



Requirements and Guidance for Cannabis Manufacturing Supplement



A compendium to the
SQF Food Safety Code for
Manufacturing, Edition 8.1

March, 2021

For Canada Only

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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Part I. Introduction and Supplement Protocols

1.1 Introduction

The use of this supplement applies to Canadian sites ONLY and is to meet those requirements for cannabis used as an ingredient in edibles or as a finished edible product that are in addition to or provide additional clarification to requirements of the SQF Food Safety Code for Manufacturing. These requirements were created by the SQF cannabis working group. The supplement can be added to any SQF certification audit at the request of the SQF registered site and/or Certification Body to assist in meeting specific regulatory or customer/supply chain requirements and should be used with other cannabis resource materials made available by SQF.

1.2 Scope and application

The supplement can be applied to any Canadian site that uses cannabis as an ingredient and is seeking certification or re-certification to the SQF Food Safety Code for Manufacturing and the scope of operations for which it applies. It shall be used in conjunction with the SQF Code. Each requirement of the supplement has been aligned with a specific element of the SQF Code. All requirements within the specific SQF Code element must be met in addition to those described within this supplement. The compendium SQF cannabis Definitions document should be used to assist in interpreting terms used in this supplement.

1.3 Supplement Duration

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

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

1.4 Addendum report and non-conformances

Non-conformities identified during the audit against the requirements of this supplement shall be graded in a similar fashion to that described within the SQF Code, namely Critical, Major and Minor. Any critical non-conformance shall be appropriately applied to its associated SQF Code element and included and handled in the certification report, along with a failure rating and/or SQF Certification withdrawal. Non-conformities shall require corrective actions by the site within SQF Code required

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timelines and be closed and approved by the certification body prior to SQF certification or re-certification. Where SQF certification is not achieved, the addendum shall be considered as not being successfully completed and must be included in any subsequent certification audits.

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

1.5 Requirements format

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

The following format is used throughout:

Section Number and Name

Element Number and Name
<p>Sub-element number: This section will describe what the SQF Cannabis Manufacturing supplement requires that is in addition to the requirements of the specific sub-element stated in the SQF code. It does not change the outcome expected or the intent of the code requirement.</p>
<p style="text-align: center;">Implementation Guidance</p> <p>What does it mean?</p> <p>This will include the interpretative comments of what the sub-element requires, or definitions of the terms used.</p> <p>What do I have to do?</p> <p>This will include suggestions of what is required to be done by the site to document and implement this additional requirement. The information provided is not considered exhaustive and may not apply in every situation. It is meant to provide guidance and interpretation.</p>
<p style="text-align: center;">Auditing Guidance</p> <p>This will/may include suggestions of what the auditor may seek as evidence of compliance for this additional requirement. The information provided is not exhaustive and may not apply in every situation.</p>

Part II – Supplement Requirements

2.1 Management Commitment

2.1.2 Management Responsibility (Mandatory)

- 2.1.2.1 The reporting structure describing those who have responsibility for food safety shall be identified and communicated within the site. **It shall clear indicate the designated quality assurance person or other resource responsible for regulations.**
- 2.1.2.3 The senior site management shall ensure adequate resources are available to achieve food safety objectives and support the development, implementation, maintenance and ongoing improvement of the SQF System. **Resource allocation and responsibility shall ensure regulation and any associated licensing is maintained and aligned with the SQF system.**
- 2.1.2.4 The owner/senior site manager shall designate an SQF practitioner for each site with responsibility and authority to:
 - i. Oversee the development, implementation, review and maintenance of the SQF System, include Good Agricultural Practices outline in 2.4.2 and the food safety plan outlined in 2.4.3;
 - ii. **Oversee and 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.
- 2.1.2.5 The SQF practitioner shall:
 - i. Be employed by the site as a company employee on a full-time basis;
 - ii. **Demonstrate awareness of the regulatory requirements for the designated food safety person (e.g. Quality Assurance Person, PCQI)**
 - iii. Have completed a HACCP-based training course;
 - iv. Be competent to implement and maintain Good Agricultural Practices; and
 - v. Have an understanding of the SQF Code and the requirements to implement and maintain SQF System relevant to the site’s scope of certification.

2.1.2 Implementation Guidance

What does it mean?

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

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

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site. Management must clearly identify and provide the resources to achieve food safety objectives and **regulation**.

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

What do I have to do?

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

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

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

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

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

2.1.2 Auditing Guidance

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

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

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regulations shall be confirmed at each site audit.

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

- Employees within the site with responsibility for food safety **and regulation** are clearly identified, are aware of their responsibilities and are trained and competent to carry out these responsibilities.
- Senior management ensures that all designated food safety **and regulatory** practices and activities are correctly documented, meet the requirements of the SQF Code and are correctly and fully implemented on all shifts. This would include a review as to the timeliness of implementation of corrective actions, action on complaints, and addressing identified gaps in the site's programs.
- There is a designated SQF practitioner who manages the implementation and maintenance of the SQF System **and applicable regulations** on a daily basis.
- The designated practitioner has the qualifications necessary to be an SQF practitioner (identified in 2.1.2.4 and 2.1.2.5) and is capable and competent to carry out this function.
- The designated practitioner has the support of senior management and has the time and availability to monitor the effectiveness of the SQF System; is competent and has the authority to take appropriate corrective actions when necessary; and communicates to relevant employees any information necessary to maintain or improve the System and **meet regulations**.

2.3 Specifications and Product Development

2.3.1 Product Development and Realization

- 2.3.1.2 Product formulation, manufacturing processes and the fulfillment of product requirements shall be validated by site trials, shelf life trials and product testing **that includes meeting regulatory limits or claims support. Product formulations shall be developed by authorized persons to ensure that they meet the designated need. The formulations should include all manufacturing instructions with regard to homogeneity, flushing sequencing, special instructions and cleanout procedures.**
- 2.3.1.3 Shelf life trials, where necessary, shall be conducted to establish **that claims and regulatory limits (such as potency, strength, homogeneity and purity) are maintained to the end of the shelf life** and to validate a product's:
- i. Handling, storage requirements including the establishment of "use by" or "best before dates";
 - ii. Microbiological criteria; and
 - iii. Consumer preparation, storage, and handling requirements.

2.3.1.2 & 2.3.1.3 Implementation Guidance

What does it mean?

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

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

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

What do I have to do?

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

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

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Any product claims must be substantiated by means of product research and/or testing, and shelf-life testing will be carried out as required. Any testing that is required may be focused on product performance (**such potency, strength, homogeneity and purity**)), customer handling or new packaging conditions. **Regulatory limits and claims testing must be met for the duration of the products shelf life.** If the supplier determines that shelf-life testing is not required, the supplier must document the reason for this decision and any supporting evidence.

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

Any adjustments to food safety must be validated and verified by the SQF practitioner prior to commercial production of the subject product **and to ensure the product meets all regulatory and licensing requirements.**

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

2.3.1.2 & 2.3.1.3 Auditing Guidance

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

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

2.3.2 Raw and Packaging Materials

- 2.3.2.2 All raw and packaging materials and ingredients shall comply with the relevant legislation in the country of manufacture and country of destination, if known.
- 2.3.2.4 Raw and packaging materials and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Verification of raw materials and ingredients shall include certificates of conformance, or certificate of analysis, or sampling and testing.

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2.3.2.2 & 2.3.2.4 Implementation Guidance

What does it mean?

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

What do I have to do?

Specifications must fully describe the materials provided. Safety-related information in raw material and ingredient specifications may include threshold levels for microbiological pathogens, factors affecting microbiological growth such as pH and water activity, threshold levels for potential chemical (**e.g. THC, CBD**) or physical contaminants and the presence or absence of known allergens. The extent to which these factors need to be included in the specifications will depend on the use of the material, the food safety risk to the finished product **and regulations that stipulate limits.**

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

Validation is testing over and above daily monitoring to ensure that established food safety limits are effective, i.e., they achieve the desired results, so that the site can have confidence that the product and process are safe. Validation methods will vary depending on the risk to finished product safety. Validation for low risk materials may include certificates of analysis or certificates of conformance, provided by a trusted vendor. For high risk materials **such as cannabis**, testing and analysis is required for validation, and must be carried out annually (refer to 2.5.1). For food-contact packaging material, this may include testing or assurances for potential chemical migration to the food product.

Specifications must also meet the standards set by regulation in the country of origin and the country (ies) of intended destination. **Federal or national regulations must be in place for cannabis edibles in order to apply this requirement.** This includes maximum residue levels, allergen declarations, and in particular, in-country labelling requirements (refer to 2.4.1).

2.3.2.2 & 2.3.2.4 Auditing Guidance

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

- Review of the procedure for developing and approving specifications;
- Confirmation that the register of raw and packaging material specifications includes all on-site materials;

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- **Review of a selected sample of material specifications to confirm agreement with relevant legislation;**
- **Review of a selected sample of material specifications, in particular for high risk materials, to ensure potential factors impacting on product safety and quality are included;**
- Availability of current copies of specifications to relevant staff;
- Interview of staff conducting validation activities;
- Review of records of validation checks.

2.3.5 Finished Product Specifications

- 2.3.5.1 Finished product specifications shall be documented, current, approved by the site and their customer, accessible to relevant staff and may include:
- i. Microbiological and chemical limits; and
 - ii. Labeling and packaging requirements.
 - iii. **Regulatory** labeling and packaging requirements.

2.3.5.1 Implementation Guidance

What does it mean?

A written finished product specification must be provided for all products covered under the site's SQF Certification. In some cases, industry sector specifications may apply for example for bulk consignments exported to world commodity markets. In other cases, the specification may be provided by the customer.

It is important that the site does not undertake to supply goods where the specification is not consistently achievable under all processing and raw material supply conditions.

What do I have to do?

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

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

2.3.5.1 Auditing Guidance

Finished product specifications will be included in the food safety manual and will initially be reviewed at the

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desk audit. At each site audit, the auditor will ensure that all specifications exist for all products included in the scope of certification and that the site is capable of and ensures compliance with the specifications.

Evidence may include:

- Every product covered by the scope of certification is covered by a specification;
- Specifications are current and agreed with customers;
- Specifications include all significant parameters required to ensure the safety of the product;
- **Specifications include all regulatory and/or licensing requirements;**
- Current versions of specifications are available to all relevant staff;
- The site has methods and criteria for sampling and testing finished product (refer 2.5.4) to ensure compliance with finished product specifications;
- The site has processes in place to ensure that product released (refer 2.4.7) meets specifications;
- Specifications are reviewed as part of the management review process (refer 2.1.3.1).

2.4 Food Safety System

2.4.1 Food Legislation (Mandatory)

- 2.4.1.1 The site shall ensure that, at the time of delivery to its customer, the food supplied shall comply with the legislation that applies to the food and its production in the country of use or sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen and additive labeling, labeling of identify preserved foods, any other criteria listed under food legislation, and to relevant established industry codes of practice. **The sale of product shall only occur with either a licensed processor or licensed retailer as per regulation definitions of “licensed” and/or within a regulatory jurisdiction (e.g. not across state line). Federal or national regulations must be in place for cannabis edibles in order to apply this requirement.**

2.4.1.1 Implementation Guidance

What does it mean?

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

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

Federal or national regulations must be in place for cannabis edibles in order to apply this requirement.

What do I have to do?

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

The site is required to demonstrate knowledge of and compliance to all applicable legislation for all products included within their scope of certification. Legislative requirements must be included in finished product specifications (refer to 2.3.5) and be tested for (refer to 2.5.4).

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

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

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

2.4.1.1 Auditing Guidance

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

- Review of the procedure to maintain and update legislative requirements;
- Applicable legislative requirements have been incorporated into specifications (refer to 2.3.2 & 2.3.5);
- Applicable legislative requirements are being applied (**e.g labels**) and being inspected and/or tested (refer to 2.5.4);
- Compliance with legislation is checked as part of internal audits (refer to 2.5.7) and the management review (refer to 2.1.3.1).
- **Customer profile and shipping information and documentation confirm sales are to valid customers (licensed if required) and to countries where product is legal and allowed across international, state or provincial borders.**
- Confirmation that SQFI and the Certification Body have been notified in writing in the event of a food safety incident requiring public notification.

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2.4.3 Food Safety Plan (Mandatory)

- 2.4.3.6 The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative use of the product.
- 2.4.3.8 The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.
- 2.4.3.10 The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure.
- 2.4.3.12 For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated level of control of the identified food safety hazard (s); and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1).

2.4.3.6, 2.4.3.8, 2.4.3.10 & 2.4.3.12

Implementation Guidance

What does it mean?

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

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

Specifically, the site shall define the intended use of its products. If the products can only legally be sold to adults the product description shall indicate that and the HACCP plan and/or GMP's shall ensure the products and packaging reflect that intended use.

What do I have to do?

The intended use of each of the products included in the scope must be identified, e.g. is the product intended to be further processed, or cooked by the consumer prior to consumption, or is it ready-to-eat. Is the product intended for consumption by a vulnerable group, or by the general population (remembering that general population includes vulnerable consumers). **In high risk commodities such as cannabis, where consumption is intended or legal for adults only, this must be included in the intended use and labels, specifications and packaging controls must reflect this.**

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For each step of the process **and for all ingredients and inputs** identified the HACCP team must identify all food safety hazards, including potential food safety hazards. Hazards will, at a minimum, be classified as microbiological, chemical and physical, but may also at the discretion of the site separate out allergens, microbial contamination, microbial growth, radiological hazards, metal, glass, etc. **Risk and hazards due to either too much or too little potency or strength of levels of THC, CBD or its derivatives. This would be applicable in ingredients or finished products.**

For each identified hazard, conduct a hazard analysis to determine the potential likelihood of the hazard occurring and the severity if it did occur (collectively referred to as the significance). There is no specified methodology for conducting a hazard analysis, although there are many methodologies used within the food industry. SQFI expects that the method used is logical, evidence based, consistently applied across all identified hazards in the HACCP Plan, and documented.

Critical limits are according to the Codex definition, “criteria that separate acceptability from unacceptability.” They are values that are set and easily measured, that identify “safe” from “unsafe” product. Critical limits must be established for each CCP and must be scientifically validated (refer to 2.5.1), or justified by regulation, customer requirements or industry code of practice. **THC, CBD or derivative critical limits, if applicable, shall minimally align with regulatory limits.**

2.4.3.6, 2.4.3.8, 2.4.3.10 & 2.4.3.12

Auditing Guidance

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

- The product and process scope of the HACCP plan is defined;
- Product descriptions are available and include relevant safety information;
- The intended use of the product is clearly defined;
- **Reference for use by legal adults as per regulation included for cannabis;**
- Potential hazards have been identified for all process steps and a hazard analysis conducted using a consistent and valid method **and includes where too much or too little THC, CBD or derivatives is a risk/hazard;**
- CCPs are correctly identified using a valid methodology;
- Critical limits are in place for every CCP, and are validated to ensure consistent product safety and **reference regulatory limits where applicable;**

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2.4.4 Approved Supplier Program (Mandatory)

- 2.4.4.1 Raw materials, ingredients, packaging materials, and services that impact on finished product safety shall meet the agreed specification (refer to 2.3.2) and be supplied by an approved supplier **and from a licensed input supplier if required and approved by regulation. Approved raw material suppliers shall notify changes in product composition where it could have an impact on product formulation (e.g. chemical level, moisture, contaminant levels and/or parameters that may be variable by crop or season).**

2.4.4.1 Implementation Guidance

What does it mean?

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

An approved supplier program is a set of procedures implemented by the site to assure the safety and quality of inputs and services. It may be based on the safety risk presented by the input, or based on historical performance or prior history of the supplier. **Specifications and approvals are linked to any regulatory requirements, if required.**

What do I have to do?

The site must be able to provide documented evidence that agricultural inputs have either been inspected or that they come from an approved supplier. The methods for selecting, evaluating, approving and monitoring an approved supplier must be documented. This will be risk-based and may be as simple as a good supply history, sourcing from certified suppliers (e.g. SQF certified suppliers **or licensed supplier by regulatory authority**) or personally auditing/inspecting the input supplier's operations, depending on risk, supplier knowledge and past history.

The site must require their input suppliers to verify they are complying with specifications for the inputs supplied. The methods of analyses must conform to recognized industry standards (refer 2.5.4) **and/or regulations**. The job functions responsible within the site's business for input inspections and supplier approval must be included in the job descriptions outlined in 2.1.3.2.

The receipt of inputs from non-approved suppliers is acceptable, but only in an emergency situation **and if allowed by regulation**, and provided the inputs are inspected before use. Records of the use of non-approved suppliers and their inspections shall be maintained.

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

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

2.4.4.1 Auditing Guidance

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

- Review of the documented approved supplier program to ensure all inputs and services that may impact on product safety and quality are included;
- The risk rating applied to suppliers is identified and controls implemented;
- There is a register of approved suppliers;
- All inputs or services in-use are included on the supplier register or listed as a non-approved supplier;
- Approval methods test for compliance with agreed specifications (refer 2.3.2, 2.3.3 **and 2.5.4**);
- **Test and approval methods and results align with regulatory and commodity requirements.**

2.4.7 Product Release (Mandatory)

What the SQF Code says

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

- i. By authorized personnel (**e.g. SQF practitioner, QA, PCQI**); and
- ii. Once all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met.

2.4.7 Implementation Guidance

What does it mean?

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

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

Refer also to 2.5.4 *Product sampling, inspection, and analysis*, 2.6.1 *Product identification* and 2.6.2 *Product trace*.

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What do I have to do?

This element is mandatory.

A site may do this by outlining in-line process measures that demonstrate that products are compliant with specified requirements. In this procedure, the site will identify those personnel responsible for collecting samples and carrying out inspections, or ensuring that inspections are carried out, and the methods for doing so.

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

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

The site must ensure that:

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

2.4.7 Auditing Guidance

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

- Review of product release procedure;
- Review of product release records;
- Understanding of personnel responsible for release, quarantine and hold of product release procedures;
- **Reviewing authorizing personnel competencies to ensure alignment with regulations where applicable;**
- Visual confirmation and follow-up on held or quarantined product.

2.5 SQF System Verification

2.5.4 Product Sampling, Inspection and Analysis

- 2.5.4.1 The methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work in progress shall be documented and implemented. The methods applied shall ensure:
- i. Inspections and analyses are completed at regular intervals as required and to agreed specification (**see 2.3.2 & 2.3.5**) and **regulatory** requirements;
 - ii. Inspections are conducted to ensure raw materials, work in process and finished products comply with the relevant specification (**see 2.3.2 & 2.3.5**), regulatory requirements and are true to label; and
 - iii. All analyses are conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods.
- 2.5.4.3 Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard, **licensed or recognized by regulatory authority if required** and shall be included on the site's contract service specifications register (refer to 2.3.3.1)

2.5.4.1, 2.5.4.3 Implementation Guidance

What does it mean?

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

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

What do I have to do?

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

The site must identify those with responsibility for sampling, inspecting and testing finished product, work-in-progress and/or inputs and identify the methods used to collect samples and complete these tests, inspection and analyses.

The types of testing that are conducted on finished product **or inputs** should be determined by the finished product **and input** specifications. Examples are varied and can include sensory analysis (e.g., taste, color, flavor, odor), physical (e.g., count, weight, size, texture), chemical (e.g., MRL's, **THC, CBD, homogeneity**), or microbiological (e.g., aerobic plate count, yeast and mold, coliforms).

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

The site must identify those with responsibility for sampling, inspecting and testing finished product, work-in-progress and/or raw materials and identify the methods used to collect samples and complete these tests, inspection and analyses.

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

Commodity specific testing plans and product and/or input may be provided by industry associations, academia or regulatory authorities and should be followed where applicable. E.g. U.S. Hemp Authority, National Cannabis Industry Association

If external laboratory analysis is used **or required by regulation**, the site must demonstrate that such analysis is completed by a recognized laboratory that is accredited to ISO 17025 or an equivalent national standard, or one that uses recognized industry standard methods (**e.g AOAC Official Method 2018.11 Quantification of Cannabinoids in cannabis dried plant material**). These methods may be described in the specifications. **The laboratory may be required to be licensed by the regulatory authority and evidence of this required license is to be kept on site by the site as part of the contract service provide records (2.3.3)**

If an internal or company laboratory is used, test methods should be checked against an accredited external laboratory at least once per year.

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

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

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

2.5.4.1 & 2.5.4.3 Auditing Guidance

Product sampling and testing procedures shall be reviewed initially at the desk audit. Compliance to the requirement will occur by observation, interview with the SQF practitioner and other relevant staff responsible for sampling and testing, and review of records at each site audit. Evidence may include:

- Methods for sampling, inspecting, and/or analyzing raw materials, finished product and work in progress are documented;
- Documented methods are approved methods and meet regulatory and customer requirements;
- Inspections are conducted as documented, and at intervals sufficient to maintain control **and as**

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per regulation and/or industry best practices;

- Inspections confirm specifications, label requirements and trade weights and measures;
- Analyses are conducted by qualified individuals and to approved methods;
- Alternative methods used are validated as equivalent to the national approved standard methods;
- External laboratories are accredited to ISO 17025 or equivalent national standard **and licensed as**

per regulations;

- Sensory evaluations are completed to internal and customer specifications;
- Records of all inspections and analyses (including sensory analyses) are accurate and maintained.

2.6 Product Identification, Trace, Withdrawal and Recall

2.6.1 Product Identification (Mandatory)

- 2.6.1.1 The methods and responsibility for identifying raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products during all stages of production and storage shall be documented and implemented. The product identification system shall be implemented to ensure:
- i. Raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are clearly identified during all stages of receipt, production, storage and dispatch; and
 - ii. Finished product is labeled **and packaged** to the customer specification and/or regulatory requirements.
- 2.6.1.3 Product start up and changeover procedures during packing shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label, and that the changeover is inspected and approved by an authorized person **(e.g SQF practitioner, QA, PCQI)**.

2.6.1.1 & 2.6.1.3 Implementation Guidance

What does it mean?

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

What do I have to do?

This element is mandatory.

The site must be able to clearly identify raw materials upon receipt and products at various stages in the process as work in progress and then as finished product.

Product that is in-process may be identified in a variety of ways. The site could use bin tags, pallet tags, colors, product tags, etc. The site must be able to demonstrate how the product identification system works for inputs, work-in-progress and for finished product.

The finished product label or bulk label needs to contain information that accurately describes the product in accordance to customer specification and/or regulatory requirements in the country of origin and intended country of destination. **(e.g. name requirements, %purity or strength, composition)**

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

When shipping finished product **(including on-line sales)**, the site must ensure the product is clearly identified and that all product identification details are accurately described on dispatch documents or otherwise included with a shipment once it leaves the business. **These documents must align with the regulations and where product can or cannot be shipped. See also 2.4.1.1.**

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2.6.1.1 Auditing Guidance

The product identification procedure shall be reviewed initially at the desk audit. Compliance to the requirements will occur by observation, and interviews with operational staff, and review of records at each site audit. The site should expect that the auditor will select product at various stages during the process and ask for the inputs and shipments to test the identification system. Evidence may include:

- There is a documented product identification system in place;
- The product identification system is effectively implemented;
- Product is clearly identified during all stages of the process;
- Finished product is labeled to customer requirements;
- Finished product is labeled to regulatory requirements in the country of origin and country of destination;
- **Finished products is shipped to destinations as per regulations;**
- All operational staff understands and uses the product identification system.

2.7 Food Defense and Food Fraud

2.7.1 Food Defense Plan (Mandatory)

What the SQF Code says

2.7.1.2 A food defense plan shall include:

- i. The name of the senior site management person responsible for food defense;
- ii. The methods implemented to ensure only authorized personnel have access to equipment, vehicles, operations and storage areas through designated access points. **Sites requiring licensing under regulations shall meet regulatory requirements for security.**
- iii. The methods implemented to protect sensitive operational points from intentional adulteration;
- iv. The measures taken to ensure the secure receipt and storage of Agricultural inputs, packaging, equipment and hazardous chemicals;
- v. The measures implemented to ensure agricultural inputs, packaging materials, work-in progress and finished products are held under secure storage and transportation conditions; and
- vi. The methods implemented to record and control access to the premises by employees, contractors, and visitors.

2.7.1 Implementation Guidance

What does it mean?

The site must document and implement a plan to assure the security of the facility and the product from damage or adulteration from sabotage or terrorist-like incident **and from theft and mis-use.**

What do I have to do?

This is a mandatory element.

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

The protocol must identify how the site limits access to designated areas of the operation to only appropriately authorized employees. The site must implement steps to protect sensitive operational points from intentional contamination **or theft.** The protocol should explain how the site ensures the secure storage and transportation of inputs, packaging, equipment, hazardous chemicals and finished product.

Specific areas of program that may be addressed include:

- Employee identification;

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- Visitor, contractor, tour access;
- Physical security of the facility (e.g., secured doors, gates, outside storage areas);
- Secure chemical storage;
- Secure storage of inputs, packaging and equipment not in use;
- Secure storage and transportation of finished product;

The protocol must define how these areas are to be addressed. The site can develop adequate measures to address specific areas to ensure control through a wide variety of solutions **however to meet regulations for licensed cannabis facilities measures may include**

- **capability for visual recordings of interior and exterior storage areas, intrusion detection system for exterior and storage areas and physical barrier for storage**
- **24/7 armed security**
- **Transportation security and tracking (e.g. GPS)**

2.7.1 Auditing Guidance

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

- Responsibilities for food defense has been assigned to a senior management representative;
- A food defense plan is in place that identifies the actions required to prevent a serious incident;
- The food defense plan identifies methods to protect sensitive operational points;
- The food defense plan identifies methods to provide authorized access to products and facilities;
- The food defense plan identifies methods to secure storage of inputs, packing materials, work-in-progress, finished product, and hazardous chemicals;
- The food defense plan identifies methods to record and control access to the premises by employees, contractors and visitors;
- **The food defense plan provides for additional regulatory requirements.**
- The food defense plan identifies methods to protect crops and harvesting equipment.

11.2 Construction of Premises and Equipment

11.2.8 Ventilation

What the SQF Code says

- 11.2.8.3 Extractor fans and canopies shall be provided in areas where cooking operations are carried out or a large amount of steam/fumes is generated and shall have the following features:
- i. Capture velocities shall be sufficient to prevent condensation build up and to evacuate all heat, fumes and other aerosols to the exterior via an exhaust hood positioned over the cooker(s);
 - ii. Fans and exhaust vents shall be insect-proofed and located so as not to pose a contamination risk **or prevent odors from being vented outside and effect neighboring areas**; and
 - iii. Where appropriate, positive air-pressure system shall be installed to prevent airborne contamination; and
 - iv. **Control ventilation in a manner that protects employees from fumes and/odors.**

11.2.8.3 Implementation Guidance

What does it mean?

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

What do I have to do?

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

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

11.2.8.3 Auditing Guidance

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

- Food processing areas have adequate ventilation;
- Cooking areas are adequately exhausted;
- There is no condensation present over product or food contact surfaces in cooker areas;
- **There are not excessive odors being vented to the outside and employees are adequately**

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protected;

- Exhaust vents are adequately fly-proofed; and
- Positive air pressure exists in high risk processing areas.

11.3 Personnel Hygiene and Welfare

11.3.1 Personnel

What the SQF Code says

11.3.1.3 Personnel with exposed cuts, sores or lesions shall not be engaged in handling or processing products or handling primary packaging materials or food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored bandage containing a metal strip or an alternative suitable waterproof and colored dressing. **A first aid kit shall be readily accessible and occupational health and safety guidelines are followed.**

11.3.1.3 Implementation Guidance

What does it mean?

In many jurisdictions, personnel requirements in food plants are covered by food safety legislation. Where this applies, the legislative requirements must underpin the requirements of 11.3.1. This element covers the basic personal hygiene requirement for working in a food manufacturing site. **These requirements might also be referenced or included under Occupational Health and Safety.**

What do I have to do?

Staff with exposed cuts, sores or lesions is not permitted to handle products unless suitable protective coverings are applied. These coverings must be monitored regularly by responsible personnel to ensure they remain effective. Bandages are to be brightly colored to ensure they can be easily seen and include a metal strip for ease of detection, if the site uses metal detection. **First aid kits must be readily accessible and protective coverings should be supplied and used by the site.**

Dressings on hands and fingers are required to be covered with a suitable glove.

11.3.1.3 Auditing Guidance

Medical screening and personal hygiene policies and procedures shall be reviewed for compliance at each site audit through observation, review of records and interviews with staff. SQF auditors will question employees on hygiene practices to ensure they are understood and applied. Evidence may include:

- Personnel with sores or cuts on hands are redeployed to low risk areas or have cuts suitably bandaged and gloved;
- **Cuts, sores or lesions are covered with protective coverings supplied by the site;**
- **A first aid kit is fully stocked and readily accessible;**
- There is no smoking, chewing, eating or drinking on harvesting rigs, or in food handling or product storage areas.

11.7 Separation of Functions

11.7.2 Receipt of Raw and Packaging Materials and Ingredients

What the SQF Code says

11.7.2.1 Dry ingredients and packaging shall be received and stored separately from frozen and chilled raw materials to ensure there is no cross contamination **and in a manner that does not affect the purity, strength, homogeneity and composition of final products.** Unprocessed raw materials shall be received and segregated to ensure there is no cross contamination.

11.7.2.1 Implementation Guidance

What does it mean?

This element relates to 11.6.1 (cold storage), 11.6.2 (storage of dry ingredients, packaging) and 2.4.5 (incoming goods and services). Dry ingredients, raw materials and packaging need to be received and stored separately from frozen and chilled products **and in manner that does not compromise its purity, strength or composition.**

What do I have to do?

Interior design and maintenance of these storage areas should be adequate to prevent a risk of contamination to stored materials and utensils. Walls and floors should be smooth and easy to clean and maintain. Since this is considered a dry storage area requirement, wet wash or water handling is not necessary.

All raw materials and work in progress shall be kept in appropriate conditions as to the type of material (refer to 11.6.1 and 11.6.2).

Special consideration must also be given to identity preserved materials (refer to 2.8.1) and materials/ingredients containing allergens (refer to 2.8.2) **and materials/ingredients containing cannabis.**

Materials shall be kept dry and free from contamination which may lead to waste of materials, potential hazards in the final product **and degradation or changes to the make-up and composition.**

11.7.2.1 Auditing Guidance

This element will be audited as part of each site audit through observation. Evidence may include:

- Dry materials and packaging are received separately from chilled/frozen materials;
- Dry materials and packaging are stored separately from chilled/frozen materials.
- **Dry materials and/or ingredients containing cannabis are stored in a manner that does not effect the purity, strength or composition.**

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11.7.4 High Risk Processes

What the SQF Code says

- 11.7.4.1 The processing of high risk food shall be conducted under controlled conditions such that sensitive areas in which high risk food has undergone a “kill” step, a “food safety intervention” or is subject to post process handling, are protected/segregated from other processes, raw materials or staff who handle raw materials to ensure cross contamination is minimized. **Where required by regulation products made containing cannabis shall be produced in a facility separate from facilities processing product that does not contain cannabis.**

11.7.4 Implementation Guidance

What does it mean?

High risk processes are those in which high risk or separately regulated foods (e.g. cannabis) are handled, exposed, stored, processed or packed.

High risk food is food that may contain pathogenic microorganisms and will support the formation of toxins or growth of pathogenic microorganisms, and has a significant likelihood of growth causing illness or injury to a consumer if not properly produced, processed, distributed and/or prepared for consumption. It may also apply to a food that is deemed high risk by a customer, declared high risk by the relevant food regulation (e.g. cannabis) or has caused a major foodborne illness outbreak (refer SQF Code, Appendix 2: Glossary).

This element outlines the specific conditions required in areas where high risk foods are processed or handled.

What do I have to do?

Facilities that are producing products that contain cannabis as well as products that do not contain cannabis will be required to keep the processes separated in a manner that will prevent the occurrence of cross contamination. Some regulations will require that building and facilities be completely separated or at least have rooms or process areas isolated in an appropriate manner. This may mean curtains, walls, distance or separate buildings and will be dependent on the regulations and types of products being produced. Environmental monitoring programs should be expanded to include swabbing and testing for the presence of cannabis in addition to the microbiological testing.

11.7.4 Auditing Guidance

Control procedures for high risk areas shall be reviewed as part of the initial desk audit. Subsequently, high risk processes will be audited as part of each site audit through observation, review of records and interviews with operating personnel. Evidence may include:

- There are control procedures in place for high risk processes;
- Control procedures are effectively implemented for high risk processes;
- High risk areas are adequately segregated **and meet regulatory requirements;**

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- An effective environmental monitoring program (EMP) is in **place and includes testing for cannabinoids;**
- The EMP includes a sampling schedule and responsibility for sampling;
- Swabbing includes transfer points and joints in equipment;
- Swabbing records are maintained.

11.8 On-Site Laboratories

11.8.1 Location

What the SQF Code says

11.8.1.1 On site laboratories conducting chemical and microbiological analysis that may pose a risk to product safety, shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel. **Where testing is supporting regulatory claims for cannabis the on-site lab shall be licensed, where required, and accredited to ISO 17025.**

11.8.1.1 Implementation Guidance

What does it mean?

On site laboratories are an option based on cost and needs of the site. In many cases, outsourcing laboratory services is applicable and reduces the risk of having on-site laboratories. In most instances, testing for monitoring purposes may be carried out in an on-site laboratory, while validation **or regulatory limit verification** activities are outsourced to an accredited laboratory.

What do I have to do?

This guidance is specific to on-site laboratories only. Laboratories must be located away from any food processing or handling activities or food contact surfaces to avoid contamination. Raw materials, ingredients, work-in-progress, packaging or exposed product shall not be exposed to laboratory waste.

Signage shall be posted at laboratory entrance(s) restricting access to trained, authorized personnel. Signage may consist solely of icons such as those published by the International Association for Food Protection to accomplish these requirements, and other local regulatory requirements must be applied.

It is not necessary for the internal laboratory to be accredited to ISO 17025 or equivalent **unless the lab is being used to verify regulatory limits and claims for cannabis**. For monitoring or other testing methods used must be justified and proficiency against an accredited laboratory is recommended to validate the testing methods.

11.8.1.1 Auditing Guidance

This element will be audited as part of each site audit through observation. Evidence may include:

- The on-site laboratory is separated from food processing and handling areas;
- Laboratory access is restricted to only authorized personnel;
- Laboratory waste is properly treated prior to disposal;
- **Laboratory credentials (e.g. 17025 accreditation) are compliance where applicable;**
- Laboratory waste is adequately contained and separated from general food waste;
- Adequate signage is available for the laboratory.