at regular intervals during loading, as applicable.
- 17.6.5.6 The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals, and the storage temperature at regular intervals during transit.
- 17.6.5.7 On arrival, prior to opening the doors, the product transport vehicle's refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently, and product temperatures shall be recorded at the start of unloading and regular intervals during unloading.
- 17.6.5.8 Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity.

Practices shall include a visual examination of each container or delivery designated as a shipment that the site receives for appropriate content, label, container/vehicle damage, or broken seals.

17.7 Separation of Functions

17.7.1 High-risk Processes

- 17.7.1.1 The processing of high-risk product shall be conducted under controlled conditions such that sensitive areas in which the high-risk product has undergone a "kill" step, a "food safety intervention," or is subject to post-process handling, are protected/ segregated from other processes, raw materials, or staff who handle raw materials to ensure cross-contamination is minimized.

Controlled conditions shall ensure that:

- i. Equipment is placed in an orderly manner to facilitate maintenance, cleaning, and operational efficiency;
 - ii. Adequate spacing between works areas, equipment, and walls is maintained;
 - iii. The flow of personnel is managed (refer to 17.7.1.3), and
 - iv. Where required by regulation, separate facilities, areas, or rooms are maintained.
- 17.7.1.2 Ambient air in high-risk areas shall be tested at least annually to confirm that it does not pose a risk to food safety.
- 17.7.1.3 Areas in which high-risk processes are conducted shall only be serviced by staff dedicated to that function.

- 17.7.1.4 Staff engaged in high-risk areas shall change into clean clothing and footwear or temporary protective outerwear when entering high-risk areas. Staff access points shall be located, designed, and equipped to enable staff to change into the distinctive protective clothing and practice a high standard of personal hygiene to prevent product contamination.
- 17.7.1.5 Product transfer points shall be located and designed, so they do not compromise high-risk segregation and minimize the risk of cross-contamination.

17.7.2 Thawing Operations

- 17.7.2.1 Thawing of product shall be undertaken in equipment and rooms appropriate for the purpose. Equipment for water thawing shall be continuous flow to ensure the water exchange rate and temperature do not contribute to product deterioration or contamination. Water overflow shall be directed into the floor drainage system and not onto the floor or shall be appropriately plumbed.
- 17.7.2.2 Air thawing facilities shall be designed to thaw product under controlled conditions at a rate and temperature that does not contribute to product deterioration or contamination.
- 17.7.2.3 Provision shall be made for the containment and regular disposal of used cartons and packaging from thawed product so that there is no risk to the product.

17.7.3 Control of Foreign Matter Contamination

- 17.7.3.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented, and communicated to all staff.

Inspections shall be performed (refer to 2.5.4.3) to ensure plant and equipment remain in good condition, and equipment has not become detached or deteriorated and is free from potential contaminants.

- 17.7.3.2 Containers, equipment, and other utensils made of glass, porcelain, ceramics, laboratory glassware, or other similar materials shall not be permitted in processing /contact zones (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers are used, or MIG thermometers are required under regulation).

Where glass objects or similar material are required in product handling/contact zones, they shall be listed in a glass inventory, including details of their location and condition.

- 17.7.3.3 Regular inspections of product handling/contact zones shall be conducted (refer to 2.5.4.3) to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass inventory.

- 17.7.3.4 Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged.

- 17.7.3.5 In circumstances where glass or similar material breakage occurs, the affected area shall be isolated, cleaned, thoroughly inspected (including cleaning equipment and footwear), and cleared by a suitably responsible person prior to the start of operations.
- 17.7.3.6 Wooden pallets and other wooden utensils used in product processing and handling areas shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection.
- 17.7.3.7 Loose metal objects on equipment, equipment covers, and overhead structures shall be removed or tightly fixed so as not to present a hazard.
- 17.7.3.8 Knives and cutting instruments used in processing and packaging operations shall be controlled, kept clean, and well maintained. Snap-off blades shall not be used in manufacturing or storage areas.
- 17.7.3.9 Gaskets, rubber impellers, and other equipment made of materials that can wear or deteriorate over time shall be inspected on a regular frequency (refer to 2.5.4.3).

17.7.4 Detection of Foreign Objects

- 17.7.4.1 The responsibility, methods, and frequency for monitoring, maintaining, calibrating, and using screens, sieves, filters, or other technologies to remove or detect foreign matter shall be documented and implemented.
- 17.7.4.2 Where detection and/or removal systems are used, the site shall establish limits for detection based on a risk assessment of the product and its packaging, and identify the location(s) of the detector(s) in the process.
- 17.7.4.3 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated, and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.
- 17.7.4.4 Records shall be maintained of the inspection of foreign object detection devices, of any products rejected or removed by them, and of corrective and preventative actions resulting from the inspections.
- 17.7.4.5 In all cases of foreign matter contamination, the affected batch or item shall be isolated, inspected, reworked, or disposed of. Records shall be maintained of the disposition.

17.8 Waste Disposal

- 17.8.1.1 The responsibility and methods used to collect and handle dry, wet, and liquid waste and store it prior to removal from the premises shall be documented and implemented. Methods shall include:
- i. Practices to minimize the development of odors, and the potential for waste to attract, harbor, or become a breeding place for pests;

- ii. Protection against contamination of raw materials, packaging materials, in-process materials, finished products, water supplies, and grounds surrounding the site; and
- iii. Control of hazardous waste.

17.8.1.2 Waste shall be removed on a regular basis and not allowed to build up in product handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken.

17.8.1.3 Waste and overflow water from tubs, tanks, and other equipment shall be discharged directly to the floor drainage system or by an alternative method that meets local regulatory requirements.

17.8.1.4 Trolleys, vehicle waste disposal equipment, collection bins, and storage areas shall be maintained in a serviceable condition, cleaned, and sanitized regularly to prevent the attraction of pests and other vermin.

17.8.1.5 Adequate provision shall be made for the disposal of all solid processing waste, including trimmings, inedible material, and used packaging.

17.8.1.6 Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials or waste considered high-risk for handling or other reasons. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

17.8.1.7 Inedible waste designated for animal feed shall be stored and handled so that it will not cause a risk to the animal or further processing. If denaturant is used to identify inedible waste, it shall be demonstrated that it does not pose a risk to animal health.

17.8.1.8 Waste held on-site prior to disposal shall be stored in a separate storage facility that is suitably insect proofed and located where it does not present any hazards.

17.8.1.9 Adequate provision shall be made for the disposal of all liquid waste from processing and product handling areas and sanitary waste.

Liquid waste shall be either removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal so as not to present a hazard.

Sewage shall be disposed of through a sewage system or other adequate means.

17.8.1.10 Reviews of the effectiveness of waste management shall form part of regular site inspections (refer to 2.5.4.3), and the results of these inspections shall be included in the relevant inspection reports.

Appendix 1: SQF Food Sector Categories

FSC	Category (Site Scope of Certification)	GFSI Industry Scopes	Applicable SQF Codes and Modules	Description	Example of Products
1	Production, Capture, and Harvesting of Livestock and Game Animals, and Apiculture	A1: Farming of Animals for Meat / Milk / Eggs / Honey	<p>The SQF Food Safety Code: Primary Animal Production:</p> <ul style="list-style-type: none"> System Elements Module 5: GPP for Farming of Animal Products 	<p>Applies to the capture, transport, holding, intensive animal husbandry, and free-range farming of animals, but does not include seafood.</p> <p>Includes:</p> <ul style="list-style-type: none"> Free-range and intensive animal production Dairy farming Game animals Egg production Apiculture 	<p>Includes but is not limited to cattle, lamb, pigs, poultry, eggs, milk, and honey.</p>
2	Indoor Growing and Harvesting of Fresh Produce and Sprouted Seed Crops	B1: Farming of Plants (other than grains and pulses)	<p>The SQF Food Safety Code: Primary Plant Production</p> <ul style="list-style-type: none"> System Elements Module 18: GAP for Indoor Farming of Plant Products 	<p>Applies to the production, harvesting, preparation, packaging, and on-site storage of plant products under controlled environment agriculture (CEA). Includes all products grown in indoor growing operations, greenhouses, mushroom farms, and sprout operations.</p>	<p>Includes but is not limited to:</p> <ul style="list-style-type: none"> All varieties of microgreens All varieties of sprouted seed Tomatoes, peppers, cucumbers, and lettuce Mushrooms
3	Growing and Production of Fresh Produce and Nuts	B1: Farming of Plants (other than grains and pulses)	<p>The SQF Food Safety Code: Plant Production</p> <p>System Elements</p> <p>Module 7: GAP for Outdoor Farming of Plant Products</p>	<p>Applies to the production, harvesting, preparation, field packing, and on-site storage of fresh whole fruit, vegetables, and nuts.</p> <p>Includes all produce grown under broad acre and intensive horticulture production system, including orchards, viticulture, aquaponics, and external nursery operations.</p>	<p>All fresh fruit and vegetable and nut varieties that are ready-to-eat (RTE) or for further processing including:</p> <ul style="list-style-type: none"> Tropical and temperate tree fruits, carrots, beets, potatoes, wine grapes Table grapes, strawberries, raspberries, blueberries, all forms of leafy greens, spring mix, tomatoes, peppers, herbs and spices and tomatoes, green onions, baby spinach, lettuce, melons, etc.

APPENDIX 1: SQF Food Sector Categories

Category (Site Scope of Certification)		GFSI Industry Scopes	Applicable SQF Codes and Modules	Description	Example of Products
FSC 4	Fresh Produce, Grain, and Nut Packhouse Operations	Bill: Pre-process Handling of Plant Products	The SQF Food Safety Code: Plant Production <ul style="list-style-type: none"> • System Elements • Module 10: GOP for Pre-processing of Plant Products 	Applies to the cleaning, shelling, packing, sorting, grading, and on-site storage (including controlled atmosphere storage) of fresh and pre-packaged whole unprocessed fruits, vegetables and nuts, and the cleaning and packing of grain and pulse products.	Includes all fruit, vegetable, grain, and nut varieties that are packed in pack houses and that may undergo controlled atmosphere storage.
5	Extensive Broad Acre Agricultural Operations	Bill: Farming of Grains and Pulses	The SQF Food Safety Code: Plant Production <ul style="list-style-type: none"> • System Elements • Module 8: GAP for Farming of Grains and Pulses 	Applies to the production, harvesting, preparation, transport, and storage of broad-acre crops including pulses, cereal, and other grains. Also includes growing and harvesting of animal feed crops.	All grain and cereal varieties for human consumption and animal feed including but not limited to wheat, oats, rice, pulse crops, hemp (where legally permitted), soy, legumes, maize, corn, cotton, pasture, silage, and hay.
6	Intensive Farming of Seafood	All: Farming of Fish and Seafood	The SQF Food Safety Code: Aquaculture <ul style="list-style-type: none"> • System Elements • Module 6: GAP for Farming of Seafood 	Applies to the intensive farming of freshwater fishes and shellfish, including purification, transport, and storage and extends to gilling, gutting, shucking, and chilling operations.	All farmed fresh fish and shellfish species including: <ul style="list-style-type: none"> • Tuna, salmon, trout, and other farmed fish spp. • Oysters, mussels, shrimp, lobster, crab, and other farmed shellfish spp.
7	Slaughtering, Boning, and Butchery	CO: Animal Primary Conversion	The SQF Food Safety Code: Animal Product Manufacturing <ul style="list-style-type: none"> • System Elements • Module 9: GMP for Processing of Animal Products 	Applies to the slaughtering, dressing, processing, on-site storage, chilling, freezing, and wholesaling of all animal species and game animals for consumption and extends to all meat cuts.	Includes uncooked poultry, pork, and red meat animal species prepared in retail butcher shops, boning rooms, and meat wholesale markets, including ground (minced) meats. Bone-in and whole muscle fillet for pork and red meat species including ground (minced) red meat. Bone-in and whole muscle poultry fillet and ground (minced) poultry meat.

APPENDIX 1: SQF Food Sector Categories

FSC		Category (Site Scope of Certification)	GFSI Industry Scopes	Applicable SQF Codes and Modules	Description	Example of Products
8	Manufactured Meats and Poultry	CI: Processing of Perishable Animal Products	The SQF Food Safety Code: Animal Product Manufacturing <ul style="list-style-type: none"> • System Elements • Module 9: GMP for Processing of Animal Products 	Applies to the processing, manufacture, transport, and on-site storage operations where meat (all red meat species and poultry) is the major ingredient including all value-adding operations (i.e. cook-chill, crumbing, curing, smoking, cooking, drying, fermenting, and vacuum packing) and chilling and freezing operations, but not canning of meat or poultry product.	Includes poultry, pork, and red meats blends and raw heat-treated and fermented poultry, pork, and red meats, including salami, hot dogs, sausages, bacon, pepperoni, and meat pastes etc.	
9	Seafood Processing	CI: Processing of Perishable Animal Products	The SQF Food Safety Code: Animal Product Manufacturing <ul style="list-style-type: none"> • System Elements • Module 9: GMP for Processing of Animal Products 	Applies to the processing, manufacture, transport, and on-site storage of all fish and seafood species and extends to value-adding operations, including dismembering, fermenting, crumbing, smoking, cooking, freezing, chilling, drying, and vacuum packing, but not canning of seafood product.	Includes: Whole fish, fish fillets, reformed fish cakes, coated fish portions uncooked fish product, sashimi, sushi surimi smoked cooked fish products chilled or frozen that require no further cooking prior to consumption.	
10	Dairy Food Processing	CI: Processing of Perishable Animal Products	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> • System Elements • Module 11: GMP for Processing of Food Products 	Applies to the processing, transport, and storage of food products from all species used for milk collection and extends to all value-adding operations, including freezing, pasteurizing, ultra-filtration, evaporation/concentration, fermentation, clarification, culturing, and spray drying of milk but not UHT operations. (refer to FSC 15). Includes milk substitutes where the technology is essentially the same.	Includes milk and cream, butter, cottage cheese, sour cream, all forms of cheese, yogurt, ice cream, and dried milk. Also includes milk substitutes such as soymilk and tofu, and infant formula.	

APPENDIX 1: SQF Food Sector Categories

FSC		Category (Site Scope of Certification)	GFSI Industry Scopes	Applicable SQF Codes and Modules	Description	Example of Products
11	Honey Processing	CIV: Processing of Ambient Stable Animal and Plant Products (mixed products)	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> • System Elements • Module 11: GMP for Processing of Food Products 	Applies to the processing, packaging, and on-site storage of food products from all species used for honey collection including clarifying and treatment operations.	Includes honey, honeycomb, pollen, and royal jelly.	
12	Egg Processing	CI: Processing of Perishable Animal Products	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> • System Elements • Module 11: GMP for Processing of Food Products 	Applies to the, grading, cleaning, processing, transport, and on-site storage of food products from all species used for egg collection and processing.	Graded, cleaned eggs and value-added products where egg is the major ingredient.	
13	Bakery and Snack Food Processing	CIV: Processing of Ambient Stable Animal and Plant Products (mixed products)	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> • System Elements • Module 11: GMP for Processing of Food Products 	Applies to the processing, packaging, and on-site storage of extruded snack foods and cake mix formulations and extends to all bakery operations.	Includes baked items such as meat pies, custard pies, bread, cookies, cakes, and mixes and all varieties of snack food.	
14	Fruit, Vegetable, and Nut Processing, and Fruit Juices	CI: Processing or Perishable Plant Products	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> • System Elements • Module 11: GMP for Processing of Food Products 	Applies to the processing, packaging, and on-site storage of all processed fruit, vegetable, and nut varieties, including freezing, fermenting drying, slicing, dicing, cutting, and modified atmosphere processing of all fruits and vegetables, and the roasting, drying, and cutting of nuts. Does not include canning of fruits and vegetables.	Includes frozen, fermented, dried, sliced, diced, cut, and modified atmosphere packaged (MAP) fruit, vegetable, and nut products, including prepared and deli salads. Includes fresh and pasteurized fruit and vegetable juices.	

APPENDIX 1: SQF Food Sector Categories

FSC		Category (Site Scope of Certification)	GFSI Industry Scopes	Applicable SQF Codes and Modules	Description	Example of Products
15	Canning, UHT, and Aseptic Operations	CIV: Processing of Ambient Stable Animal and Plant Products (mixed products)	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> • System Elements • Module 11: GMP for Processing of Food Products 	Applies to the processing of low-acid canned foods and sterilization (retorting) UHT, or other high-temperature or high-pressure processes (HPP) not covered elsewhere and the manufacture of the associated hermetically sealed containers.	Includes: The commercial sterilization of fish, meats, fruits and vegetables, and other low-acid soups and sauces in metal or glass containers or retort pouches. Does not include pasteurization of dairy, fruit, or vegetable juices, but does include UHT treatment of <ul style="list-style-type: none"> • Milk or milk products; or • Egg or egg products; or • Fruit or vegetable juices. • Canned pet food (refer to FSC 32) 	
16	Ice, Drink, and Beverage Processing	CIV: Processing of Ambient Stable Animal and Plant Products (mixed products)	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> • System Elements • Module 11: GMP for Processing of Food Products 	Applies to fermentation, concentration aseptic filling, or drying operations processes. Does not include powdered milk and pasteurization and UHT treatment of milk or milk products or fruit and vegetable juicing operations. Does not apply to dry beverage ingredients (e.g. tea, coffee).	Includes carbonated soft drinks, carbonated and non-carbonated waters, mineral water, ice, liquid tea and coffee, energy drinks, wine, beer, and other alcoholic beverages.	
17	Confectionary Manufacturing	CIV: Processing of Ambient Stable Animal and Plant Products (mixed products)	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> • System Elements • Module 11: GMP for Processing of Food Products 	Applies to the processing, packaging, and on-site storage of all types of confectionary and extends to all chocolate and imitation chocolate-based processing.	Includes all confectionary products that undergo refining, conching, starch molding, compression, extrusion, and vacuum cooking.	

APPENDIX 1: SQF Food Sector Categories

FSC		Category (Site Scope of Certification)	GFSI Industry Scopes	Applicable SQF Codes and Modules	Description	Example of Products
18	Preserved Foods Manufacturing	CIV: Processing of Ambient Stable Animal and Plant Products (mixed products)	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> System Elements Module II: GMP for Processing of Food Products 	Applies to the processing, packaging, and on-site storage of all foods preserved under high temperature processes not covered elsewhere, compositionally preserved foods that are not high-temperature processed or other alternative acceptable methods not covered elsewhere.	Includes dressings, mayonnaise, sauces, marinades, pickled foods, peanut butter, mustards, jams, and fillings.	
19	Food Ingredient Manufacturing	K: Production of Bio-chemicals or Bio-cultures used as Food Ingredients or Processing Aids in Food Production	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> System Elements Module II: GMP for Processing of Food Products 	Applies to the processing, blending, re-packaging, and on-site storage of dry food ingredients, cultures, and yeast, but does not include dairy products, fermented meats, or other fermented products mentioned elsewhere.	Includes starter cultures used in cheese, yogurt, and wine manufacture and cultures used in the baking industry and other products used for the preservation of foods. Other additional products include additives, preservatives, flavorings, colorings, soup mixes, sauces, dehydrated culinary products, salt, sugar, spices, and other condiments. Applies to dried tea and coffee products.	
20	Recipe Meals Manufacturing	CIII: Processing of Perishable Animal and Plant Products (mixed products)	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> System Elements Module II: GMP for Processing of Food Products 	Applies to the processing, receipt, controlled temperature on-site storage of foods prepared from a range of ingredients (mixed foods) that require cooking, heating, freezing, or refrigerated storage prior to serving.	Includes ready-to-eat (RTE) chilled meals and desserts, frozen meals, pizza, frozen pasta, soups, and meal solutions, sous vide products, and freeze-dried and dehydrated meals. Includes sandwiches, wraps, plated or boxed meals, and high-risk desserts for distribution to food service.	

APPENDIX 1: SQF Food Sector Categories

Category (Site Scope of Certification)		GFSI Industry Scopes	Applicable SQF Codes and Modules	Description	Example of Products
FSC 21	Oils, Fats, and the manufacturing of Oil or Fat-based Spreads	C11: Processing of Perishable Animal and Plant Products (mixed products)	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> • System Elements • Module 11: GMP for Processing of Food Products 	Applies to the manufacture of all animal and vegetable oils and fats and to the manufacture of margarine. Includes clarifying and refining processes.	Includes shortening (animal and vegetable), oils - olive, peanut, corn, vegetable, sunflower, safflower, canola, nut, seed, hemp (where legally permitted), and oil-based spreads such as margarine and oil-based spreads.
22	Processing of Cereal Grains	C11: Processing of Perishable Plant Products	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> • System Elements • Module 11: GMP for Processing of Food Products 	Applies to the processing of cereals of all varieties, including sorting, grading, picking, handling of bulk grains, milling, and extruding.	Includes wheat, maize, rice, barley, oats, millet, pasta, hemp (where legally permitted), and breakfast cereals.
23	Food Catering and Foodservice	E: Catering	The SQF Food Safety Code: Foodservice <ul style="list-style-type: none"> • System Elements • Module 16: GRP for Foodservice 	Applies to all on-site food preparation and service activities, including, storage, and distribution undertaken with mixed foods that are ready-to-eat and do not require further treatment or processing by the consumer. Only applies to products prepared on-site that are ready to eat, ready to serve.	Includes food service caterers, retail delicatessen/self-serve facilities, restaurants, fast food outlets, delicatessens, school cafeterias (canteens), hospital/institution meal services, childcare centers, and mobile and home delivery food services. Includes sandwiches, wraps, and high-risk desserts that are prepared on-site.
24	Food Retailing	F1: Retail/ Wholesale	The SQF Food Safety Code: Food Retail <ul style="list-style-type: none"> • System Elements • Module 15: GRP for Retail 	Applies to the receipt, handling, storage, and display at retail level of stable or pre-processed and packaged foods and/or food intended for further preparation by the consumer. Retailers that prepare ready-to-eat (RTE) foods must include FSC23 also.	Includes all foods distributed and sold through retail outlets. Does not include foods that are prepared on-site.

APPENDIX 1: SQF Food Sector Categories

FSC		Category (Site Scope of Certification)	GFSI Industry Scopes	Applicable SQF Codes and Modules	Description	Example of Products
25	Repackaging of Products not Manufactured On-site	CIV: Processing of Ambient Stable Animal and Plant Products (mixed products)	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> • System Elements • Module 11: GMP for Processing of Food Products 	Assembling of whole produce and packaged products (e.g. nuts, hard candy, dried fruit, and beef jerky) that are manufactured elsewhere. Applies to products not covered elsewhere.	Includes gift baskets, festive hampers, and presentation packs.	
26	Storage and Distribution	G: Provision of Storage and Distribution Services for missing word?	The SQF Food Safety Code: Storage and Distribution <ul style="list-style-type: none"> • System Elements • Module 12: GDP for Transport and Distribution of Food Products 	Applies to dedicated distribution centers, warehouses, and transport operators involved in the receipt, storage, consolidation, and distribution of perishable fresh produce and general food lines, including chilled, frozen, dry goods, stable or pre-processed and packaged foods, and/or food intended for further preparation by the consumer at wholesale level.	Includes all transportation, storage, and delivery of perishable and shelf-stable foods sold through markets, retail, and foodservice facilities. Includes transportation, storage, and delivery of all varieties of fresh unprocessed fruit, vegetable, and nut products.	
27	Manufacture of Food Packaging	I: Production of Food Packaging	The SQF Food Safety Code: Manufacture of Food Packaging <ul style="list-style-type: none"> • System Elements • Module 13: GMP for Manufacture of Food Packaging 	Applies to the manufacture and on-site storage of food sector packaging materials. Includes items that may be used in food manufacturing or food service facilities, including paper towels, napkins, disposable food containers, straws, stirrers.	All food-grade packaging materials, including flexible films, paperboard-based containers, metal containers, flexible pouches, glass containers, plastic and foam containers (PET, polystyrene, etc.), and single-use foodservice products (e.g., paper towels, napkins, disposable food containers, straws, stirrers).	

APPENDIX 1: SQF Food Sector Categories

FSC		Category (Site Scope of Certification)	GFSI Industry Scopes	Applicable SQF Codes and Modules	Description	Example of Products
31	Dietary Supplements Manufacturing	K: Production of Bio-chemicals or Bio-cultures used as Food Ingredients or Processing Aids in Food Production	The SQF Food Safety Code: Dietary Supplements Manufacturing System Elements Module 17: GMP for Processing of Dietary Supplements	Applies to the manufacture, blending, packaging, and on-site storage of dietary supplements.	Includes vitamins, probiotics, natural health products, protein blends, and label supplements.	
32	Pet Food Manufacturing	CI, CII, CIII, or CIV as applicable	The SQF Food Safety Code: Pet Food Manufacturing <ul style="list-style-type: none"> System Elements Module 4: GMP for Processing of Pet Food Products 	Applies to the Pet Food Manufacturing intended for consumption by domestic animals and speciality pets.	Includes dry and moist pet foods and treats, semi-raw, chilled, or frozen product. Does not include canned pet food (refer to FSC 15).	
33	Food Processing Aides Manufacturing	K: Production of Bio-chemicals or Bio-cultures used as Food Ingredients or Processing Aids in Food Production	The SQF Food Safety Code: Food Manufacturing <ul style="list-style-type: none"> System Elements Module 11: GMP for Processing of Food Products 	Applies to the manufacture, storage, and transport of chemicals and aides used in the food processing sectors.	Includes food-grade lubricants, processing aides, and chemicals for clean-in-place systems.	
34	Animal Feed Manufacturing	D: Production of Feed	The SQF Food Safety Code: Animal Feed Manufacturing <ul style="list-style-type: none"> System Elements Module 3: GMP for Animal Feed Production 	Applies to the manufacture, blending, transport, and storage of animal feeds.	Includes compounded and medicated feeds.	

Appendix 2: Glossary

A

Accreditation: Approval by an Accreditation Body that is a member of the International Accreditation Forum (IAF) and a signatory to the Multilateral Recognition Agreement (MLA) confirming that the management system of a certification body complies with the ISO/IEC 17065:2012 (or subsequent version) and the Criteria for SQF Certification Bodies requirements and that the certification body is suitable to be granted a license by SQFI to provide the service in the licensed territory (ies).

Airlock: A space which permits the passage of people between one environment and another with two doors in series which do not open simultaneously, and thus minimizes the transfer of pests, dust, odors, or air from one area to the other.

Allergens: Typically, naturally occurring proteins in foods or derivatives of them that cause abnormal immune responses.

Ambient Air: Atmospheric air within an enclosed food facility.

Annual/Annually: Occurring once per year.

Approved Supplier (s): A supplier (s) that has been assessed and approved by a site based on risk assessment as capable of meeting the sites food safety and quality requirements for goods and services supplied.

Audit: Refer to SQF Audit

Audit Checklist: The form listing SQF food safety and/or quality Code elements specific to a registered site's audit scope and date which is downloaded from the SQFI assessment database and is used by the SQF food safety and/or quality auditor when conducting an SQF food safety and/or quality audit.

Auditor: Refer to SQF Auditor

B

Blackout Period: Dates nominated by the site and agreed by the certification body when an unannounced audit cannot occur due to legitimate business reasons (e.g., maintenance, raw material shortage).

C

Central Site: An SQF certified site at which activities are planned to control and manage a network of SQF certified sub-sites within an SQF multi-site program (refer to SQFI's multi-site program requirements).

Certificate: An official document in a format approved by the SQFI issued to a site by a licensed certification body attesting to the successful completion of an SQF food safety and/or quality certification audit and/or a re-certification audit.

C

Certification: A process by which a licensed SQF certification body confirms compliance of a site's SQF Food Safety and/or Quality System to the SQF Food Safety and/or Quality Code, as appropriate, following a certification audit or re-certification audit. The terms, "certify," "certifies", and "certified" shall have a corresponding meaning under the SQF Program. completion of an SQF food safety and/or quality certification audit and/or a re-certification audit.

Certification Audit: An audit of a site's complete SQF System, where the site's SQF System has not been previously certified or has been previously certified but requires certification as the earlier certification has been revoked or voluntarily discontinued by the site.

Certification Body (also Licensed Certification Body): An entity which has entered into a license agreement with the SQFI authorizing it to certify a site's SQF System in accordance with the ISO / IEC 17065:2012 (or subsequent version) and the Criteria for SQF Certification Bodies.

Certification Cycle: The annual period between a site's certification/re-certification audits.

Certification Number: A unique number provided by the certification body and included on the certificate, issued to a site that has successfully completed an SQF food safety or quality certification audit.

Certification Program: As defined by the Global Food Safety Initiative, a systematic plan which has been developed, implemented, and maintained for the scope of food safety. It consists of a standard and food safety system in relation to specified processes or a food safety service to which the same plan applies. The food safety program should contain at least a standard, a clearly defined scope, and a food safety system.

Certification Program Owner, or CPO (GFSI): As defined by the Global Food Safety Initiative, an organization which is responsible for the development, management, and maintenance of a Certification Program.

Codex Alimentarius Commission (Codex): The internationally recognized entity whose purpose is to guide and promote the elaboration and establishment of definitions, standards and requirements for foods, and to assist in their harmonization and, in doing so, to facilitate international trade. The Commission Secretariat comprises staff from the Food and Agriculture Organization and the World Health Organization. The Codex Alimentarius Commission adopted the principles of the Hazard Analysis and Critical Control Point (HACCP) system in 1997.

Competence: Ability to apply knowledge and skills to achieve intended results (ISO 19011).

Compressed Air Monitoring: A program that includes particles, water, oil, microbiological, and relevant gaseous testing in compressed air or other gases. A verification of the effectiveness of compressor maintenance and filtration that a management facility has in place.

Contract Manufacturer (or co-man, co-manufacturer): Facilities that are contracted by the SQF certified site to produce, process, pack and /or store part of or all of one or more products included in the site's SQF scope of certification. In some cases, a product may be manufactured interchangeably at the certified site and by the contract manufacturer. In other cases, a contract manufacturer may only be used intermittently to fulfill or supplement the certified site's production. Contract manufacturers must follow the requirements outlined in the SQF Food Safety Code.

C

Corporation (or corporate): A head office. An entity that does not manufacture or handle product but oversees and contributes to the Food Safety and/or Quality Management System at an SQF certified site owned by the corporation.

Correction: Action to eliminate a detected non-conformity. Has the same meaning as “corrected”.

Corrective Action: Action to eliminate the cause of a detected non-conformity identified at a food safety audit, a deviation identified at a quality audit, or other undesirable situation and to prevent recurrence. Also referred to as ‘corrective and preventative action’ (refer to “root cause analysis”).

Crisis Management: The process by which a site manages an event (e.g., a flood, a drought, a fire, pandemic, etc.) that adversely affects the site’s ability to provide continuity of supply of safe, quality food, and requires the implementation of a crisis management plan.

Customer: A buyer or person that purchases goods or services from the SQF certified site.

D

Dietary Supplement: A product containing one or more vitamins, herbs, enzymes, amino acids, or other ingredients, that is taken orally to supplement or augment the consumer’s diet.

It includes products not generally covered under food safety regulations in the country of manufacture or sale, and may include alternative or traditional medicines not regulated the country of manufacture or sale.

Dietary supplements may also be referred to as a natural health products or alternative names that align with specific regulations in the country of manufacture or sale.

Deviation: A non-conformity raised against the SQF Quality Code. Deviations are graded as follows:

- **A minor quality deviation** is an omission or deficiency in the quality system that produces unsatisfactory conditions that if not addressed may lead to a quality threat but not likely to cause a system element breakdown.
- **A major quality deviation** is an omission or deficiency in the quality system producing unsatisfactory conditions that carry a significant quality threat and are likely to result in a system element breakdown.

No critical deviations are raised at a quality systems audit.

E

Environmental Monitoring Program (EMP):

A program which includes pathogen or indicator swabbing as appropriate to detect risk in the sanitary conditions in the processing or food handling environment. A verification of the effectiveness of the pathogen controls that a management facility has in place.

Exempt (or exemption): A term applied to elements of the SQF Food Safety and Quality Code that the site does not wish to be included in the SQF System audit, and has submitted a written request to the certification body to exclude, prior to commencement of any scheduled audit activity.

In the SQF Food Safety Code, mandatory elements of the system elements cannot be exempted. The certification body must confirm the reasons for exemption as part of the site audit.

The term also applies to products, processes or areas of the site that the site wishes to exclude from the audit. A request is to be submitted to the certification body in writing prior to the audit activity and is listed in the site description in the SQFI assessment database.

F

Facility: The site's premises at its street address. The production, manufacturing, or storage area where product is produced, processed, packaged, and/or stored, and includes the processes, equipment, environment, materials and personnel involved. The facility must be managed and supervised under the same operational management. The facility is the site audited during an on-site audit (refer to "site").

Feed: Any single or multiple materials, whether processed, semi-processed, or raw, which is intended to be fed directly to food-producing animals.

Feed Safety: The principles and practices applied to feed production and manufacturing to ensure that feed does not cause harm to animals or humans.

Food: Any substance, usually of animal or plant origin, intentionally consumed by humans, whether processed, partially processed, or unprocessed.

May include water, alcoholic and non-alcoholic drinks, materials included in a processed food product and any other substance identified by regulation (legislation) as a food.

Food Contact Packaging: Food packaging is the material around a food that contains and protects the food through the supply chain. Food contact packaging is the containing material in direct contact with the food.

Food Defense: As defined by the US Food and Drug Administration, the efforts to prevent intentional food contamination by biological, physical, chemical, or radiological hazards that are not reasonably likely to occur in the food supply.

Food Defense Plan: A set of written documents that is based upon food defense principles and incorporates a vulnerability assessment, includes mitigation strategies, and delineates food defense monitoring, corrective action, and verification procedures to be followed. (www.fda.gov)

Food Fraud: As defined by Michigan State University, a collective term used to encompass the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, feed, or food packaging and/or labelling, product information; or false or misleading statements made about a product for economic gain. It may also include gray market or stolen goods.

F

Food Fraud Mitigation Plan: A plan designed to address the risk factors identified in the food fraud vulnerability assessment.

Food Fraud Vulnerability Assessment: A risk-assessment-style evaluation of a food's vulnerability to food fraud.

FMI: A not-for-profit corporation, working with and on behalf of the entire food industry to advance a safer, healthier and more efficient consumer food supply chain, having its principal offices at 2345 Crystal Drive, Suite 800, Arlington, VA 22202, United States of America.

Food Quality Plan: As described in the SQF Quality Code, it is based on the CODEX HACCP method and includes process controls at quality points in production to monitor product quality, identify deviations from control parameters and define corrections necessary to keep the process under control.

Food Safety Culture (GFSI): Shared values, beliefs and norms that affect mindset and behavior toward food safety in, across and throughout an organization.

Elements of food safety culture are those elements of the food safety management system which the senior management of a company may use to drive the food safety culture within the company. These include, but are not limited to:

- Communication about food safety policies and responsibilities
- Training
- Employee feedback on food safety related issues
- Performance measurement.

Food Safety Event: An incident within the food supply chain where there is a risk, potential risk or perceived risk of illness or confirmed illness associated with the consumption of a food, and which requires intervention. (fscf-ptin.apeec.org)

Food Safety Fundamentals: An entry level Code for new and developing businesses that covers basic Good Agricultural or Aquaculture Practices (GAPs), Good Manufacturing Practices (GMPs), or Good Distribution Practices (GDPs) and defines the essential elements that must be implemented to meet relevant legislative and customer food safety requirements. Sites that comply with the SQF Code certification requirements for the Food Safety Fundamentals Code receive a certificate from an SQFI licensed certification body.

Food Safety Plan: As described in the SQF Food Safety Codes, a prepared plan based on the CODEX HACCP method that includes process controls at control points in production to monitor product safety, identify deviations from control parameters and define corrections necessary to keep the process under control.

Food Sector Category (FSC): A classification scheme established to assist in a uniform approach to management of the SQF Program and defines the manufacturing, production, processing, storage, wholesaling, distribution, retailing and food service activities and other food sector services. Food sector categories are applied to site, auditor, trainer, and consultant registration as defined by SQFI.

G

General Requirements: The current edition of the document entitled “Criteria for SQF Certification Bodies: SQF Guidance on the Application of ISO/IEC 17065:2012, General Requirements for Certification Bodies,” published SQFI.

Global Food Safety Initiative (GFSI): The Global Food Safety Initiative is a private organization, established and managed by the international trade association, the Consumer Goods Forum. The GFSI maintains a scheme to benchmark food safety standards used to certify producers, manufacturers warehouses, food retailers, and other businesses within the food supply chain.

Good Practice Elements: Management and operational practices which define the best practice handling and hygiene elements for food or feed production, manufacturing, storage, transport, and retail.

- Good Agricultural/Operating Practices (GAPs/GOPs) apply to fruit, vegetable, and grain farms
- Good Aquaculture Practices (GAPs) apply to intensive seafood farming
- Good Distribution Practices (GDPs) apply to independent food warehouse and transport facilities
- Good Manufacturing Practices (GMPs) apply to food and feed manufacturing
- Good Production Practices (GPPs) apply to livestock farms
- Good Retail Practices (GRPs) apply to retail food outlets

H

HACCP (GFSI): Hazard Analysis and Critical Control Point.

A system which identifies, evaluates, controls and monitors hazards relating to food safety and specified by Codex Alimentarius (CAC / RCP 1-1969).

HACCP Method: The implementation of pre-requisite programs and the application of HACCP principles in the logical sequence of the twelve steps as described in the current edition of the CODEX Alimentarius Commission Guidelines. The SQF Food Safety and Quality Codes utilize the HACCP method to control food safety hazards and quality threats in the segment of the food chain under consideration.

HACCP Plan: A document prepared in accordance with the CODEX HACCP method to ensure control of hazards which are significant for food safety or the identification of quality threats for the product under consideration.

HACCP Training: Training in the principles and application of a HACCP system based on the Annex of the Codex Alimentarius Commission General Principles of Food Hygiene.

The training shall be:

1. Recognized as a HACCP training course used extensively in a country.
2. Administered and delivered by a recognized institution.
3. The acquired knowledge of the candidate shall be assessed as part of the training program.

H

Hazardous Chemicals and Toxic

Substances: Solids, liquids or gasses that are radioactive, flammable, explosive, corrosive, oxidizing, asphyxiating, pathogenic, or allergenic, including but not restricted to detergents, sanitizers, pest control chemicals, lubricants, paints, processing aids, bio-chemical additives, which if used or handled incorrectly or in increased dosage may cause harm to the handler and/or consumer.

Hazardous or toxic chemicals may be prescribed by regulation as “dangerous goods” and may carry a “poison,” “Hazmat” or “Hazchem” label depending on the jurisdiction.

High Risk Area: A segregated room or area where high risk food processes are performed, and which require a higher level of hygienic practice to prevent contamination of high-risk food by pathogenic organisms.

High Risk Food: Food or food product with known attributes for microbiological growth, physical or chemical contamination, or which may allow for the survival of pathogenic microbial flora or other contaminants which, if not controlled, may contribute to illness of the consumer. It may also apply to a food that is deemed high risk by a customer, declared high risk by the relevant food regulation or has caused a major foodborne illness outbreak.

High Risk Food Process(es): A process that requires specific controls and/or a higher level of hygienic practice to prevent food contamination from pathogens.

I

Industry Code of Practice: Industry norms, rules or protocols established by industry groups which provide practical, industry specific guidelines on meeting regulations while meeting industry needs.

Information Communication Technology (ICT): The use of technology for gathering, storing, retrieving, processing, analyzing, and transmitting information. It includes software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, drones, video cameras, wearable technology, artificial intelligence, and others. (Reference: IAF MD:4, Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes; The International Accreditation Forum)

Ingredients: Minor materials (e.g., spices) used to supplement the conversion of raw materials in the food manufacturing process (refer to “raw materials”).

Inspection Area: A designated station close to the process (es) for the purpose of monitoring food safety and/or quality attributes and parameters.

L

Legality: Legality refers to national federal, state and/or local regulations applicable to the certified product in the country of manufacture and intended markets.

Licensed Certification Body: Refer to “Certification Body”

M

Mandatory Elements: System elements that must be implemented and audited for a site to achieve SQF food safety certification. Mandatory elements cannot be exempted during a certification/re-certification audit.

Maximum Residue Limits (MRLs): Are set by local regulation or CODEX Alimentarius Commission, and apply to maximum allowable trace levels of agricultural and veterinary chemicals in agricultural produce, particularly produce entering the food chain.

Multi-site Certification: Multi-site certification involves the designation and certification of a central site (i.e. manufacturer, packer, warehouse) into which a network of certified sub-sites all performing the same function feed into. The central site and all sub-sites are all located in the one country and operate under the same food safety legislation (refer to Appendix 4: Requirements for Multi-site Certification)

Multi-site Program: An SQF multi-site program is comprised of a central SQF certified site under which activities are planned to manage and control the food safety management systems of a network of sub-sites under a legal or contractual link (refer to Appendix 4: Requirements for Multi-site Certification)

N

Non-conformance (or non-conformity): Is non-fulfillment of a requirement (ISO/IEC 19011). The levels and definitions of non-conformance within the SQF Food Safety Codes are:

- **A minor non-conformance** is evidence of a random or infrequent failure to maintain compliance to a requirement, but which does not indicate a breakdown in the food safety management system or that food safety is compromised. It is evidence of an incomplete or inappropriate implementation of SQF requirements which, if not corrected, could lead to system element breakdown
- **A major non-conformance** is a failure of a system element, a systemic breakdown in the food safety management system, a serious deviation from the requirements, and/or absence of evidence demonstrating compliance to an applicable system element or Good Operating Practices. It is evidence of a food safety risk to products included in the scope of certification.
- **A critical non-conformance** is a breakdown of control (s) at a critical control point, a pre-requisite program, or other process step and judged likely to cause a significant public health risk and/or where product is contaminated.

N

A critical non-conformance is also raised if the certification body deems that there is systemic falsification of records relating to food safety controls and the SQF System.

Non-conforming Equipment: Processing, packing, storage, transport, or handling equipment that is not suitable for the intended purpose and may potentially compromise food or feed safety and/or quality.

Non-conforming Product: In-process or finished food or feed product that does not meet specifications for food safety and/or quality as applicable and which may be unsafe.

N/A: Stands for “not applicable” and may be reported during the SQF food safety and/or quality audit by the food safety and/or quality auditor when, in the consideration of the auditor, an element does not apply.

N/A may also be reported to avoid double debiting, for example where a non-conformity has been raised against a similar, but more appropriate element. In this case, the element will be reported as N/A.

O

On-site Laboratories: A designated and enclosed area in the site in which chemical, microbiological and other product testing is conducted and if not controlled could lead to contamination and requires the use of good laboratory practices.

On-site Visit: An unannounced visit to a site by an authorized certification body auditor to verify the effective implementation of corrective actions that resulted from suspension at the previous re-certification audit. Depending on the cause of the suspension, the site visit occurs either within thirty (30) days or sixty (60) days of the certification body receiving the site’s corrective action plan.

P

Pests: Vermin, including birds, rodents, insects, or other unwanted species that can carry disease and pose a risk to packaging, feed, or food.

Pet Food: Any substance intended for consumption by domestic animals and specialty pets. It includes dry and moist pet foods and treats, semi-raw, canned, chilled, or frozen product.

Plan: As defined by ISO 9001, a document(s) used to establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization’s policies (refer to Food Safety (Quality) Plan).

Potable: Water that is safe to drink.

P

Pre-requisite Program: A procedural measure that when implemented reduces the likelihood of a food safety hazard or a food quality threat occurring, but one that may not be directly related to activities taking place during production.

Primary Producer or Producer: A sole entity involved in the pre-farm gate production, field packing, storage and supply of agricultural product produced and/or harvested under their exclusive control.

Processing: A series of operational steps in which the nature of the food is changed. Processing includes but is not limited to repacking, over bagging and re-labeling of food, slaughtering, dismembering, sorting, grading, cleaning, treating, drying, salting, smoking, cooking, canning, purifying, and the pasteurization of food.

Processing Aid: Any substances intentionally used in the processing of raw materials, foods or their ingredients to fulfil a certain technological purpose during treatment or processing, but which does not form part of the finished product.

Product: A food or feed substance that applies to a specific food sector category as defined by SQFI.

Proficiency Testing: Proficiency testing calibrates the performance of laboratory personnel and in-process testers who conduct microbiological, chemical, or physical analysis of ingredients, materials, work-in-progress, finished products and the processing environment by means of interlaboratory comparisons.

Program: A plan(s) used to establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies. Examples include allergen management program or an environmental monitoring program.

Purity: The absence of contaminants that could cause a food safety hazard.

Q

Quality: A measure of exceeding customer or corporate expectations and a state of being free from defects, deficiencies, and significant variation.

Quality Threat: An identified risk that has the potential, if not controlled, to affect the quality of a product.

R

Raw Materials: The primary material from which a food or feed product is made. Raw materials may be unprocessed, ie primary agricultural materials, or processed, i.e., the form has been substantially changed prior to receipt by the site (refer to "ingredients").

Re-certification: A re-certification by a certification body of a site's SQF Food Safety or Quality System as a result of a re-certification audit. Re-certified shall have a corresponding meaning.

R

Re-certification Audit: An audit of the site's SQF Food Safety or Quality System within thirty (30) calendar days either side of the anniversary of last day of the initial certification audit.

Relevant Authority: National, state or local government, commission or statutory board that establishes and controls legislative requirements concerning the safety of agricultural and food products throughout the supply chain.

Recoup: Product that is intact and requires no further processing or handling but is repackaged for distribution. For example, mixing of partial cases to build one complete case. May also be referred to as "repack."

Regulatory Warning: A formal notification or advisory from a relevant authority to a certified site regarding a breach in legislative requirements.

Remote Activities: The actions that occur to collect objective evidence from a location other than the physical location of the audited organization as part of a full systems audit.

Rework: Food, materials, and ingredients, including work-in-progress that has left the normal product flow and requires action to be taken on it before it is acceptable for release and is suitable for reuse within the process.

Risk Assessment: It is the process of determining the level of action needed to prevent or eliminate an adverse food safety (or quality) event, or determining the likelihood and consequence of an adverse food safety (or quality) outcome if planned activities do not occur as expected. Risk assessment is part of a risk management strategy.

Root Cause Analysis (or RCA): A method of problem solving to identify and resolve the core issue(s) that cause a non-conformity, deviation, or other adverse food safety or quality event.

Rules of Use: The rules and procedures contained in SQF Logo and/or Quality Shield Rules of Use and includes the certificate schedule and any modification, variation or replacement of the SQF trademark rules of use.

S

Scope of Certification: The specific site, food sector categories and products to be covered by the certificate.

Season or Seasonal: A period in which the major activity is conducted over not more than five consecutive months in a calendar year; for example, harvesting and packing during the apple season.

Service: One or more activities performed between the supplier and the customer and is generally tangible (ISO/IEC 17065).

SQFI Select Site: Recognition on the SQFI certificate for a site that has voluntarily committed to annual unannounced re-certification audits (refer to "unannounced audit").

Senior Site Management: Individuals at the highest level on-site responsible for the business operation and implementation and improvement of the food safety and quality management system.

S

Site: The specific location where an SQF Food Safety or Quality System is implemented by a food business involved in the production, manufacture, processing, transport, storage, distribution, or sale of food, beverages, packaging, animal feed, or pet food.

Site Audit: The on-site component of a certification or re-certification audit that reviews the site's products and processes to determine the effective documentation and implementation of the site's SQF Food Safety or Quality System (refer to "on-site visit").

SQF Audit: A systematic and independent examination of a site's SQF Food Safety and/or Quality System by an SQF food safety and/or quality auditor to determine whether food safety, quality systems, hygiene and management activities are undertaken in accordance with that system documentation and comply with the requirements of the SQF Food Safety and/or Quality Code, as appropriate, and to verify whether these arrangements are implemented effectively.

The audit can be conducted in part using remote activities using information communication technology (ICT) from a location other than the physical location of the audit site.

SQF Auditor: A person registered by the SQFI to audit a site's SQF Food Safety and/or Quality System. An auditor must work on behalf of a licensed certification body. The terms "SQF auditor" and "SQF contract auditor" shall have the same meaning.

SQF Consultant: A person who is registered by SQFI to assist in the development, validation, verification, implementation, and maintenance of SQF System on behalf of client site in the food industry categories appropriate to their scope of registration.

SQF Logo: Means the SQF logo depicted in SQF Logo Rules of Use.

SQF Practitioner (also SQF Quality Practitioner): An individual designated by a site to oversee the development, implementation, review and maintenance of the site's SQF System. The SQF practitioner qualification details are verified by the SQF food safety or quality auditor during the certification/re-certification audit as meeting the requirements of the SQF Food Safety and/or Quality Code.

The SQF Food Safety practitioner and SQF Quality practitioner may or may not be the same person.

SQF Program: The SQF Food Safety and/or Quality Code and all associated rules, quality shield, intellectual property and documents.

SQF Quality Shield: Means the SQF shield depicted in SQF Quality Shield Rules of Use.

SQF System: A risk management and preventative system that includes a food safety plan or food quality plan implemented and operated by a site to assure food safety or quality. It is implemented and maintained by an SQF practitioner, audited by an SQF food safety or quality auditor and certified by a licensed certification body as meeting the requirements relevant to the SQF Food Safety or Quality Code.

SQF Trainer: An individual contracted to a licensed SQF training center that has applied and met the requirements listed in the "Criteria for SQF Trainers" published by SQFI and, upon approval, is registered under SQFI to provide consistent training on the SQF Program.

SQFI: The SQF Institute, a division of FMI.

SQFI Assessment Database: The online database used by SQFI to manage site registration, site audits, close out of corrective actions, and site certification.

S

System Elements: The SQF food safety or quality management requirements for each SQF Code that are applied by all sites throughout the supply chain for SQF certification (i.e., clauses 2.1 – 2.9).

Standard: A normative document and other defined normative documents, established by consensus and approved by a body that provide, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Sub-site: An SQF certified site which operates under a contractual link to an SQF certified central site within an SQF multi-site program (refer to Appendix 4: Requirements for SQF Multi-site Certification).

Supplier: The entity that provides a product or service to the SQF certified site.

Surveillance Audit: A six (6) month audit of a site's SQF System where the site received a 'C – comply' rating at the last certification or re-certification audit, or if the site is suspended as a result of a 'F– fails to comply' rating at a surveillance or re-certification audit.

T

Technical Expert: An individual engaged by a licensed SQF certification body to provide a high level of technical support to the certification audit team. The technical expert shall be approved by SQFI prior to the certification/re-certification audit, and demonstrate a high degree of expertise and technical competence in the food sector category under study, and a sound knowledge and understanding of the HACCP method.

Trademarks: A recognizable label, logo, or mark which identifies a raw material or finished product with a particular producer, manufacturer, or retailer.

Training Center: An entity which has entered into a license agreement with SQFI to deliver SQFI-licensed training courses, including the Implementing SQF Systems Training Courses, the Advanced SQF Practitioner Course, and the Implementing SQF Fundamentals Course, training courses.

U

Unannounced Audit: A re-certification audit that is conducted once every three (3) years and thirty (30) days on either side the initial certification anniversary date without prior notice to the SQF certified site.

The first three-year cycle commences with the initial certification audit date. Within the first three years of certification, the site is required to have one unannounced audit. Thereafter, there is an unannounced audit every three years.

A site may forgo the three-year certification cycle requirement and voluntarily elect to have annual unannounced re-certification audits. Sites with annual unannounced re-certification audits shall be recognized on the SQFI certificate as an "SQFI select site" (refer to "SQF select site").

V

Validation : That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP food safety (or quality) plan, when properly implemented, will effectively control the hazards (Codex).

Verification: Those activities, other than monitoring, that determine the validity of the HACCP food safety (or quality) plan and ensure that the system is operating according to the plan (Codex).

Verification Schedule: A schedule outlining the frequency and responsibility for carrying out the methods, procedures or tests additional to those used in monitoring, to determine that the HACCP study was completed correctly, that the relevant SQF System is compliant with the relevant food safety and/or food quality plan and that it continues to be effective.

W

Water Treatment: The microbiological, chemical, and/or physical treatment of water for use in processing or cleaning, to ensure its potability and suitability for use.

Appendix 3: SQF Logo Rules of Use

1 Introduction

- 1.1 The SQF logo is owned by SQFI. Sites obtain no property in the SQF logo.
- 1.2 SQFI delegates any or all of its functions described herein to a licensed certification body (CB) as stipulated in their Safe Quality Food Institute Certification Body License Agreement.
- 1.3 These rules of use regulate the use of the SQF logo by certified sites only. These rules of use do not regulate the use of the SQF logo by SQFI, certification bodies (CBs) or other entities licensed by SQFI to use them, unless otherwise provided for in this or another instrument.

2 Conditions for Use

- 2.1 Sites who achieve and maintain certification to the SQF Food Safety Fundamentals, the SQF Food Safety Code and/or the SQF Quality Code are granted permission by their CB to use the SQF logo. Electronic SQF logo files are to be obtained from the CB.
- 2.2 A site shall, for the duration of its certification, have the right to use the SQF logo. There will be no fee payable by sites for the right to use the SQF logo, other than fees payable to obtain and maintain certification.
- 2.3 Subsidiary companies and site addresses not included on the certificate of registration are not certified to use the SQF logo.
- 2.4 Sites may only use the SQF logo in accordance with these rules of use, which are designed to protect the integrity and enhance the value of the SQF logo.

3 Reproduction

- 3.1 Reproduction of the SQF logo is to be clear, precise, of the highest standard and follow the usage guidelines in the table below.

Color Format	For Use On
Full Color Reproduction: outlined in 3.2 below. Or Single Color Reproduction: black and white.	<ul style="list-style-type: none"> brochures, flyers, advertisements, press releases, company website, email signature lines internal documents and training materials

- 3.2 The following guidelines govern full color reproduction.



PMS 3005C

CMYK: C=100, M=34, Y=0, K=2

APPENDIX 3: SQF Logo Rules of Use

- 3.3 To ensure readability, do not reproduce the SQF logo smaller than indicated below. Larger variation to these dimensions is permitted provided it is proportional to the dimensions given below.



- 3.4 Where it is demonstrated that alternative reproduction of the SQF logo enhances the status of the SQF logo and/or SQFI, then the alternative is permitted provided it is approved by the CB. All requests must be provided in writing per certified site to the CB and SQFI.

4 Obligations of a Site

- 4.1 A site must:
- Direct any queries regarding their intended use of the SQF logo to the CB who issued their certificate;
 - Discontinue any use of the SQF logo to which SQFI or the CB reasonably objects;
 - Operate entirely within the scope of its certificate, including the certification schedule;
 - Give SQFI, their CB and/or their agents access to examine all items bearing or indicating the SQF logo for the purpose of confirming compliance with these rules of use and the certificate.

5 Grounds for Ceasing Use of the SQF Logo

- 5.1 Permission for a site to use the SQF logo will be suspended and/or withdrawn:
- If the site's certification is suspended, withdrawn, relinquished or not renewed;
 - If the site breaches or fails to comply with these rules of use;
 - If the site uses the SQF logo in a way that, in the opinion of SQFI or the CB, is detrimental to the SQF logo or the SQF program as a whole, is misleading to the public or otherwise contrary to law; or
 - If the site has an administrator, receiver, receiver and manager, official manager or provisional liquidator appointed over its assets or where an order is made or a resolution passed for the winding up of the site (except for the purpose of amalgamation or reconstruction) or the site ceases to carry on business or becomes bankrupt, applies to take the benefit of any law for the relief of bankrupt or insolvent debtors or makes any arrangement or composition with its creditors.
- 5.2 The site shall be notified by their CB in writing if their use of the SQF Logo has been suspended or withdrawn.

6 Disclaimer

- 6.1 SQFI may alter these rules of use or make new rules. No such alteration or new rule shall affect the use of the SQF logo by a site until six (6) months have expired from the date the alteration or new rules of use are first published by SQFI on its website (sqfi.com) unless specified by SQFI.