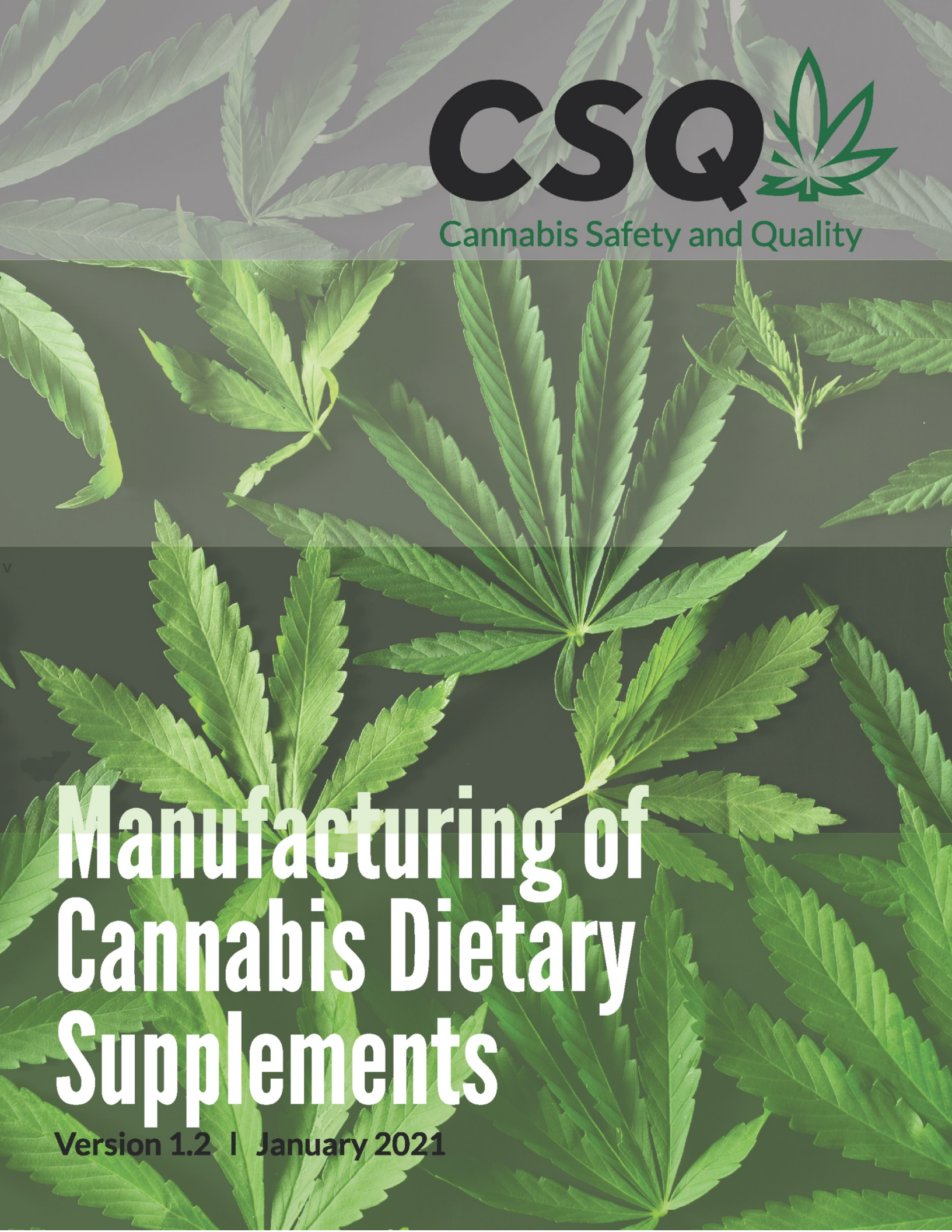

CSQ

Cannabis Safety and Quality

Manufacturing of Cannabis Dietary Supplements

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1.0 Cannabis Safety and Quality Management System General Requirements

1.1 Cannabis Safety and Quality System

1.1.1 Cannabis Safety and Quality System General Requirements

The location shall have a documented cannabis safety and quality system in either electronic and/or hard copy format. It should outline, at a minimum, the requirements of the Cannabis Safety and Quality (CSQ) Audit Requirements and promote the production of a safe, quality, and regulatory compliant product. The cannabis safety and quality system shall:

a) Be implemented and made readily available to all relevant staff
b) Include all Standard Operating Procedures (SOPs), Pre-Requisite Programs (PRPs), forms, logs, diagrams, and other supporting documentation needed to support the cannabis safety and quality system
c) Include a copy of local regulations and other supporting documentation needed to support and implement regulatory compliance
d) Include the parameters for the use of the CSQ Logo on marketing and promotional materials in compliance with the CSQ Certification Program Requirements
e) Be maintained and updated as needed

1.1.2 Cannabis Safety, Quality, and Regulatory Compliance Policy

The location shall have a documented cannabis safety, quality, and regulatory compliance policy that states the location's commitment to producing safe, quality, and regulatory compliant products and shall include measurable objectives and be communicated to all applicable staff.

1.1.3 Cannabis Safety and Quality Culture

The location shall have a documented plan for the development and continuous improvement of the location's cannabis safety and quality culture. The locations cannabis safety and quality culture plan shall, at minimum, consist of the following:

a) Communication of the cannabis safety and quality culture plan to employees
b) Training requirements and program for employees involved with product safety and quality
c) How improvements will be undertaken and measured
d) An annual review of the cannabis safety and quality culture plan

1.2 Management Responsibility

1.2.1 Organizational Structure

The location shall have an organizational chart showing the reporting structure of the company. The organizational chart shall clearly document what personnel is a part of the HACCP team and who are responsible for cannabis safety and quality. The location shall:

a) Ensure there are documented job descriptions for all personnel involved in cannabis safety and quality
b) Identify what employee is responsible for managing the CSQ system and designate a backup for this individual
c) Ensure employees responsible for managing the location's CSQ system shall either demonstrate strong knowledge of cannabis safety and quality through experience or by the completion of the CSQ 101 training course

1.2.2 Commitment to Cannabis Safety and Quality

The location shall have documented clear objectives to maintain and continuously improve the safety and quality of their products. These objectives shall:

a) Include measurable goals
b) Be clearly communicated to all relevant staff
c) Be reviewed and monitored at least quarterly

1.2.3 Resource Management

The location's senior management shall ensure adequate resources are made available, in a timely manner, to implement, maintain, review, and improve product safety and quality. The location shall have a system in place to ensure that all relevant staff is kept informed of the following:

a) Industry scientific and technological advancements
b) Relevant legislation and regulatory requirements

1.2.4 Management Review

The location's senior management shall attend management review meetings, at least annually, to review the location's cannabis safety and quality system's continuing stability, adequacy, effectiveness, and regulatory compliance. Meeting records shall be kept and clearly communicated to all relevant staff. The management reviews shall include:

a) Follow-up actions from the previous management review meeting
b) Customer complaints or any other customer feedback
c) Internal and external audit results and findings (including regulatory inspections)
d) Risk mitigation plans and corrective actions
e) Resource requirements and allocation
f) Verification of the entire cannabis safety and quality system (including the HACCP plan)
g) Review of any changes that could affect product safety and/or quality

1.3 Complaint Management

1.3.1 Complaint Management

The location shall have a documented procedure on the investigation and resolution of complaints. This procedure shall include:

a) Who is responsible for investigating and communicating the complaint
b) Who is responsible for resolving the complaint
c) How the location tracks and analyzes customer complaint data
d) The corrective action process outlined in 1.8.2

1.4 Regulatory Compliance

1.4.1 Regulatory Compliance

The location shall ensure that all products comply with all regulatory requirements for which the product is being manufactured and supplied to. Examples include, but are not limited to, compliance with the following:

a) Cannabinoids Potency
b) Terpenes
c) Microbials
d) Pesticides
e) Residual Solvents
f) Heavy Metals
g) Food Safety requirements
h) Shelf-life studies
i) Packaging requirements
j) Labeling requirements
k) Seed-to-Sale Traceability
l) Interstate or international trade regulations

1.5 HACCP Plan

1.5.1 HACCP Plan General Requirements

The location shall have in place a HACCP system including prerequisite programs and Standard Operating Procedures (SOPs) to identify and control all product safety hazards. The HACCP system shall be thorough and based on the Codex Alimentarius HACCP principles.

1.5.2 Process Flow

The location shall have a documented process flow diagram that covers each product or process. The flow diagram shall cover each step of the process from raw material receipt to storage and distribution and identify any Control Point (CP), Quality Control Point (QCP), or Critical Control Point (CCP).

1.5.3 Hazard Analysis

The location shall conduct a hazard analysis to identify and record all potential hazards (biological, chemical, and physical) that are reasonably expected to occur for each product and at each step of the process.

1.5.4 Critical Control Points

The location, based on the results of the hazard analysis, shall identify steps in the process that require control. Control points shall then be reviewed further to identify those that are critical. Critical Control Points (CCPs) shall effectively eliminate a significant hazard or reduce it to an acceptable level.

1.5.5 Critical Limits

The location shall identify and document the critical limits for each Critical Control Point (CCP). The critical limits shall be measurable and effectively define and separate compliant and non-compliant products.

1.6 Document Control and Record-Keeping

1.6.1 Document Control

The location shall have a procedure in place to manage documents that are part of the cannabis safety and quality system. The document control procedure shall include:

a) A master list of all controlled documents
b) A method for the identification of the most current version
c) The process for the authorization of amendments for changes to any documents and how old documents are replaced
d) A process to ensure that all documents are safely stored and are readily available to all relevant staff

1.6.2 Record-Keeping

The location shall have a procedure in place to maintain legible records for a time period that meets customer requirements, product shelf-life, and legal requirements. Records shall be readily accessible and be stored securely to prevent damage, theft, or unwanted changes. Records that are stored electronically shall be limited to authorized personnel and backed up to prevent loss.

1.7 Non-Conforming Product

1.7.1 Hold and Release

The location shall have in place a documented procedure for the hold and release of non-conforming raw materials, work-in-progress, finished products, and packaging materials. The procedure shall:

a) Ensure that non-conforming goods are clearly identifiable by all staff
b) Ensure that non-conforming goods are quarantined and stored to prevent accidental release
c) Include a process for the decision making by qualified and authorized personnel on the continued use or disposal of the non-conforming goods

1.7.2 Rework

The location shall have in place a documented procedure for the rework of raw materials, work-in-progress, and packaging materials. The procedure shall ensure rework products are clearly identifiable by all staff and include how each batch of rework is inspected and analyzed before its release for use.

1.7.3 Product Identification and Traceability

The location shall have in place a documented procedure for the identification and traceability of all raw materials, work-in-progress, finished products, and packaging materials throughout the entire process. The procedure shall ensure:

a) All raw materials, work-in-progress, finished products, and packaging materials are clearly identified throughout the entire process
b) Finished products are traceable to the customer (one forward)
c) Raw materials and packaging materials are traceable to the manufacturing supplier (one backward)
d) Where rework is performed, traceability is maintained
e) The testing of the identification and traceability procedure at least annually during a mock recall

1.7.4 Recalls, Voluntary Withdrawals, and Regulatory Warnings

The location shall have in place a documented procedure for the recall and withdrawal of products. The procedure shall include:

a) A list of key personnel responsible for initiating, handling, and investigating a product recall or withdrawal with specific responsibilities identified
b) An up-to-date list of key contacts that includes the above key personnel involved in the product recall or withdrawal, emergency services, customers, suppliers, regulatory agencies, and the certification body
c) A plan for communicating key information to customers, suppliers, regulatory agencies, certification body, and consumers
d) How the location plans to recover or dispose of affected products
e) The testing of the recall and withdrawal procedure at least annually during a mock recall (Location is also required to perform a mock recall in under 2 hours while the auditor is present during the onsite facility evaluation)

1.8 Risk Mitigation and Corrective Actions

1.8.1 Risk Mitigation

The location shall have in place a documented procedure for risk mitigation. Risk mitigation plans shall include the following:

a) Legible and clear documentation of the potential hazard
b) Identification of the root cause of the potential hazard
c) The personnel responsible for addressing and preventing the potential hazard from occurring and ensuring the preventive controls in place are being executed and verified
d) Any immediate action to prevent the potential hazard from occurring
e) An appropriate timescale for the implementation of a permanent risk mitigation plan for the potential hazard
f) Verification that the risk mitigation plan has been effectively implemented

1.8.2 Corrective Actions

The location shall have in place a documented procedure for corrections and corrective actions. Corrective actions shall include the following:

a) Legible and clear documentation of the non-conformance
b) Identification of the root cause of the non-conformance
c) The personnel responsible for addressing and correcting the non-conformance
d) The immediate action to remedy or address the non-conformance
e) An appropriate timescale for the implementation of a permanent correction of the non-conformance
f) Verification that the correction has been effectively implemented

1.9 Validation and Verification

1.9.1 Validation

The location shall have a documented procedure for the validation of the following at least annually:

a) Critical limits set for all Control Points (CPs), Quality Control Points (QCPs), and Critical Control Points (CCPs)
b) Current Good Manufacturing Practices (cGMPs)
c) Any change to the process that could affect the safety or quality of the product
d) The entirety of the location's cannabis safety and quality system

1.9.2 Verification

The location shall have a documented procedure for all verification activities. The procedure shall include:

a) Who is responsible for each verification activity
b) The frequency of the verification activities
c) How each verification activity is monitored and documented

1.10 Crisis Management, Security, and Fraud Prevention

1.10.1 Crisis Management

The location shall have in place a documented crisis management procedure. The procedure shall include:

a) A list of all personnel and contact information for those who are responsible for managing a crisis
b) A list of emergency contacts
c) Methods for how the location responds and handles all foreseeable disasters
d) Methods for how the location identifies, isolates and releases affected products according to 1.7.1
e) How the location plans to communicate with authorities, regulatory agencies, customers, and other external organizations
f) At a minimum, annual review and testing of the crisis management plan

1.10.2 Security

The location shall have in place a documented procedure for the defense against acts of theft, bioterrorism, or intentional acts of adulteration. The procedure shall include the following in addition to applicable regulatory requirements:

a) A threat assessment that identifies any potential threats and steps taken to mitigate these threats
b) What measures the location has in place to ensure only authorized personnel have access to sensitive areas
c) Methods in place to protect products from intentional adulteration throughout the entire process
d) Secured and locked access to all cannabis raw materials (i.e. flower), cannabis waste, work-in-progress, and final product
e) Methods to ensure the secured transportation of all cannabis products
f) Formal training for all personnel involved with the location's security on-site and during transportation
g) At a minimum, annual review and testing of the security plan

1.10.3 Fraud Prevention

The location shall have in place a documented fraud prevention procedure. The procedure shall be reviewed at least annually and shall include:

a) A vulnerability assessment to identify any potential vulnerabilities to mislabeling, product substitution, dilution, counterfeiting or other acts of fraud
b) Measures in place to control and mitigate identified vulnerabilities
c) Provisions for how the location verifies label claims, such as organic, strain of cannabis, etc.

1.11 Product Development and Specifications

1.11.1 Product Development

The location shall have in place a procedure for the development and approval of all new products or changes to existing product formulation, raw materials, growing or processing methods. The procedure shall:

a) Ensure all new products or changes to existing products are formally verified and approved by the HACCP Team
b) Include a process for trial runs, when necessary, to validate that the current manufacturing equipment is capable of producing a safe and quality product

1.11.2 Finished Product Specifications

The location shall have finished product specifications for all products produced. Finished product specifications shall meet all safety and quality requirements set forth by the CSQ Audit Requirements and all applicable regulatory requirements and be reviewed, at minimum, annually. This includes all key information including, but not limited to, the following:

a) Microbiological and chemical limits
b) Physical appearance standards
c) Labeling and packaging requirements
d) Intended use and target market
e) Ingredients (including allergens)
f) Shelf life
g) Storage and handling conditions
h) Dosage of the products THC and CBD as labeled
i) Heavy metal tolerances
j) Pesticide residue tolerances
k) Residual solvents tolerances
l) Potency variability specifications
m) Absence of mycotoxins

1.11.3 Raw Materials

The location shall have documented specifications for raw materials and packaging materials that are in compliance with all safety and quality requirements set forth by the CSQ Audit Requirements and all applicable regulatory requirements. Packaging materials should be appropriate for the intended use and stored in conditions that do not pose a risk to product safety or quality. The location shall have a procedure for the acceptance and release of raw materials and packaging materials on receipt. The procedure should include a sensory inspection (e.g. visual, olfactory, etc.) and at least one of the following requirements:

a) Product sampling or testing
b) Certificate of Analysis (COA) or Certificate of Conformance (COC)

1.11.4 Labeling

The location shall have documented specifications for finished product labeling that is in compliance with all safety and quality requirements set forth by the CSQ Audit Requirements and all applicable regulatory requirements. The location shall have a system in place to verify that potency, ingredient, allergens, clinical warnings, label claims, and batch and harvest information are accurate based on raw materials and processes used to create the product. Whenever changes occur to raw materials, processes, or legislation, the location shall review labeling information.

1.12 Suppliers and Services

1.12.1 Approved Supplier Program

The location shall conduct a risk assessment for all raw materials and packaging materials to determine the risk associated with each incoming product. This risk assessment shall be reviewed at least annually. All incoming raw materials and packaging materials shall meet agreed safety and quality specifications. The location shall have in place a documented procedure for approving suppliers of raw materials and packaging materials. The procedure shall include:

a) Who is responsible for the approval and monitoring of suppliers
b) How the location selects, evaluates, approves, and monitors suppliers
c) A provision for the use of non-approved temporary suppliers for emergencies and how the location verifies the safety and quality before use
d) The annual review of all approved suppliers

1.12.2 Contract Producers and Manufacturers

The location shall have in place a documented procedure for the approval and monitoring of contract producers and manufacturers. The location shall ensure that contract producers and manufacturers do not negatively affect the safety or quality of the location's products and ensure ethical sourcing is maintained. The location shall be able to verify the contract producer's or manufacturer's compliance with the CSQ Standard by way of a second or third-party audit.

1.12.3 Contract Service Suppliers

The location shall have in place a documented procedure for the approval and monitoring of contract service suppliers. The location shall ensure that contract service suppliers do not negatively affect the safety or quality of the location's products.

5.0 Manufacturing of Cannabis Dietary Supplements Requirements

5.1 Processing Practices

5.1.1 Process Flow, Segregation and Cross-Contamination Prevention

The location shall have a system in place to ensure process flow is designed to promote segregation and prevent cross-contamination. In addition, the location shall have a documented map of the facility designating high-risk areas or zones.

5.1.2 Personnel Processing Practices

The location shall have a system in place to ensure that all personnel handle raw materials, work-in-progress, finished products, and packaging materials in a way that does not negatively affect the product's safety or quality.

5.1.3 Allergen Management

The location shall have a system in place that effectively controls allergens and meets legal requirements for labeling applicable in the country and/or region for sale. Locations that do not produce allergenic products shall, at minimum, address how the location prevents unintended allergens from entering the manufacturing process from suppliers, employees, and visitors. The location shall have in place a documented procedure for the control of allergenic materials. The procedure shall include:

a) A risk assessment of all allergenic raw materials and processing aids
b) Identification of all allergens handled onsite
c) Identification, handling, cleaning, changeover, and storage methods used to prevent cross-contamination of allergens
d) How the location addresses unintended allergens from entering the processing process
e) Verification of labeling according to 1.11.4

5.2 Foreign Matter

5.2.1 Foreign Matter Control

The location shall exclude all wood, glass, brittle plastic, ceramics, or other similar materials from areas where open products are handled where possible. The location shall have no loose objects on equipment or overhead structures. The location shall keep all pallets clean and in good repair. The location shall have in place a documented procedure for the control of foreign matter. The procedure shall include:

a) A facility inspection process to ensure the facility, equipment and tools remain in good repair as to not cause a potential foreign matter contamination
b) Provision for the protection of the damage, breakage or deterioration of wood, glass, brittle plastic, ceramic, or other similar objects that cannot be removed from the processing area and how the location monitors the objects
c) A list of all wood, glass, brittle plastic, ceramic or other similar objects that are in open product areas, including their specific location
d) Methods for how the location controls the use of metal cutting instruments used in processing and packaging operations

5.2.2 Foreign Matter Detection

The location's foreign matter detection equipment shall be fit for its purpose and effectively remove or detect foreign matter. The location shall have in place a documented procedure for the detection of foreign matter, appropriate to the location's risks. The procedure shall include:

a) How the location plans to detect foreign matter
b) The methods used to monitor and verify foreign matter detection
c) Provision for the inspection and investigation of foreign matter that is removed by detection devices
d) The calibration of foreign matter detecting equipment in accordance with 5.6.3

5.2.3 Managing Foreign Matter Contamination

The location shall have in place a documented procedure for the management of foreign matter contamination. The procedure shall include:

a) The methods used to quarantine and inspect the area of the foreign matter contamination
b) The methods used to remove and clean the foreign matter contamination
c) The methods and responsibility for deciding if the potentially affected product is used for rework or disposed of

5.3 Sampling, Testing, and Inspections

5.3.1 Product Sampling and Testing

The location shall schedule and conduct sampling and testing to ensure finished products meet product specifications and regulatory requirements. Sampling and testing shall be conducted against nationally or internationally recognized standards. Where external laboratories are used, the laboratory shall be accredited to ISO/IEC 17025. Where internal laboratories are used for finished product compliance testing, the laboratory shall be accredited to ISO/IEC 17025. Where internal laboratories are only used for internal quality control, the laboratory is not required to be accredited to ISO/IEC 17025. Internal laboratories shall be separated from the product handling areas, be suitably designed for the intended purpose, and not pose a risk to product safety or quality. The location shall have in place a documented procedure for the sampling and testing of finished products. The procedure shall include:

a) Who is responsible for sampling and testing and how the location ensures staff carrying out sampling and testing analysis are competent and qualified
b) Methods, frequency, and limits that are used for sampling and testing
c) Trending of sampling and testing records
d) Evaluation and release procedures that meet the requirements of 1.7.1

5.3.2 Environmental Monitoring

The location shall have in place a documented procedure for environmental monitoring. The procedure shall include:

a) Who is responsible for the environmental monitoring program
b) Methods, frequency, and limits that are used for sampling
c) Trending of environmental monitoring records

5.3.3 Internal Audits

The location shall conduct internal audits to verify the effectiveness of the entire cannabis safety and quality system at least annually. All applicable requirements of the CSQ Standard shall be audited using the CSQ Audit Requirements. In addition to the annual internal audit of the entire cannabis safety and quality system, the location shall conduct monthly internal audits to verify the location is maintaining current Good Manufacturing Practices (cGMPs). The site shall have in place a documented procedure for conducting internal audits. The procedure shall include:

a) Who is responsible for conducting internal audits and how the site ensures staff carrying out internal audits are competent and qualified
b) Methods and frequency of internal audits
c) How the location communicates audit results and corrective actions to relevant staff
d) Trending of audit records and corrective actions

5.4 Storage and Distribution

5.4.1 Stock Management

The location shall have a system in place to ensure that raw materials, work-in-progress, rework, and finished products are utilized to ensure effective stock rotation (e.g. FIFO) and are used within the allocated shelf life. The location shall ensure that products held under overflow conditions are monitored and do not negatively affect the safety or quality of the product.

5.4.2 Dry Storage

The location shall have an area to store dry products that are suitable for its purpose and constructed to protect the product from contamination. The location shall ensure that packaging material is stored separately from raw materials and finished products.

5.4.3 Controlled Temperature and Atmosphere Storage

The location shall have an area to store raw materials and finished products that is suitable for its purpose and constructed to protect the product from contamination. The location shall ensure the controlled temperature and atmosphere storage area is fitted with a temperature and humidity monitoring device and have a system in place to ensure specified temperatures and humidity are maintained. The location shall also ensure that any condensation is controlled and discharged into a drainage system.

5.4.4 Unloading, Loading, and Shipping Practices

The location shall have in place a documented procedure for unloading, loading, and shipping practices. The procedure shall include:

a) The inspection process before unloading or loading
b) The methods used to ensure minimal exposure of the product to detrimental conditions
c) The methods used to ensure the prevention of cross-contamination and that the product maintains its integrity throughout the unloading, loading, and shipping process
d) The methods used to ensure the load is secure from tampering or external elements

5.5 Construction and Layout of Buildings

5.5.1 Exterior

The location shall be in a location that does not interfere with product safety or quality and follow all local laws and regulations. The location shall ensure:

a) The location’s construction is maintained and in good repair
b) The location’s grounds and surrounding area are maintained and free from debris, standing water, and excessive dust
c) The location shall maintain all vegetation growth around the exterior of the facility to ensure there is no harborage of pests
d) Roadways, loading and unloading areas under the locations control are maintained and free from debris

5.5.2 Interior

The location shall be suitable for the intended purpose and mitigate opportunities for cross-contamination between and during operations. The location shall ensure:

a) All floors, walls, doors, windows, ceilings, drains and other building fixtures are constructed to not pose a risk to product safety or quality, are designed to be easily cleanable, are maintained and in good repair
b) Light fixtures and skylights are constructed to not pose a risk to product safety or quality, are of appropriate intensity, are maintained and in good repair
c) Windows, light fixtures, and skylights that could pose a risk to product safety and quality are shatterproof or protected against breakage
d) Adequate ventilation and extraction to prevent condensation or excessive dust is provided
e) All external openings are effectively sealed when closed and prevent dust and pests from entering the building

5.6 Equipment, Maintenance, and Calibration

5.6.1 Equipment

The location's equipment shall be suitable for its intended purpose. The location shall ensure all equipment is designed not to pose a risk to product safety or quality, easily cleanable, maintained, and in good repair. The location shall:

a) Ensure equipment is stored in a manner that does not pose a risk to product safety
b) Ensure all hoses are stored on racks and off the floor
c) Have all tools used for cleaning be color-coded or labeled as to its purpose

5.6.2 Maintenance

The location shall ensure that the building and equipment are maintained as to not pose a threat to product safety or quality. The location shall have in place a documented procedure for the maintenance of the building and equipment. The procedure shall include:

a) A master preventative maintenance schedule
b) How the location documents unplanned maintenance
c) Process for maintenance staff for alerting the appropriate supervisor when repairs pose a threat to product safety or quality
d) Process for ensuring that product safety or quality is not jeopardized during maintenance
e) Process for ensuring that any product contamination hazards (tools, lubricants, debris, etc.) are completely removed from the area being maintenance before the commencement of operations
f) A provision for how the location controls and monitors temporary repairs, so as not to pose a risk to product safety or quality, and ensures that temporary repairs don't become permanent

5.6.3 Calibration

The location shall ensure all equipment used to measure factors that affect product safety or quality are calibrated appropriately. The location shall:

a) Identify all equipment being calibrated with the valid calibration due date
b) Calibrate equipment against national or international standards and according to regulatory requirements and manufacturers recommendations
c) Protect calibrated equipment against damage and unauthorized adjustment

5.7 Water Safety and Quality

5.7.1 Water Safety and Quality Management

The location shall ensure all water used onsite is potable and in compliance with regulatory requirements. Tempered water is required where handwashing or cleaning of equipment is completed. The location shall conduct a microbiological and chemical analysis of the onsite water supply within the facility at a minimum annually. All water analysis shall be conducted by an accredited ISO 17025 laboratory. Backflow prevention devices shall be installed on hoses, taps, and other similar water dispensing devices.

5.7.2 Ice Safety and Quality Management

The location shall ensure all ice used in the processing process as an aid or ingredient shall be from a verified potable source and in compliance with regulatory requirements.

5.8 Air Safety and Quality

5.8.1 Air Safety and Quality Management

The location shall test ambient air in processing areas, at minimum, annually. The location shall ensure all air or other gases that come in contact with the product or manufacturing processes are filtered and monitored at an appropriate frequency to ensure it does not pose a risk to product safety or quality. The location shall ensure that appropriate measures are taken for odor elimination.

5.9 Waste Management

5.9.1 Standard Waste Disposal

The location shall ensure all standard waste is removed regularly to prevent accumulation and the attraction of pests. The location shall ensure the designated waste areas and containers are:

a) Clearly identified
b) Clean and maintained regularly
c) Kept sealed or closed when possible
d) Removed or emptied regularly

5.9.2 Cannabis Waste Disposal

The location shall ensure all cannabis waste is disposed of according to regulatory requirements and does not accumulate. The location shall ensure all cannabis waste and waste areas are:

a) Clearly identified and labeled according to regulatory requirements
b) Cleaned and maintained regularly
c) Kept sealed and restricted to authorized personnel
d) Removed or emptied regularly and according to regulatory requirements

5.10 Pest Prevention

5.10.1 Pest Control Program

The location shall effectively prevent pest infestations. The presence of pest infestations on location shall be identified and eliminated so that they do not pose a risk to product safety or quality. The location shall have in place a documented pest control program that is reviewed annually, at a minimum. The program shall:

a) Clearly define the responsibilities of the location and/or contractors involved in the development, implementation, and maintenance of the pest control program
b) Include a bait station map that identifies the type, location and number of the traps or bait stations used
c) Ensure that traps, bait stations, insect light traps, and pheromone traps are located as to not pose a risk to product safety or quality
d) Include a list of regulatory compliant pesticides used with their Safety Data Sheets (SDS)
e) Include the frequency of the monitoring of pest traps or bait stations
f) Include how the location records and trends the sighting of pests and how the location effectively handles recommendations from pest control personnel
g) Describe what to do when staff come in contact with a trap or bait stations contents

5.10.2 Pest Control Personnel

The location shall ensure that all personnel, either location staff or external contractors, involved with the application of pesticides do not pose a threat to product safety or quality. Pest control personnel shall:

a) Be trained and qualified to conduct pest control activities and meet regulatory compliance
b) Be licensed and approved by the relevant authorities
c) Only use regulatory compliant pesticides
d) Provide a documented report of findings and pesticides used during the inspection

5.11 Cleaning and Sanitation

5.11.1 Cleaning and Sanitation Program

The location shall ensure the building and equipment are maintained cleanly and hygienically, as to not pose a risk to product safety or quality. Cleaning operations should not interfere with manufacturing operations and should not pose a potential risk to product safety or quality. Suitable cleaning areas should be provided for the cleaning of equipment and tools. Storage for clean equipment and tools should be separate from dirty equipment and tools. The location shall have in place a written cleaning and sanitation program. The program shall include:

a) What is to be cleaned
b) Method for cleaning, including what cleaning chemicals and materials are to be used
c) The frequency of cleaning based on risk
d) Who is responsible for cleaning
e) Who is responsible for verification and what method is used to verify cleanliness

5.12 Chemical Controls

5.12.1 Chemical Control and Storage

The location shall control and store all chemicals in compliance with regulatory requirements. The location shall:

a) Have a chemical approval procedure and list of approved chemicals specific to that location's operations
b) Store all chemicals to ensure that they do not pose a risk to product safety or quality
c) Store food-grade chemicals separately from non-food grade chemicals
d) Store chemicals in their original container or clearly labeled secondary containers
e) Ensure that chemical storage areas are adequately ventilated, have appropriate signage identifying the area, and be restricted to authorized personnel only
f) Ensure that chemical storage areas include the appropriate protective clothing, first aid equipment, and a list of approved chemicals with their respective Safety Data Sheets (SDS)
g) Dispose of all chemicals in accordance with regulatory compliance

5.13 Personnel Hygiene and Welfare

5.13.1 Hand Washing

The location shall ensure personnel are effectively washing their hands at appropriate frequencies. The location shall ensure:

a) All personnel have clean hands and that hands are washed after handling something that could pose a threat to product safety or quality
b) Hand washing stations are located upon entering processing areas and in easily accessible locations through product handling areas
c) Hand washing stations have a potable water supply, are at the appropriate temperature, and are installed with a hands-free soap dispenser and paper towel dispenser
d) Signage instructing personnel to wash their hands is prominently displayed near hand washing stations in a language understood by all staff

5.13.2 Personnel Health Control

The location shall have a procedure in place to ensure employees are not a vector for the transmission of diseases to products. The location shall:

a) Inform all employees of the signs and symptoms of infectious diseases which would prevent them from working with products
b) Have a system in place for all employees to report symptoms to senior management
c) Ensure employees with exposed cuts, sores or lesions do not handle product
d) Ensure minor exposed cuts are covered with bandages with metal strips and disposable gloves
e) Ensure areas, where the spillage of bodily fluids (blood, vomit, etc.) occurs, are adequately quarantined, cleaned, and sanitized, and released by authorized personnel

5.13.3 Personnel Hygiene Practices

The location shall have a procedure in place to ensure that personnel practices do not negatively affect product safety or quality. The procedure shall ensure:

a) Smoking, chewing tobacco, eating, and drinking are only conducted in permitted areas away from product handling areas (drinking water is permitted in designated product handling areas as long as it does not pose a risk to product safety or quality)
b) Personnel do not wear false fingernails, fingernail polish, or false eyelashes
c) Personnel fingernails are kept short and clean
d) Personnel do not wear excessive perfume or aftershave

5.13.4 Clothing, Jewelry, and Personnel Belongings

The location shall have in place procedures to ensure that personnel clothing, jewelry, and other personnel belongings do not pose a risk to product safety or quality. The location shall ensure:

a) That there are a sufficient number of protective clothing items for each employee
b) Protective clothing is suitable to prevent contamination of the product
c) Racks are provided at appropriate entrances and exits to ensure there is no contamination of clothing
d) Hair and beard nets are worn by all personnel involved with product handling
e) That all protective clothing (unless disposable) is effectively cleaned, either by an approved contractor or in house, at a frequency that minimizes risk to product safety and quality
f) That dirty and clean protective clothing is adequately separated, and clean clothes are protected from contamination
g) Gloves are replaced at a frequency that does not pose a risk to product safety or quality
h) No jewelry, except for a plain wedding band or medical alert bracelet, shall be worn

5.13.5 Employee Facilities

The location shall ensure employee facilities are sufficient to accommodate all personnel, are clean and maintained, and are designed to minimize the potential risk of product safety and quality. The location shall ensure:

a) Restrooms are easily accessible to personnel and do not open directly into product handling areas
b) Changing facilities are provided for all personnel and provide an area for employees to store personal items and outside clothing
c) Lunch facilities are separated from product handling areas and provide an area for employees to store their food in a clean and hygienic manner

5.13.6 Visitors

The location shall have a system in place to ensure no visitor poses a threat to product safety or quality. Visitors shall:

a) Not be allowed to enter product handling areas if they are showing signs of illness
b) Be informed on the location's specific current Good Manufacturing Practices (cGMPs)
c) Wear suitable clothing and footwear
d) Remove all jewelry and other loose objects
e) Practice good personnel hygiene and handwashing practices

5.14 Training

5.14.1 Training of Personnel

The location shall have in place a documented training program to ensure that all personnel, including temporary employees and contractors, are adequately trained before commencing work. The location shall have at least one individual on the cannabis safety and quality team formally trained in HACCP. Additionally, the employee(s) responsible for creating, implementing, and maintaining the CSQ system shall be formally trained via the CSQ 101 training course or demonstrate a strong knowledge of cannabis safety and quality through work experience. The training program shall include:

a) At a minimum, formal training on current Good Manufacturing Practices (cGMPs) and basic HACCP principles by a qualified individual
b) A training matrix indicating what each employee has been trained on
c) A provision for refresher training completed at least annually

Appendix 1: Terms and Definitions

Adenosine Triphosphate (ATP) – ATP is found in all animal, plant, bacterial, yeast, and mold cells. It occurs in food and in microbial contamination. The ATP test uses bioluminescence to detect the presence of ATP left on a surface after cleaning to verify the removal of product that could contribute to microbiological contamination on product contact surfaces.

Adulteration – to make imperfect by adding extraneous, improper, or inferior ingredients.

Allergen – substances that cause an exaggerated immune response in some people and that may result in a runny nose, watery and/or itchy eyes, a rash, wheezing, serious illness or (occasionally) death.

Butane Hash Oil (BHO) – a potent concentrate of cannabinoids made by dissolving marijuana in its plant form in a solvent (usually butane). The resulting product has very high THC levels (generally more than flowers or hashish) and is a thick, sticky oil. BHO is also referred to as honey oil, "dabs" or "dabbing," earwax, or shatter, depending on the manufacturing method.

Bud – Bud refers to the actual flower of the marijuana plant. These are the fluffy parts that are harvested and used for recreational or medicinal purposes as they contain the highest concentrations of active cannabinoids.

Bud Tender - This is the attendant working behind the counter at your local dispensary or retail cannabis shop who may be able to answer your questions on strains, cannabis products, and make suggestions based on your needs.

Cannabinoids – are the chemical compounds unique to cannabis that act upon the human body's cannabinoid receptors, producing various effects including pain relief and other medically beneficial uses. Cannabis' most well-known cannabinoid is tetrahydrocannabinol (THC) due to the fact that it is the most abundant, and also because it produces the psychoactive effects (or the "high") that drives the plant's recreational use. However, there are several known cannabinoids all with varying effects.

Cannabis – a plant genus that produces three species of flowering plants: *Cannabis sativa*, *Cannabis indica*, and *Cannabis ruderalis*.

Calibration – the adjustment of an instrument for accuracy relative to an established standard.

Cannabidiol (CBD) – a type of cannabinoid found in cannabis and second only to THC when it comes to average volume in cannabis plants.

Certificate of Analysis (COA) – a document containing test results that are provided to the customer by the supplier to demonstrate that product meets the defined test.

Cleaning in Place (CIP) – the process of cleaning and sanitizing processing equipment in its assembled position without the need for dismantling and cleaning the individual parts.

Clone – refers to a clipping from a cannabis plant, which can then be rooted and grown through a cloning process of the mother plant, from which the clone was cut.

Concentrates – a potent consolidation of cannabinoids that are made by dissolving cannabis in its plant form into a solvent. The resulting product has very high cannabinoid levels and can produce varying range of products. Referred to by a variety of slang terms, the classification of concentrates is often dependent on the manufacturing method and the consistency of the final product.

Contamination – a condition that can affect a product that has been exposed to and faced introduction of foreign matter, including filth, a poisonous substance or pests, disease-causing microorganisms or parasites, or toxins.

Control Point – any step in the process at which a hazard can be controlled, reduced, or eliminated.

Critical Control Point – a point, step, or procedure in a process at which a control can be applied and is essential to prevent or eliminate a hazard or reduce such a hazard to an acceptable level.

Critical Limit – a maximum and/or minimum value, or combination of values, to which a biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process preventive control or at a CCP.

Cross-Contamination – a situation that occurs when micro-organisms, allergens, chemicals, or other hazards that are carried by utensils, hands, towels or other items are transferred from one product, raw material, or surface to another.

Dab – a dab is a slang term used to refer to a dose of cannabis concentrates "dabbed" onto a red-hot surface and inhaled.

Dispensary – a general term used to refer to any location where a consumer can legitimately and safely access cannabis, whether the business is technically an access point, pick-up location, co-op, collective or any other version of a legal cannabis distributor.

Edibles – are food items that have been infused with cannabis extracts. They are commonly baked goods such as cookies and brownies, but options as varied as flavored drinks, candies, and other products exist as well.

Environmental Monitoring Program (EMP) – a program for the evaluation of the effectiveness of controls on preventing contamination from the manufacturing environment.

Foreign Matter – any substance or object that does not naturally or normally belong in a product.

Good Agricultural Practices (GAP) – are the basic environmental and operational conditions necessary to produce safe, wholesome agricultural products.

Good Handling Practices (GHP) – refers to the best practices for post-harvest handling of agricultural products to minimize contamination.

Good Manufacturing Practices (GMP) – outlines the conditions and practices the industry must follow for processing safe products under sanitary conditions, including personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, and defect action levels considerations.

Hash – short for hashish, which is derived from cannabis plants and can be used for consumption. Production involves the removal of the plant's trichomes by sieving or filtering. Once the cannabinoid-laden powder has been collected, it is typically pressed and ready to be used.

Hazard – a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of a control.

Hazard Analysis Critical Control Point (HACCP) – a systematic approach that identifies, evaluates and controls hazards significant to product safety.

Hemp – a fibrous product that can be produced from the male cannabis plant and can be used in the manufacture of rope, paper, beauty products, and a vast array of other products.

Hydroponics – refers to a system of horticulture that does not use soil. Plants are grown in water and receive their nutrients from the addition of solutions rather than soil.

Integrated pest Management (IPM) – an effective and environmentally sensitive approach to pest management that relies on a combination of common-sense practices. The information in combination with available pest

control methods is used to manage pest damage by the most economical means and with the least possible hazard to the people, property, and environment.

Kief – a collected amount of trichomes that have been separated from the rest of the cannabis flower. Since trichomes are the sticky crystals that contain the vast majority of the plant's cannabinoids, kief is known to be extremely potent.

Location – the facility of an organization that is being audited against the CSQ Standard.

Mitigation Strategies – controls to remove, or reduce to an acceptable level, an identified risk, vulnerability, or threat.

Pathogen – a bacterium, virus, or other microorganism that can cause disease.

Pests – any animal or insect of public health importance, including, but not limited to birds, rodents, roaches, flies, and larvae that may carry pathogens that can contaminate products.

Pest Harborage – any condition or structural defect that provides a place for pests to live and reproduce.

Phenotype – refers to the general physical characteristics of the plant such as height, color, branching, leaf configuration down to cell structure.

Potable Water – water suitable for drinking, free from pollutants and harmful organisms, and conforms to local legal requirements.

Prerequisite Program (PRP) – all procedures used in the site, which address operational conditions providing the foundation for the HACCP plan. Examples include Cleaning & Sanitation Programs, Good Manufacturing Practices Program, Pest Management Programs, etc.

Pre-roll – is a commonly used term that refers to a pre-rolled cannabis cigarette, also known as a joint.

Preventive Control – risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packaging, or holding of product would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe manufacturing, processing, packaging, or holding at the time of analysis.

Processing Aid – is a substance not typically consumed by itself that is used in the production process and which may end up in the finished product.

Personal Protective Equipment (PPE) – PPE is protective clothing, helmets, goggles, or other garments or equipment designed to protect the wearer's body from injury or infection.

Quality – meeting of customers' specifications and expectations.

Quarantine – the holding of any raw material or product while awaiting confirmation of its suitability for intended use or sale.

Raw Material – commodities, parts or substances that are assembled or processed to form a final product

Rework – the process of re-manufacturing of semi-final and final products, to obtain a final product that complies with the customer requirements. It can also refer to material in a processed or semi processed state that is intended to be re-used in subsequent manufacturing steps.

Risk – the likelihood of an occurrence and the size of the consequences of an adverse event.

Risk Analysis – a process that includes risk assessment, risk management, and risk communication.

Risk Assessment – the process of identifying a hazard and characterizing the risk presented by that hazard in qualitative or quantitative terms.

Root Cause – the underlying cause(s) of a problem.

Specification – a detailed, exact statement of prescribed requirements for incoming materials or finished products.

Standard Operating Procedure (SOP) – a set of step-by-step instructions compiled by a site to help employees carry out operations.

Strain – a specific variety of a plant species. Strains are developed to produce distinct desired traits in the plant and are usually named by their breeders. Strain names often reflect the plant's appearance, its promised buzz, or its place of origin.

Supplier – a person or organization that provides a product or service.

Tetrahydrocannabinol (THC) – the most well-known and most abundantly available cannabinoid in cannabis plants. THC is also the component in cannabis that is responsible for the psychoactive effects, or the "high." Also known as delta-9-tetracannabinol, it was first isolated in 1964 and is thought to serve as a natural defense for the plant against pests.

Threat Assessment – a risk assessment designed to examine a location's processes for potential product security.

Tincture – a liquid cannabis extract usually made with alcohol or glycerol that is often dosed with a dropper. Tinctures can be flavored and are usually placed under the tongue, where they are absorbed quickly.

Topical – a type of cannabis product where the active properties of the flowers have been extracted and added to a product such as a lotion or a cream that is applied to the skin.

Traceability – the identification of any suspect raw material of finished product and its initial shipment location.

Trichome – the resin production glands of the cannabis plant where THC, CBD, and other cannabinoids are produced.

Validation – confirmation of plausibility for a specific intended use or application through the provision of objective evidence that specified requirements have been fulfilled.

Verification – confirmation of truthfulness through the provision of objective evidence that specified requirements have been fulfilled.

Vulnerability Assessment – a risk assessment designed to examine processes and the supply chain for potential fraud.

Work in Progress (WIP) – partially manufactured products.

Appendix 2: Audit Process

Audit Preparation:

- Download the most current and applicable CSQ Standard
- Designate an employee (and backup) to manage the CSQ System
- Take the CSQ 101 Training
- Sign an agreement with a licensed Certification Body (CB)
- Conduct an internal audit or receive an external mock audit against applicable standard
- Correct any non-conformances from internal/mock audit

Audit Planning:

- Schedule offsite document evaluation and onsite evaluation with CB
- Ensure all appropriate personnel are present the day of the onsite audit

Offsite Documentation Evaluation:

- Submit all applicable CSQ documentation to CB
- Submit any other additional documentation as requested by the CB
- Review any non-conformances and make corrections before the onsite evaluation

Onsite Facility Evaluation:

- Opening meeting
- Facility inspection
- Documentation review
- Conduct mock recall
- Closing meeting

Post Audit:

- Close out non-conformances within 30 days from onsite evaluation
- CB reviews corrective actions, supporting evidence, and root cause analysis
- If all corrective actions are satisfactory, a certificate will be issued within 45 days from onsite evaluation

Maintenance:

- Continuous improvement of location's CSQ System
- Ongoing proper use of CSQ Logo
- Ongoing communication with CB for:
    - Scope extensions
    - Major changes to ownership (or other factors that affect certification)
    - Any recalls, voluntary withdrawals, or regulatory warnings
- Schedule annual certification audit or 6-month surveillance audit

Appendix 3: Audit Standards and Product Categories

Growing and Cultivation of Cannabis Plants – BI, BII	
Applies to both Pre-Harvest and Post-Harvest activities of cultivating cannabis plants. This includes seed farming (breeders), growing of cannabis plants, harvesting of cannabis plants, and packaging of raw flower products without further processing (e.g. Whole Flower, Pre-Rolls, etc.).	
Manufacturing and Extraction of Cannabis – CII	
Applies to the manufacturing and extraction process of cannabis plants using solventless extraction, CO2 extraction, hydrocarbon extraction, ethanol extraction, or other extraction methods. This includes kief/dry sift, bubble hash, rosin, live resin, shatter, wax, tinctures, distillate, RSO, etc.	
Manufacturing and Infusion of Cannabis into Food & Beverage Products – CIV	
Applies to the manufacturing and infusion or addition of cannabis flower or cannabis derivatives into shelf-stable food and beverage products consumed by humans or animals. Examples of acceptable products are listed below.	
Baked Goods & Snack Foods	Baked Goods, Baked Snacks, Brownies, Cakes, Chips, Cookies, Cupcakes, Donuts, Granola Bars, Muffins, Pastries, Pies, Protein Bars, Popcorn, Rice Cakes, Snack Bars, etc.
Confectionary	Candy, Candy Bars, Caramels, Chocolate Bars, Fudge, Gummy Candy, Hard Candies, Mints, Lollipops, etc.
Preserved Foods	Honey, Jam, Jelly, Maple Syrup, Sauces, etc.
Beverages	Alcoholic Beverages, Coffee, Energy Drinks, Fermented Drinks, Flavored Drinks, Flavored Water, Kombucha, Smoothies, Soda, Tea, etc.
Food Ingredients & Additives	Cooking Oils, Dry coffee Blends, Dry Drink Mixes, Dry Tea Blends, Flavor Enhancers, Flavor Extracts, Food Additives, Ingestible Oils, Seasonings, Spices, etc.
Dry Animal Food/Feed	Dry Animal Feed, Dry Pet Food, Dry Pet Treats, etc.
Manufacturing of Cannabis Dietary Supplements – K	
Applies to the manufacturing and infusion or addition of cannabis flower or cannabis derivatives into dietary supplements that are taken orally. This includes tablets, capsules, gummies, liquids, energy bars, and powders that are labeled as dietary supplements.	