Cannabis Safety & Quality

CSQ Dietary Supplement Addendum

CSQ
DIETARY SUPPLEMENTS

CSQ Dietary Supplement Addendum

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Part 1: CSQ Dietary Supplement Addendum Overview

1.1. Introduction

This document outlines the management of and certification to the CSQ Dietary Supplement Addendum. The CSQ Dietary Supplement Addendum is designed to complement the CSQ Certification Program and covers additional audit requirements specific to licensed operations processing and producing cannabinoid-containing dietary supplement products.

This document contains the following three (3) parts:

1) CSQ Dietary Supplement Addendum Overview
2) CSQ Dietary Supplement Addendum Audit Requirements
3) Appendixes

The development of the CSQ Dietary Supplement Addendum is based on ASTM, ISO, cGACP, cGMP, HACCP, AHPA and other internationally recognized dietary supplement standards and best practices, as well as various applicable international regulatory requirements. When updates or changes to the CSQ Dietary Supplement Addendum are necessary, changes shall be communicated to impacted stakeholders and made publicly available.

1.2. Ownership and Addendum Management

The CSQ Certification Program and the CSQ Dietary Supplement Addendum is owned by ASI Global Standards, LLC at 500 NW Plaza, Suite 700 St. Ann, MO 63074. ASI Global Standards retains the ownership and copyright of all CSQ Certification Program related documents and holds the agreements for all involved Certification Bodies, Accreditation Bodies, and Training Organizations. The day-to-day operations of the CSQ Certification Program are managed by the CSQ Certification Program Owner. For more information see the CSQ Certification Program, Part 1, Section 1.2 CSQ Certification Program Ownership and Management.

1.3. CSQ Dietary Supplement Addendum Scope

The CSQ Dietary Supplement Addendum is a scope extension for CSQ Certified, Level 2 and Level 3, licensed operations processing, producing, handling, storing, distributing, or selling cannabinoid herbal materials, substances, and/or products as dietary supplements and/or as dietary supplement ingredients, regardless of regulatory classification.

The CSQ Dietary Supplement Addendum can be added to any Level 2 or Level 3 CSQ Certification, CSQ Cultivation, CSQ Extraction, or CSQ Manufacturing. The CSQ Dietary Supplement Addendum Audit Requirements are in addition to the applicable CSQ Audit Requirements.

1.4. CSQ Dietary Supplement Addendum Audit Requirements

The CSQ Dietary Supplement Addendum is intended for the audit, certification, and registration of safety and quality management systems meeting the CSQ Dietary Supplement Addendum Audit Requirements. The CSQ Dietary Supplement Addendum Audit Requirements are incorporated into four (4) modules.

Table 1: CSQ Dietary Supplement Addendum Audit Requirements

Module	Module Title	Audit Requirements
Module 1	General Requirements	Facility and Facility Infrastructure
		Single-Service Articles
		Retention (Reserve) Samples
		Voucher Samples
Module 2	Requirements for Master Production Records	Master Production Record Procedures
		Creation of Master Production Records
Module 3	Requirements for Batch Records	Batch Records – General Requirements
		Batch Records – Documentation at the Time of Performance
Module 4	Requirements for Botanical Identity of Cannabinoid Materials and Products	Product Specifications – Botanical Identity
		Documentation of Botanical Identity
		Validation and Verification of Botanical Identity
		Confirmation and Maintenance of Botanical Identity

1.5. Audit Process

Scheduling: Scheduling the audit will be done by a CSQ licensed Certification Body. The CSQ Dietary Supplement Addendum audit will be scheduled in the CSQ Database. Certification audits for the CSQ Dietary Supplement Addendum can be scheduled concurrently with certification audits for any CSQ Certification, or separately, but not prior to achieving a CSQ Certification.

Auditor Selection: The CSQ licensed Certification Body will select the auditor that is approved for Dietary Supplements.

Minimum Duration: The minimum audit duration for the CSQ Dietary Supplement Addendum is four (4) hours.

Audit Report: Audit reports shall be provided not later than 72 hours after completion of the audit. For concurrent certification audits, audit reports for the CSQ Dietary Supplement Addendum shall be provided separately from audit reports for the CSQ Certification Program.

Scoring: Scoring for the CSQ Dietary Supplement Addendum will be Pass/Fail. All nonconformances shall be corrected with objective corrective actions completed within thirty (30) days for a passing score. Any nonconformances shall be classified as either minor or major but do not impact the scoring of the addendum. Any critical findings during the audit may impact the CSQ Certification of the licensed operation.

Corrective Actions: All nonconformities identified during the audit must be addressed by the licensed operation following the rules outlined in the CSQ Certification Program, Part 2, Section 3, Subsection 3.2.

Certification: CSQ Certified Licensed Operations passing the CSQ Dietary Supplement Addendum audit shall be awarded a new certificate stating their certification to both the CSQ Certification Program and the CSQ Dietary Supplement Addendum. Licensed operations new to the CSQ Certification Program passing concurrent audits shall receive one certificate stating their certification to both. Within the CSQ Certificate will be a note stating the licensed operation has also passed the CSQ Dietary Supplement Addendum.

Part 2: CSQ Dietary Supplement Addendum Audit Requirements

NOTE: The following audit requirements are required to achieve a certification to the CSQ Dietary Supplement Addendum and are in addition to those of the CSQ Certification Program.

Module 1: General Requirements

1.1. Facility and Facility Infrastructure Maintenance

Licensed operations producing cannabinoid herbal materials, cannabinoid substances, or cannabinoid products intended to be dietary supplements shall ensure documented facility and facility infrastructure maintenance procedures and practices address sources of contamination from any areas and land boarding the facility, all buildings, and the grounds not under the licensed operation's control failing to be maintained in accordance with the applicable requirements of the CSQ Certification Program.

1.2. Single-Service Articles

Licensed operations producing cannabinoid herbal materials, cannabinoid substances, or cannabinoid products intended to be dietary supplements shall ensure all single-service articles (e.g. utensils intended for one-time-use, paper towels, etc.) are stored in appropriate containers, handled, dispensed, used, and disposed in a manner that protects against contamination.

1.3. Retention (Reserve) Samples

Licensed operations producing cannabinoid herbal materials, cannabinoid substances, or cannabinoid products intended to be dietary supplements shall have documented procedures and practices in place to collect and hold retention (reserve) samples of each batch of cannabinoid material it receives and each batch of cannabinoid product it distributes.

Retention (reserve) sample procedures shall ensure, at minimum:

a) Retention (reserve) samples are held in a manner that protects against contamination and deterioration.

b) Retention (reserve) samples are held under conditions consistent with product labels, or if no storage conditions are recommended on the label, under ordinary storage conditions, or if the product is not shelf-stable, frozen.

c) Retention (reserve) samples are held using the same container-closure system in which the packaged and labeled finished product is distributed, or if distributing products to be packaged and labeled, using a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which it is distributed for packaging and labeling elsewhere.

d) Retention (reserve) samples are identified with the product name, batch, lot, or control number, and any other relevant information.

e) Retention (reserve) samples are retained for use in appropriate investigations for one (1) year past the shelf-life date (if shelf-life dating is used), or for two (2) years from the date of distribution of the last batch associated with the reserve sample, unless otherwise required.

f) Retention (reserve) samples consist of at least twice the quantity necessary for all tests or examinations to determine whether or not the product meets product specifications.

1.4. Voucher Samples

Licensed operations producing cannabinoid herbal materials, cannabinoid substances, or cannabinoid products intended to be dietary supplements using voucher samples to verify the botanical identity of cannabinoid materials and cannabinoid products shall have documented procedures and practices in place to collect and preserve voucher samples of each batch of cannabinoid material it receives and each batch of cannabinoid product it distributes.

Voucher sample procedures shall ensure, at minimum:

a) Voucher samples shall be collected and preserved using appropriate equipment (e.g. field press, etc.).

b) Voucher samples are labeled with the botanical identity, date of preparation, person who prepared the voucher, and relevant harvest or production information (e.g. harvest or production date, cultivation or production site, etc.).

c) Voucher samples are assigned a voucher number which corresponds to all harvest or production batch numbers associated with a given voucher.

d) Voucher samples are maintained according to Retention (Reserve) Sample requirements.

Module 2: Requirements for Master Production Records

2.1. Master Production Record Procedures

Licensed operations processing and producing cannabinoid herbal materials, cannabinoid substances, or cannabinoid products intended to be dietary supplements shall have documented procedures and practices in place for preparing and following a documented master production record for each product produced, and for each batch size, to ensure uniformity in the finished product from batch to batch.

Master production records must:

a) Identify specifications for the points, steps, or stages in the production process where control is necessary to ensure the safety and quality of the product (i.e. critical control points and critical limits), and that the product is packaged and labeled as specified in the master production record (i.e. product specifications).

b) Establish controls and procedures (i.e. process controls) to ensure that each batch of dietary supplement produced meets specification, including but not limited to:

    1. The double-checking by a second operator of the weighing or measuring of all components.

    2. The double-checking by a second operator of each addition of components to the batch.

2.2. Creation of Master Production Records

Licensed operations producing cannabinoid herbal materials, cannabinoid substances, or cannabinoid products intended to be dietary supplements shall have documented procedures and practices in place for ensuring master production records meet the requirements of the CSQ Dietary Supplement Addendum and all applicable regulatory requirements.

Each master production record must include:

a) The name of the product to be produced and the strength, concentration, weight, or measure of each active ingredient for each batch size.

b) A complete list of components (e.g. ingredients, accessories, packaging materials, labels, etc.) and equipment to be used.

c) An accurate statement of the identity and quantity of each component to be used, including packaging materials and labels.

d) The identity and weight or measure of each active ingredient that will be declared on the label and the identity of each ingredient/component that will be declared on the ingredients list of the product (when required).

e) A statement of any intentional overage amount of any active ingredient (where allowed).

f) A statement of theoretical yield expected at each point, step, or stage of the production process where control is needed to ensure the safety and quality of the product.

g) A statement of expected yield when the process is completed including the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is necessary, a material review is conducted, and disposition decision is made.

h) A description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label.

i) Documented instructions, including the following:

    1. Specifications for each point, step, or stage in the production process where control is necessary to ensure the safety and quality of the product (i.e. critical control points), and that the product is packaged and labeled as specified in the master production record (i.e. product specifications), including all equipment settings and critical process parameters.

    2. Procedures for sampling and testing, including any cross-references to procedures for tests or examinations.

    3. Specific actions (i.e. process and preventive controls) necessary to perform and verify points, steps, or stages in the production process where control is necessary to ensure the safety and quality of the product (i.e. critical control points), and that the product is packaged and labeled as specified in the master production record (i.e. product specifications), including all equipment settings and critical process parameters.

    4. Special notations and precautions to be followed.

    5. Corrective action plans for use when a specification is not met.

Module 3: Requirements for Batch Records

3.1. Batch Records – General Requirements

Licensed operations producing cannabinoid herbal materials, cannabinoid substances, or cannabinoid products intended to be dietary supplements shall have documented procedures and practices in place for preparing and following documented batch records for each product produced, and for each batch size, to ensure uniformity from batch to batch, the production process was followed appropriately, and process deviations and nonconformities can be identified and tracked.

Batch records must include:

a) The batch, lot, or control number (as applicable):

   1. Of the finished batch of product.

   2. Each lot of packaged and labeled product from the finished batch of product.

   3. Each lot of product, from the finished batch of product, distributed to another licensed operation.

b) The identity of equipment and production lines used in producing the batch and the equipment settings used and measurements/readings obtained/observed.

c) The date and time of the maintenance, cleaning, and sanitizing of the equipment and production lines used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is retained.

d) The unique identifier assigned to each component (or, when applicable, to a product that you receive from a supplier for packaging or labeling as a product), packaging, and label used.

e) The identity and weight or measure of each component/ingredient used/incorporated.

f) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of production.

g) The actual results obtained during any monitoring operation.

h) The results of any testing or examination performed during the batch production, or a cross-reference to such results.

i) Documentation that the finished product meets specifications for regulatory compliance and defined in the master production record.

3.2. Batch Records – Documentation at the Time of Performance

Licensed operations producing cannabinoid herbal materials, cannabinoid substances, or cannabinoid products intended to be dietary supplements shall have documented procedures and practices in place for ensuring batch records capture, at the time of performance, data related to:

a) Production of the batch, including:

1. The date on which each step of the master production record was performed; and

2. The initials of the person(s) performing each step, including:

    i. The initials of the person responsible for weighing or measuring each component/ingredient used in the batch.

    ii. The initials of the person responsible for verifying the weight or measure of each component/ingredient used in the batch.

    iii. The initials of the person responsible for adding the component/ingredient to the batch.

    iv. The initials of the person responsible for verifying the addition of components/ingredients to the batch.

b) Packaging and labeling operations, including:

1. The unique identifier assigned to packaging and labels used, the quantity of the packaging and labels used, and, when label reconciliation is required, reconciliation of any discrepancies between issuance and use of labels.

2. An actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the master production record.

3. The results of any tests or examinations conducted on packaged and labeled products (including repackaged or relabeled products), or a cross-reference to the physical location of such results.

c) Quality assurance and quality control activities, including:

    1. Review of batch record(s), including:

        i. Review of any monitoring operation requiring control.

        ii. Review of the results of any tests and examinations, including tests and examinations conducted on components/ingredients, in-process materials, finished batches of products, and packaged and labeled products.

    2. Approving or rejecting any reprocessing or repackaging activities.

    3. Approving and releasing, or rejecting, the batch for distribution, including any reprocessed batch.

    4. Approving and releasing, or rejecting, the packaged and labeled product, including any repackaged or relabeled product.

d) Any required material review and disposition decision.

e) Any reprocessing or rework.

Module 4: Requirements for Botanical Identity of Cannabinoid-Containing Materials and Products

4.1. Product Specifications – Botanical Identity

Licensed operations producing cannabinoid herbal materials, cannabinoid substances, or cannabinoid products intended to be dietary supplements shall include the botanical identity as a product specification in addition to internal product specifications, those of the buyer, and regulatory product safety and quality requirements.

Appropriate specifications shall be documented and established for cannabinoid herbal materials, cannabinoid substances, and cannabinoid products intended to be dietary supplements for maintaining botanical identity and reflecting intended use and buyer and seller and regulatory requirements.

NOTE: Producers of cannabinoid products intended to be dietary supplements MUST have specifications for each cannabinoid ingredient/material used in the production of each cannabinoid product. If the cannabinoid ingredient/material used is a cannabinoid substance, specifications MUST include those for the cannabinoid substance and all cannabinoid herbal materials used in the production of the cannabinoid substance.

4.2. Documentation of Botanical Identity

Licensed operations producing cannabinoid herbal materials, cannabinoid substances, or cannabinoid products intended to be dietary supplements shall have documented procedures and practices in place for ensuring the botanical identity is documented with as much specificity as appropriate and botanical identity statements are accurate.

Botanical identity statements shall include but are not limited to:

a) The scientific name, genus, species (if applicable and relevant), subspecies/variety (if applicable and relevant), and author (if necessary for clarity).

b) The local ethnic name and common name (where available).

c) The variety or cultivar or hybrid name, ecotype, chemotype, or phenotype (if applicable and relevant).

d) In the case of materials represented as belonging to a landrace grown or collected in a specific region, the locally named line, including the source of the original seeds, plants, or propagation materials (if known).

e) For cannabinoid herbal materials, at minimum, the specific plant part(s), whether the material is fresh or dried, and physical form (e.g. whole, ground, milled, etc.).

f) For cannabinoid substances, at minimum, the specific type of concentrate or extract, whether the substance is "live" or not, and consistency (e.g. dry/solid, soft/semi-solid, liquid, etc.).

g) For cannabinoid products, at minimum, the botanical identity statement of the cannabinoid herbal material(s) and/or substance(s) used to produce each cannabinoid product.

h) Any other information relevant to declaring the identity of the botanical material, substance, or product.

4.3. Validation and Verification of Botanical Identity

Licensed operations producing cannabinoid herbal materials, cannabinoid substances, or cannabinoid products intended to be dietary supplements shall have documented procedures and practices in place to validate and verify the botanical identity of each batch of cannabinoid material and product received and each batch of cannabinoid product produced.

Botanical identity validation and verification procedures shall ensure, at minimum:

a) Methods and personnel responsible for validating and verifying botanical identity are defined and documented.

b) ONLY authorized and qualified personnel are responsible for validating and verifying botanical identity.

c) When morphological characteristics are used as a method of validating and verifying botanical identity:

    1. Morphological characteristics shall be documented with detailed descriptions of the organoleptic, macroscopic, and microscopic characteristics observed, along with drawings, photographs, and/or photomicrographic evidence.

    2. Where potential adulterating species are known (e.g. outdoor cultivation operations), the presence or absence of features characteristic of the adulterant are documented.

    NOTE: Morphological characteristics on their own are insufficient to validate and verify botanical identity of cannabinoid substances and products and MUST be combined with chemical analysis or DNA analysis to be deemed sufficient.

d) When chemical characteristics or DNA or spectrometry are used as a method of validating and verifying botanical identity:

1. Chemical characteristics, DNA fingerprints, and spectrums shall be documented with detailed descriptions of the characteristics observed (presence or absence of peak or bands or spectrum, relative intensities or ratio of peaks or spectrum, DNA markers, reference spectrum, etc.), along with chromatographs, DNA barcodes or fingerprints, and/or spectrographic evidence.

2. Where potential adulterating species are known (e.g. outdoor cultivation operations), the presence or absence of features characteristic of the adulterant are documented.

NOTE: Due to the infancy of spectrographic analysis of cannabinoid herbal materials and cannabinoid substances and lack of reference spectrum, spectrometry shall ONLY be used in combination with chemical analysis or DNA analysis, and shall NOT be deemed sufficient to validate and verify botanical identity of cannabinoid herbal materials or cannabinoid substances on its own.

e) When voucher samples or retention (reserve) samples of cannabinoid herbal materials and cannabinoid substances (e.g. viable seeds, dried harvested materials, botanical extracts, etc.) are used as a method of validating and verifying botanical identity:

1. Where voucher samples are used, they follow Voucher Sample requirements.

2. Where retention (reserve) samples are used, they follow Retention (Reserve) Sample requirements.

3. Where samples of viable seed are kept as evidence of botanical identity, the samples MUST come from the actual batch of seed used for planting.

4. Where samples of cannabinoid herbal materials used in production and processing are kept as evidence of botanical identity, the samples MUST come from the actual batch of cannabinoid herbal material prior to any processing.

5. Where samples of cannabinoid substances used in production and processing are kept as evidence of botanical identity, the samples MUST come from the actual batch of cannabinoid substance and prepared in their final form, prior to any further processing.

4.4. Confirmation and Maintenance of Botanical Identity

Licensed operations producing cannabinoid materials and cannabinoid products intended to be dietary supplements shall have documented procedures and practices for ensuring the botanical identity and safety and quality requirements of cannabinoid materials and cannabinoid products are confirmed and maintained throughout shipping and receiving, production and processing, storage and handling, and distribution.

Part 3: Appendices

3.1. Applicable Cannabinoid Materials and Products

The CSQ Dietary Supplement Addendum covers, but is not limited to, the following cannabinoid materials and products intended to be dietary supplements:

- Live Cannabis Products
- Cannabinoid Herbal Materials and Products
- Cannabinoid Pre-Roll Products
- Cannabinoid Substance Products
- Cannabinoid Vape Products
- Miscellaneous Inhalable Cannabinoid Products
- Ingestible Cannabinoid Products
- Topical-Use Cannabinoid Products
- Animal/Pet Cannabinoid Products

3.2. References

The CSQ Dietary Supplement Addendum has been developed based on the following regulations, standards, and guidance documents:

- Regulations:
    - United States, Code of Federal Regulations, Chapter 21, Part 111 – Good Manufacturing Practices for Dietary Supplements
    - United States, Code of Federal Regulations, Chapter 21, Part 120 – Hazard Analysis and Critical Control Points
- Guidance Documents:
    - American Herbal Products Association (AHPA), Good Agricultural and Collection Practices and Good Manufacturing Practices for Botanical Materials, May 2023 (Revised)

3.3. Terminology

Hemp, n—refers to any *Cannabis* sativa plant or derived product meeting regulatory specifications of an authority having jurisdiction to be classified as hemp.

Marijuana, n—refers to any *Cannabis* sativa plant or derived product meeting regulatory specification of an authority having jurisdiction to be classified as marijuana.

Cannabis, n—refers to any *Cannabis* sativa plant or derived product regardless of regulatory classification.

Cannabinoid-Containing Dietary Supplement(s), n—refers to cannabinoid-containing herbal materials, pre-rolls, and substances, and inhalable, ingestible, and topical-use consumer products containing cannabinoids specifically marketed, labeled, and sold as a dietary supplement, regardless of regulatory classification.

Cannabinoid-Containing Herbal Material(s), n—refers to the flowering tops (i.e. the buds/flowers) of any *Cannabis* sativa plant, regardless of regulatory classification.

Cannabinoid-Containing Pre-roll(s), n—in reference to cannabinoid-containing herbal products intended to be combusted and inhaled, means a cigarette-like , regardless of regulatory classification.

Cannabinoid-Containing Substance(s), n—refers to the resins and glandular trichomes of any *Cannabis* sativa plant, preparations therefrom, and extracted, refined, converted, or manufactured cannabinoids, regardless of regulatory classification.

Cannabinoid-Containing Product(s), n—refers to cannabinoid-containing herbal materials, pre-rolls, and substances, and inhalable, ingestible, and topical-use consumer products containing cannabinoids, regardless of regulatory classification.

Inhalable Cannabinoid-Containing Product(s), n—refers to cannabinoid-containing products specifically intended for inhalation through combustion or vaporization.

> Discussion: Inhalable cannabinoid-containing products includes cannabinoid-containing herbal materials, pre-rolls, and substances along with formulated cannabinoid-containing substances specifically intended for inhalation through combustion or vaporization.

Ingestible Cannabinoid-Containing Product(s), n—refers to both liquid and solid cannabinoid-containing products specifically intended to be ingested.

Topical-Use Cannabinoid-Containing Product(s), n—refers to cannabinoid-containing products specifically intended for dermal and/or mucosal absorption.

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