U.S. Hemp Authority™
Certification Program

Guidance Procedures for Growers & Processors

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Table of Contents

1 GROWER................................................................................................................................... 2
  1.1 General Terms & Definitions............................................................................................... 2
  1.2 Registration / Application / Notification........................................................................... 4
    1.2.1 Registration / Application Guidance........................................................................... 4
    1.2.2 Notification of Changes to the Licensor by the Licensee........................................... 4
  1.3 Personnel Guidance........................................................................................................... 5
    1.3.1 Sanitation Measures for Personnel........................................................................... 5
    1.3.2 Personnel and Employee Safety Measures............................................................ 5
  1.4 Sampling and Handling Hemp for THC & CBD Analysis.................................................. 6
    1.4.1 Definitions ................................................................................................................ 6
    1.4.2 Sampling Timeline and Grower Responsibilities ....................................................... 7
    1.4.3 Pre-Harvest Sampling Procedure ............................................................................ 7
    1.4.4 Handling Procedures of Pre-Harvest Samples........................................................... 7
    1.4.5 Post-Harvest Sampling Procedures for Floral Material ........................................... 7
    1.4.6 Handling Procedures of Post-Harvest Samples......................................................... 8
  1.5 Contaminant Testing and Hemp Cannabinoid Quantification:......................................... 9
    1.5.1 Potency / Cannabinoid Quantification....................................................................... 9
    1.5.2 Purity & Contaminants.............................................................................................. 9
  1.6 Storage and Distribution.................................................................................................... 12
  1.7 Record Retention............................................................................................................... 13

2 PROCESSOR ............................................................................................................................. 15
  2.1 General Terms & Definitions............................................................................................ 15
  2.2 Registration / Application / Notification.......................................................................... 17
    2.2.1 Registration / Application Guidance........................................................................ 17
    2.2.2 Notification of Changes to the Licensor by the Licensee.......................................... 17
  2.3 Personnel Guidance......................................................................................................... 18
  2.4 Employee Training ......................................................................................................... 19
  2.5 Physical Plant and Grounds ............................................................................................ 21
  2.6 Quality Management Systems......................................................................................... 23
    2.6.1 Specifications Must Be Established for:................................................................... 23
    2.6.2 Guidance for Quality Management Systems Personnel....................................... 24
    2.6.3 Guidance Requirements for Hemp Laboratory Operations.................................... 24
  2.7 Supplier Qualification & Specifications.......................................................................... 26
2.8 Sampling and Handling Hemp for THC & CBD .............................................................. 27
  2.8.1 Definitions ............................................................................................................. 27
  2.8.2 Sampling Timeline and Grower Responsibilities ................................................ 28
  2.8.3 Pre-Harvest Sampling Procedure ..................................................................... 28
  2.8.4 Handling Procedures of Pre-Harvest Samples .................................................. 28
  2.8.5 Post-Harvest Sampling Procedures for Floral Material .................................... 28
  2.8.6 Handling Procedures of Post-Harvest Samples ................................................ 29

2.9 Testing and Hemp Cannabinoid Quantification: ...................................................... 30
  2.9.1 Potency / Cannabinoid Quantification ................................................................. 30
  2.9.2 Purity & Contaminants ....................................................................................... 30

2.10 Equipment and utensils .......................................................................................... 34

2.11 Production and Process Control .......................................................................... 35

2.12 Production and Process Control Systems Master Manufacturing Record ............ 36

2.13 Packaging and Labeling Hemp ............................................................................. 37
  2.13.1 Labeling Practices ............................................................................................. 37
  2.13.2 Guidance for Packaging and Labeling Operations ......................................... 37
  2.13.3 Quality Control Procedures Shall Include: ....................................................... 38

2.14 Storage and Distribution ....................................................................................... 39

2.15 Quality Control Operations Related to Product Complaints, Adverse Events, and
    Recalls ....................................................................................................................... 40

2.16 Import / Export ...................................................................................................... 41
  2.16.1 Import ................................................................................................................. 41
  2.16.2 Export ............................................................................................................... 41

2.17 Record Retention ................................................................................................... 43
1 GROWER

1.1 GENERAL TERMS & DEFINITIONS

The following Definitions and Interpretations apply to such terms when used in this U.S. Hemp Authority™ Certification Program.

**Adulteration** refers to a food that may be considered adulterated if it contains "any poisonous or deleterious substance which may render it injurious to health.....or if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is."

**Batch** means a specific quantity of hemp that is uniform, that is intended to meet specifications for identity, purity, strength, and composition, and that is produced during a specified period of time according to a single manufacturing record.

**Batch number, or lot number** means any distinctive group of letters, or numbers, or any combination of them, from which the complete history of the processing, packaging, labeling, and/or storage of a batch or lot of hemp product can be determined.

**Biomass** means the amount of living matter in a given habitat, expressed either as the weight of organisms per unit area or as the volume of organisms per unit volume of habitat.

**Component** means any substance intended for use in the manufacture of hemp, including those that may not appear in the finished batch of the hemp.

**Growth medium** means the solid, liquid or semi-solid substance used to support the growth of the plant.

**Hemp** means Cannabis plant varieties and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

**Industrial hemp** means Hemp.

**Ingredient** means any substance that is used in the manufacture of hemp and that is intended to be present in the finished batch of the hemp product.

**In-process material** means any material that is compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any way for use in the manufacture of the hemp product.

**Lot** means a batch, or a specific identified portion of a batch, or, in the case of a hemp product produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is uniform and that is intended to meet specifications for identity, purity, strength, and composition.

**Microorganisms** means yeasts, molds, bacteria, viruses, toxins, and other similar microscopic organisms which may or may not have a health or sanitary concern.
Pest means any objectionable insect or other animal including but not limited to birds, rodents, flies, mites, and larvae.

Physical plant or facility means all or any part of a building or facility used for or in connection with manufacturing, processing, packaging, labeling, or storage of hemp products or ingredients.

Processor means making a transformative change to the hemp plant or product following harvest.

Product complaint means any communication that contains any allegation, written, electronic, or oral, expressing concern, which may or may not have been related to the quality of a hemp product.

Quality means that the hemp product meets the established specifications for identity, purity, strength, and composition, and limits on contaminants, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration.

Quality Management Systems means a planned and systematic operation or procedure for ensuring the quality of a hemp product.

Quality Management Systems personnel means any person, persons, or group, within or outside the organization, designated to be responsible for quality control operations.

Representative sample means a sample with an adequate number of units that are intended to ensure that the sample accurately portrays the material being sampled.

Reserve sample means a representative sample of product that is held for a designated period of time.

Sanitize means to adequately treat cleaned equipment, containers, utensils, etc., by a process that is effective in destroying microorganisms of public health concern.
1.2 REGISTRATION / APPLICATION / NOTIFICATION

Prior to the hemp grower planting any seed, a license or agreement with the state must be obtained. The following information is typical of what is required to make the application before a license will be issued: (Each state may have different regulations – refer to application)

1.2.1 Registration / Application Guidance

- Name of the person or corporation to whom the license or authorization is to be issued
- Address of the farm or place including county and township or legal description
- The number of acres
- Global Positioning System coordinates
- Intended purpose of hemp, e.g., foods, dietary supplements, fiber production, etc.
- In the case of a plant breeder, the variety of hemp that may be cultivated; and
  - Any conditions that are necessary to minimize security, public health or safety hazards related to the licensed or authorized activities
  - Specify if the hemp is for food or non-food purposes

1.2.2 Notification of Changes to the Licensor by the Licensee

Every licensee shall notify the state of any changes to the information provided on the application, within 15 days after the change (unless otherwise required by the state), including:

- Corporate name or ownership, or officers, and the replacement of an officer, or director
- Any change to the address of the licensee
- The replacement of an individual referred to as a licensee
- Any change in the mailing address of the licensee
- Any change in the ownership of the land used to cultivate hemp
- Any change to the approved cultivar being sown or, in the case of a plant breeder, to the variety of hemp being sown, including any genetic modification
1.3 **PERSONNEL GUIDANCE**

Qualified employees who grow, manufacture, package, or label industrial hemp shall be qualified to do so, and those responsible for quality control or performing any quality control operations must have the education, training, or experience to perform the assigned functions.

Supervisors shall be qualified by education, training, or experience to supervise.

1.3.1 **Sanitation Measures for Personnel**

Contamination prevention and hygienic measures shall be taken to exclude from any operations any person who might be a source of microbial contamination.

Such measures shall include the following:

- Exclude personnel from working in any operations who may have an illness, infection, open lesion, or any other abnormal source of contamination
- Instructing employees to notify their supervisor if there is a possibility that they have a health condition described above
- Wearing outer garments in a manner that protects against the contamination
- Maintaining adequate personal cleanliness
- Washing hands thoroughly, and sanitizing if necessary, in a hand-washing facility
- Removing or covering all unsecured jewelry and other objects that might fall into components, hemp, equipment, or packaging
- Using gloves when appropriate
- Wearing, where appropriate, hair nets, caps, beard covers, shoes, PPE, etc.

1.3.2 **Personnel and Employee Safety Measures**

Personnel and employee safety measures shall include the following:

- Appropriate and adequate first aid equipment
- Adequate bathrooms and changing rooms
- Appropriate OSHA warnings, labels, and training
- Appropriate training and personal protective equipment for pesticide application
1.4 SAMPLING AND HANDLING HEMP FOR THC & CBD\textsuperscript{1} ANALYSIS

1.4.1 Definitions

delta-9-THC means delta-9-tetrahydrocannabinol concentration.

Authority having jurisdiction usually means the state, but it could be FDA,\textsuperscript{2} USDA,\textsuperscript{3} county or city.

Certified seed means seed for which a certificate or any other instrument has been issued by an agency authorized under the laws of a state, territory, or province to certify seed and which has standards and procedures approved by the United States Secretary of Agriculture to ensure the genetic purity and identity of the seed certified.

Plot means a contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of hemp throughout the area.

ppm means parts per million.

ppb means parts per billion.

Post-harvest sample means a sample taken from the harvested hemp material from a particular plot’s harvest. The entire plot’s harvest must be in the same form (e.g., intact-plant, flowers, ground materials, etc.), homogenous, and not mixed with non-hemp materials or hemp materials from another plot.

Pre-harvest sample means a composite, representative portion from plants in a hemp plot collected in accordance with the procedures as defined by the state providing authority.

Processing means converting an agricultural commodity into a marketable form.

Prohibited variety means a variety or strain of Cannabis excluded from the state providing authority.

Sample means a sufficient amount of material that is representative of the population from which it is taken. A sample may be a particular plant part, including inflorescence (flower), leaf, stalk or seed, or it may be a processed product (oil, extract, powder, etc.). Unprocessed hemp samples must be dried to a sufficiently low moisture content so as not to harbor growth of microorganisms.

Seed source means the origin of the seed or propagules as determined by the state providing authority.

\textsuperscript{1} Cannabidiol.
\textsuperscript{2} U.S. Food & Drug Administration.
\textsuperscript{3} U.S. Department of Agriculture.
1.4.2 Sampling Timeline and Grower Responsibilities

a. The grower shall refer to the jurisdiction having authority to determine a timeline.
b. During the sampling, the grower or an authorized representative shall be present at the growing site.
c. Floral materials harvested for phytocannabinoid extraction shall not be moved beyond the processor, nor commingled, nor extracted, until test results are complete.

1.4.3 Pre-Harvest Sampling Procedure

a. Adequate personal protective equipment shall be used.
b. Proper equipment shall be used to prevent cross contamination.
c. The material selected for pre-harvest sampling will be determined by the grower. Cuttings will be collected to make one representative sample.
d. Refer to the authority having jurisdiction to determine adequate number of samples and proper locations. In the absence of jurisdictional requirements, the following guidance is given.
   i. Clip the top 12 inches of hemp plant’s primary stem, including female floral material.
   ii. Take cuttings from at least five (5) hemp plants within the plot.
   iii. Place the complete sample in a paper bag.
   iv. Seal the bag by folding over the top once and staple the bag shut.
   v. A separate sample must be taken from each non-contiguous plot of a given variety.
   vi. A separate sample must be taken for each variety.
   vii. Samples shall be secured in a paper bag (to allow for air-drying during transport).
   viii. Label the sample container with a sample ID.

1.4.4 Handling Procedures of Pre-Harvest Samples

a. Samples will be taken for drying and storage.
b. Samples should be arranged in a single layer for drying.
c. Drying oven will be used when possible.
d. Samples in the oven will be left in the labeled sample bag.
e. If selected for testing, the entire sample will be sent to a testing lab for analysis.

1.4.5 Post-Harvest Sampling Procedures for Floral Material

a. Refer to the authority having jurisdiction to determine adequate number of samples and proper locations. In the absence of jurisdictional requirements, the following guidance is given.
b. Adequate personal protective equipment shall be used.
c. Proper equipment shall be used to prevent cross contamination.
d. The plot selected for sampling shall be designated by the pre-harvest sample results. The material selected for post-harvest sampling from this plot will be determined by the grower. All post-harvest samples of floral material shall be taken from the designated harvested plot materials in the form (intact-plant, flowers, ground materials, etc.) in which the material will be sent to the processor.
e. Grower must inventory the entire harvest to determine the form in which it exists and follow the protocol as appropriate in parts (a), (b), or (c) below.
   i. If, upon inventory, the grower determines that the entire harvest is not in a homogenous form (intact-plant, flowers, ground materials, etc.), it must be
determined to take additional samples or other course of action or take the pre-harvest results.

ii. For intact-plant post-harvest samples:
1. Ensure that the entire harvest is accounted for and in the same form (i.e., intact-plants).
2. Clip the top 12 inches of hemp plant, primary stem, including female floral material.
3. Take cuttings from at least five (5) non-adjacent hemp plants within the harvest’s storage/drying area.
4. Place the complete sample in a paper bag.
5. Seal the paper bag by folding over top once and stapling to keep closed.
6. Complete sampling procedures in parts (d) and (e) above.

iii. For ground plant or ground floral material post-harvest samples:
1. Ensure that the entire harvest is accounted for and in the same form (i.e., all harvested material whether whole plant or floral material only must be ground with no intact plants or whole flowers remaining from that harvest).
2. Sample material from bag or container.
3. Sample from a minimum of four (4) locations within the containers from a given harvest.
4. Place the complete sample in a plastic sample container.
5. Seal the plastic sample container.
6. Complete sampling procedures in parts (d) and (e) above.

iv. For post-harvest samples in other forms (e.g., trimmed floral material, or floral material and stems, etc.):
1. Ensure that the entire harvest is accounted for and in the same form (i.e., all harvested material must be uniform).
2. Randomly collect at least one cup of material by volume.
3. Place the complete sample in a paper bag or plastic container and seal the container, as appropriate.
4. Complete sampling procedures in parts (d) and (e) above.

v. A separate sample must be taken for each plot designated for post-harvest sampling.

vi. Samples shall be labeled and prepared for transport to the lab.

vii. Label the sample container with a sample ID.

1.4.6 Handling Procedures of Post-Harvest Samples

a. The entire sample will be sent to the testing lab for analysis.
b. Hemp crops generated from certified seed will incur pre-harvest testing of at least five percent (5%) of growing plots per variety, per seed source.
c. Hemp crops from planting materials other than certified seed will incur pre-harvest testing of at least fifty percent (50%) of growing plots per variety, per seed source.
d. 100% of post-harvest samples will be tested.
1.5 CONTAMINANT TESTING AND HEMP CANNABINOID QUANTIFICATION:

1.5.1 Potency / Cannabinoid Quantification

To ensure that methods measuring cannabinoids are fit for purpose, laboratories should adopt the attached SMPR 2017.002 approved by Cannabis stakeholders with AOAC except for the following revisions:

a. List only four compounds: THC, THCA, CBD, and CBDA as the main analytes of interest, with the other 10 listed in the SMPR optional.

b. List all target plant parts of hemp (flower, leaf, stalk, seed) and oils/extracts.

Cannabinoid potency methods must be able to determine the concentration of target cannabinoids to effectively distinguish Cannabis as either legal hemp or marijuana. Specifically, methods must be accurate and precise at concentrations that bracket 0.3% THC.

1.5.2 Purity & Contaminants

Hemp products intended for human consumption or topical use may be subject to FDA and state regulations regarding harmful substances and contaminants.

Guidance for contaminants (heavy metals, microorganisms, pesticides and residual solvents) has been published in the American Herbal Pharmacopoeia (AHP) Cannabis monograph and the American Herbal Products Association (AHPA) Guidance Policies.

Limits for the following contaminants are listed in the following references:

- Heavy metals: AHP Cannabis Monograph/AHPA Guidance Document*
- Microbiology: AHP Cannabis Monograph**/AHPA Guidance Document
- Pesticides: AHP Cannabis Monograph/FDA PAM/AHPA Guidance Document
- Solvents: AHP Cannabis Monograph/USP <467>/AHPA Guidance Document

Note: * AHPA guidance does not include the stricter limits for lead consumption required in the state of California under Proposition 65

** Microbiology limits are based on products consumed orally.

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4 AOCA International (Association of Analytical Communities); SMPR is standard method performance requirements.
AOAC SMPR® 2017.002

Standard Method Performance Requirements (SMPRs) for Quantitation of Cannabinoids in Dried Plant Materials

Intended Use: Consensus-Based Reference Method

1 Purpose

AOAC SMPRs describe the minimum recommended performance characteristics to be used during the evaluation of a method. The evaluation may be an on-site verification, a single-laboratory validation, or a multi-site collaborative study. SMPRs are written and adopted by AOAC stakeholder panels composed of representatives from the industry, regulatory organizations, contract laboratories, test kit manufacturers, and academic institutions. AOAC SMPRs are used by AOAC expert review panels in their evaluation of validation study data for method being considered for Performance Tested Methods® or AOAC Official Methods of Analysis®, and can be used as acceptance criteria for verification at user laboratories.

2 Applicability

The method will be able to identify and quantify individual cannabinoids (as listed in Tables 1 and 2) in dried plant materials.

3 Analytical Technique

Any analytical technique(s) that measures the analytes of interest and meets the following method performance requirements is/are acceptable.

4 Definitions

Dried plant materials.—Dried whole or milled flower plant material from *Cannabis sativa* and its hybrids.

Limit of quantitation (LOQ).—The minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

Quantitative method.—Method of analysis which response is the amount of the analyte measured either directly (enumeration in a mass or a volume), or indirectly (color, absorbance, impedance, etc.) in a certain amount of sample.

Repeatability.—Variation arising when all efforts are made to keep conditions constant by using the same instrument and operator repeating during a short time period. Expressed as the repeatability standard deviation (SD) or % repeatability relative standard deviation (%RSD).

Reproducibility.—The standard deviation or relative standard deviation calculated from among-laboratory data. Expressed as the reproducibility standard deviation (SDr) or % reproducibility relative standard deviation (%RSDr).

Recovery.—The fraction or percentage of spiked analyte that is recovered when the test sample is analyzed using the entire method.

5 Method Performance Requirements

See Tables 3 and 4.

<table>
<thead>
<tr>
<th>Table 1. Required cannabinoids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common name</td>
</tr>
<tr>
<td>Cannabis</td>
</tr>
<tr>
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<tr>
<td></td>
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<tr>
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<td></td>
</tr>
<tr>
<td>CBN</td>
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<td></td>
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<tr>
<td>THC</td>
</tr>
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<td></td>
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<tr>
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<tr>
<td>THCA</td>
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<td></td>
</tr>
</tbody>
</table>

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### Table 2. Additional, desirable cannabinoids

<table>
<thead>
<tr>
<th>Name</th>
<th>Abbreviation</th>
<th>IUPAC name</th>
<th>CAS No.</th>
<th>Molecular structure</th>
<th>Reference material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannabichromene</td>
<td>CBC</td>
<td>2-Methyl-2-(4-methylpent-3-enyl)-7-pentyl-5-chromenol</td>
<td>20675-51-8</td>
<td><img src="image" alt="Cannabichromene" /></td>
<td>Certifant Sigma Aldrich</td>
</tr>
<tr>
<td>Cannabichromenic acid</td>
<td>CBCA</td>
<td>5-Hydroxy-2-methyl-2-(4-methyl-3-penten-1-yl)-7-pentyl-2H-chromene-6-carboxylic acid</td>
<td>20408-52-0</td>
<td><img src="image" alt="Cannabichromenic acid" /></td>
<td>No reference material</td>
</tr>
<tr>
<td>Cannabidivarinic acid</td>
<td>CBDVA</td>
<td>2,4-Dihydroxy-3-[[1R,6R]-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-6-propylbenzoic acid</td>
<td>31932-13-5</td>
<td><img src="image" alt="Cannabidivarinic acid" /></td>
<td>Certifant</td>
</tr>
<tr>
<td>Cannabigerol</td>
<td>CBG</td>
<td>2-[[2(E)]-3,7-dimethylocta-2,6-dienyl]-5-pentyl-benzene-1,3-diol</td>
<td>25654-31-3</td>
<td><img src="image" alt="Cannabigerol" /></td>
<td>Certifant Lippomed AG</td>
</tr>
<tr>
<td>Cannabigerolic acid</td>
<td>CBGA</td>
<td>3-[[2(E)]-3,7-dimethylocta-2,6-dienyl]-2,4-dihydroxy-6-pentylbenzoic acid</td>
<td>25555-57-1</td>
<td><img src="image" alt="Cannabigerolic acid" /></td>
<td>Certifant Echo Pharmaceuticals</td>
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<tr>
<td>Cannabidivarin</td>
<td>CBDV</td>
<td>2-[[1S,6S]-3-methyl-6-(prop-1-en-2-yl)cyclohex-2-enyl]-5-propylbenzene-1,3-diol</td>
<td>24274-48-4</td>
<td><img src="image" alt="Cannabidivarin" /></td>
<td>Certifant SPEX Certprep</td>
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<tr>
<td>Δ⁹-Tetrahydro-cannabinol</td>
<td>Δ⁹THC</td>
<td>6,6,9-Trimethyl-3-pentyl-6a,7,10a-tetrahydrobenzo[c] chromen-1-ol</td>
<td>5957-75-5</td>
<td><img src="image" alt="Δ⁹-Tetrahydro-cannabinol" /></td>
<td>Certifant SPEX Certprep</td>
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<tr>
<td>Tetrahydro-cannabinoin</td>
<td>THCV</td>
<td>6,6,9-Trimethyl-3-propyl-6a,7,8,10a-tetrahydro-6H-benzo[c] chromen-1-ol</td>
<td>28172-17-0</td>
<td><img src="image" alt="Tetrahydro-cannabinoin" /></td>
<td>Certifant USP</td>
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<tr>
<td>Tetrahydrocannabinin acid</td>
<td>THCVA</td>
<td>28172-17-0</td>
<td></td>
<td></td>
<td>No reference material</td>
</tr>
</tbody>
</table>
1.6 STORAGE AND DISTRIBUTION

Storage of hemp shall be under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and composition of the components and hemp are not affected.

Storage of hemp and hemp products shall be properly labeled at all times to prevent contaminations and unintended comingling.

Storage of hemp and hemp products shall be properly labeled to indicate a hold or available for release.

Storage of material in-process shall be identified under conditions that prevent mix-ups, contamination, and deterioration.

Storage of material in-process shall be held under appropriate conditions of temperature, humidity, and light.

Storage of packaging and labels shall be under conditions adequate to prevent the packaging and labels from being adversely affected.

Distribution of hemp products shall be under conditions that will protect the products against contamination and deterioration.
1.7 RECORD RETENTION

Growers/licensee shall keep the records, electronically or hard copy, that contain the following information for at least five (5) years after obtained:

- Source of the hemp seed (imported or purchased or grown), name and address and the country of origin
- Name and (licensee name) license number of the person from whom the seed was purchased
- Form in which the hemp is imported, purchased or sold
- Variety of hemp
- Germination certificate
- Site history, including water quality
- Statement of appropriate growth mediums
- Images of product and labels if available
- Curing or drying records
- Processing records
- Quantity of each form of hemp imported, purchased, or sold
- Date of planting and harvest
- Date of each pesticide, herbicide, fungicide and fertilizer application, if any
- Destination of the hemp that is sold, name and address of the purchaser and the country to which it is exported,
- Date that each shipment of hemp is sent or received
  - Name of the carrier
  - Results of any tests
  - Quantity shipped
- Name and (licensee name) license number of the person to whom the seed was sold.
- Results of all tests
PROCESSOR
2 PROCESSOR

2.1 GENERAL TERMS & DEFINITIONS

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Industrial Hemp means Hemp.

Ingredient means any substance that is used in the manufacture of hemp and that is intended to be present in the finished batch of the hemp product.

In-process material means any material that is compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any way for use in the manufacture of the hemp product.

Lot means a batch, or a specific identified portion of a batch, or, in the case of a hemp product produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is uniform and that is intended to meet specifications for identity, purity, strength, and composition.

Microorganisms means yeasts, molds, bacteria, viruses, toxins, and other similar microscopic organisms which may or may not have a health or sanitary concern.
**Pest** means any objectionable insect or other animal including but not limited to birds, rodents, flies, mites, and larvae.

**Physical plant** or facility means all or any part of a building or facility used for or in connection with manufacturing, processing, packaging, labeling, or storage of hemp products or ingredients.

**Processor** means making a transformative change to the hemp plant or product following harvest.

**Product complaint** means any communication that contains any allegation, written, electronic, or oral, expressing concern, which may or may not have been related to the quality of a hemp product.

**Quality** means that the hemp product meets the established specifications for identity, purity, strength, and composition, and limits on contaminants, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration.

**Quality Management Systems** means a planned and systematic operation or procedure for ensuring the quality of a hemp product.

**Quality Management Systems personnel** means any person, persons, or group, within or outside the organization, designated to be responsible for quality control operations.

**Representative sample** means a sample with an adequate number of units that are intended to ensure that the sample accurately portrays the material being sampled.

**Reserve sample** means a representative sample of product that is held for a designated period of time.

**Sanitize** means to adequately treat cleaned equipment, containers, utensils, etc. by a process that is effective in destroying microorganisms of public health concern.
2.2 **REGISTRATION / APPLICATION / NOTIFICATION**

Prior to the hemp processor processing any seed or hemp product, a license or agreement with the state must be obtained. The following information is typical of that required to make the application before a license will be issued: (Each state may have different regulations – refer to application)

### 2.2.1 Registration / Application Guidance

- Applicant’s contact information, including a copy of current driver’s license for applicant and each proposed signing authority
- Full names of each individual who will be primarily responsible for the processing or handling of the applicant’s hemp material
- Research plan, including the estimated quantity of hemp material to be processed annually
- Address of each location and GPS coordinates of each building or site where hemp will be stored, processed or handled
- Map(s) depicting each site where hemp will be processed, or stored, and designating entrances and specific points where GPS coordinates were taken
- Seed/propagule acquisition plan, including a list of proposed affiliated growers
- Material acquisition plan, including a list of proposed affiliated growers
- Marketing plan, including the type of products to be marketed and to whom
- Consent to all statements in the Acknowledgments Section in the Processor/Handler Application
- Quality Management Systems

### 2.2.2 Notification of Changes to the Licensor by the Licensee

Every licensee shall notify the state of any changes to the information provided on the application, within 15 days after the change, including:

- Corporate name or ownership or officers and the replacement of an officer, or director
- Any change to the address to the licensee
- The replacement of an individual referred to as a licensee
- Any change in the mailing address of the licensee
- Any change in the ownership of the land used to cultivate hemp
- Any change to the approved cultivar being sown or, in the case of a plant breeder to the variety of hemp being sown
2.3 PERSONNEL GUIDANCE

Qualified employees who manufacture, package, or label hemp shall be qualified to do so and those responsible for quality control or performing any quality control operations, must have the education, training, or experience to perform the assigned functions.

Supervisors shall be qualified by education, training, or experience to supervise.

Contamination prevention and hygienic measures shall be taken to exclude from any operations any person who might be a source of microbial contamination.

Such measures could include the following:

- Excluding personnel from working in any operations that may have, an illness, infection, open lesion, or any other abnormal source of contamination
- Instructing employees to notify their supervisor if there is a possibility that they have a health condition described above
- Wearing outer garments in a manner that protects against the contamination
- Maintaining adequate personal cleanliness
- Washing hands thoroughly, and sanitizing if necessary, in a hand-washing facility
- Removing or covering all unsecured jewelry and other objects that might fall into components, hemp, equipment, or packaging
- Using gloves when appropriate
- Wearing, where appropriate, hair nets, caps, beard covers, shoes, PPE, etc.

Personnel and employee safety measures shall include the following:

- Appropriate and adequate first aid equipment
- Adequate bathrooms and changing rooms
- Appropriate OSHA warnings, labels, and training
- Appropriate training and personal protective equipment for pesticide application
2.4 **EMPLOYEE TRAINING**

A. Quality Assurance (QA) or Training Manager shall ensure all personnel receive adequate training to complete assigned responsibilities safely and effectively prior to beginning the work.

B. All staff receive training upon hiring.

C. Ongoing training related to job and Good Manufacturing Practices (GMP) requirements are conducted no less frequently than a yearly basis. All personnel are trained to follow Standard Operating Procedures (SOP) relevant to the tasks assigned to them.

D. The training program ensures all staff are trained or notified on the following, as required by job or regulatory requirements:

   1. Company policies and procedures
   2. Emergency procedures
   3. Hazardous materials
   4. Hygiene and food-handling safety
   5. Industry policies and standards
   6. Labeling and packaging
   7. Product quality
   8. Product testing
   9. Regulatory inspections
  10. Recordkeeping
  11. Sanitation and cleaning procedures
  12. Security
  13. Sexual harassment
  14. Specific job training as required
  15. Violations and enforcement
  16. Worker health and safety

E. Training may be conducted internally, or by external parties, trade associations or consultants

F. Key personnel responsible for managing and supervising manufacture, quality assurance and quality control should have the managerial and professional or technical skills and experience to assume responsibility for ensuring that products consistently meet standards and specifications.

   1. Job descriptions and organizational charts are used to establish areas of responsibility and are available to personnel.
   2. The responsibilities placed on any one person should not be so extensive as to compromise the effective execution of assigned duties in relation to GMP.
   3. Personnel in responsible positions should have adequate authority to perform their duties.
   4. QA shall reinforce training effectiveness through testing comprehension, observing behaviors in the workplace, and providing timely feedback.
   5. Personnel with less than the required qualifications or experience should be provided with a training program designed to make up deficiencies.
   6. Personnel should be sufficiently fluent in spoken and written English to respond to training, accept and implement instructions exactly, and where their duties require it, fill out forms correctly.
7. General Precautions for Training: Personnel shall not be permitted to sign or initial a document unless they have been trained in the task associated with the signature and in the significance of the signature.

8. Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled, should be given specific training.

9. Visitors or untrained personnel should not be permitted into production, storage or Quality Control (QC) areas without training.

10. Casual or contract personnel (including cleaners) should also receive appropriate induction training in GMP.

G. Records retention: training records shall be retained for at least two years.
2.5 **Physical Plant and Grounds**

Facilities used in the processing, packaging, labeling, or holding of hemp shall be adequate in size, construction, and design.

Facilities shall provide adequate space for the equipment and materials necessary for normal operations as well as maintenance, cleaning, and sanitizing operations and to prevent contamination.

Equipment that controls temperature and humidity as well as fans and other air-blowing equipment used shall be adequate for the size of the facility.

Aisles or working spaces between equipment and walls shall be adequate to permit all persons to perform their duties.

Adequate light shall be available in all areas as needed.

Facilities shall be maintained to protect against contamination of hemp.

Facilities shall be maintained in a state of repair sufficient to prevent hemp or products contamination.

Facility shall have adequate bathrooms and changing rooms.

Facility shall have a sanitary/cleaning plan.

Cleaning compounds, sanitizing agents, pesticides, and other toxic materials must be free from microorganisms and be safe and adequate under the conditions of use.

Pest control includes not allowing animals or pests in any area of the facilities except guard or working dogs.

Insecticides, fumigants, fungicides, herbicides, or rodenticides shall be used with care and in the intended manner.

Water supply needs to be safe and sanitary, at suitable temperatures, and under pressure as needed for appropriate use.

Plumbing in the facility shall be of an adequate size and design and be adequately installed and maintained to satisfy operational needs.

Floor drainage shall be adequate for operations and to prevent contamination of hemp products or components.

Sewage disposal shall be adequate for operational needs and bathrooms.

Hand-washing facilities shall be available and designed to ensure that an employee's hands are not a source of contamination of hemp products.

Trash disposal shall be adequate to minimize odors, the attraction of pests, or becoming a source of contamination.

Grounds shall be maintained to protect against contamination of hemp.
Ground maintenance includes:

- Properly storing equipment, removing litter and waste, and cutting weeds or grass so that it does not attract pests, harbor pests, or provide pests a place for breeding
- Maintaining roads, yards, and parking lots to prevent contamination of hemp products
- Adequately operating waste treatment and disposal
2.6 QUALITY MANAGEMENT SYSTEMS

Quality management systems (QMS) must be developed and implemented for manufacturing, packaging, labeling, and holding operations.

Quality management systems based on food safety programs such as HACCP may be used to complement or substitute for some prerequisite requirements. Personnel with sufficient expertise in food safety and preventive controls, having undergone Preventative Controls Qualified Individual (PCQI) training required under the Food Safety Modernization Act (FSMA), are required to administer food safety programs.

2.6.1 Specifications Must Be Established for:

A. Any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the hemp product.

B. For each component used in the manufacture of a hemp product
   1. Component specifications as follows:
      a. Identity specification;
      b. Specifications that are necessary to ensure purity, strength and composition of limits on those types of contamination that may adulterate or may lead to the adulteration of the finished batch of the hemp product to ensure the quality of the hemp product.

C. For the in-process production:
   1. In-process specifications for any point, step, or stage in the master manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the hemp products;
   2. Relevant and valid documentation for meeting the in-process specifications, in combination with meeting component specifications, will help ensure that the specifications are met for the identity, purity, strength, and composition of the hemp products and for limits on those types of contamination that may adulterate, or may lead to adulteration of the finished batch of the hemp product; and
   3. Quality control personnel must review and approve the documentation of the U.S. Hemp Authority™ Certification Program.

D. Specifications must be established for hemp product labels (label specifications) and for packaging that may come in contact or quality of the hemp product.

E. Each hemp product manufactured must have established product specifications for the identity, purity, strength, and composition of the finished batch of the hemp product, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of, the finished batch of the hemp product to ensure the quality of the hemp product.

F. Products received from a supplier for packaging or labeling as a hemp product (and for distribution rather than for return to the supplier), must have specifications to provide sufficient assurance that the product received is adequately identified and is consistent with your purchase order.
G. Specifications must be established for the packaging and labeling of the finished hemp products, including specifications that ensure the use of the specified packaging and the specified label.

H. Written procedures must be established for Quality Management Systems, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing.

2.6.2 Guidance for Quality Management Systems Personnel

Quality management systems personnel must ensure that the manufacturing, packaging, labeling, and holding operations ensure the quality of the hemp product and that the hemp product is packaged and labeled as specified in the master manufacturing record. Quality management personnel must perform operations that include:

1. Approving or rejecting all processes, specifications, written procedures, controls, tests, and examinations, and deviations from or modifications to them, that may affect the identity, purity, strength, or composition of a hemp product;

2. Reviewing and approving the documentation setting forth the basis for qualification of any supplier;

3. Reviewing and approving the documentation setting forth the basis as to why meeting in-process specifications, in combination with meeting component specifications, will help ensure that the identity, purity, strength, and composition are met.

2.6.3 Guidance Requirements for Hemp Laboratory Operations

Hemp laboratory operations shall establish and follow written procedures for laboratory operations, including written procedures for the tests and examinations to be conducted to determine whether specifications are met.

Adequate laboratory facilities shall be available to perform whatever testing and examinations are necessary to determine whether:

A. Components used meet specifications

B. In-process specifications are met as specified in the master manufacturing record

C. All laboratory control processes must be reviewed and approved by quality control personnel, including the following:

1. Use of criteria for establishing appropriate specifications

2. Use of sampling plans for obtaining representative samples
   a. Components, packaging, and labels
   b. In-process materials
   c. Product received for packaging or labeling
      I. Use of criteria for selecting appropriate examination and testing methods
      II. Use of criteria for selecting standard reference materials used in performing tests and examinations
      III. Use of test methods and examinations in accordance with established criteria
D. The following requirements apply to laboratory methods for testing and examination:

1. Verification of that the laboratory examination and testing methodologies are appropriate for their intended use, using ISO 17025\textsuperscript{5} requirements as guidance

2. Identify and use the appropriate scientifically valid method for each established specification for which testing or examination is required to determine whether the specification is met

3. Identify and use the appropriate reference materials that have been produced and certified under ISO 17034 requirements. Reference materials must be accompanied with a certificate of analysis that lists the certified purity of the material. Preferably, materials are certified by an independent third-party laboratory using highly precise methods such as Nuclear Magnetic Resonance (NMR)

\textsuperscript{5} International Organization for Standardization.
2.7 **Supplier Qualification & Specifications**

A. QA shall assess suppliers of starting materials (where possible by direct audit) and assign, where appropriate “approved supplier” or “certified supplier” status. Suppliers are evaluated based on level of risk.

B. Material should not be granted “approved supplier” status except in relation to materials in sealed containers bearing the manufacturers’ original label and batch, lot or equivalent number.

C. QA shall evaluate suppliers of materials, equipment, consumables and services which affect the quality of materials and their measurement. QA shall maintain records of supplier evaluations and list those approved.

D. Specifications for materials shall be reviewed and discussed with suppliers on a periodic basis. All aspects of the production and control of materials, in addition to handling, labeling, and packaging requirements, as well as complaints and rejection procedures, are reviewed and approved by both manufacturer and the supplier.

E. Suppliers are responsible for the following:
   - Meeting product specifications with valid tests and verifications for materials
   - Ensuring the integrity of product and packaging
   - Ensuring all documentation establishes traceability from raw materials to customer delivery, including orders, delivery notes, product labels, specifications and test results

F. Material specifications include, where applicable:
   - Standard product name to be used in production documents, and compendia name if applicable
   - Supplier’s product code and trade names
   - Supplier’s name and address
   - A unique reference code for the material specification and approval date
   - Tests and limits for identity, purity, physical and chemical characteristics, microbiological standards (where appropriate) and assay or potency
   - Details of, or reference to, the test methods to be used by the manufacturer
   - Approved or certified supplier(s) of the material
   - Type of packaging, storage conditions and precautions
   - Physical appearance and characteristics
   - Precautions or reference to appropriate parts of a standard procedure
   - Period during which approval will remain valid (e.g. review frequency or date)
2.8 SAMPLING AND HANDLING HEMP FOR THC & CBD

2.8.1 Definitions

delta-9-THC means delta-9-tetrahydrocannabinol concentration. Same as THC.

Authority having jurisdiction usually means the state, but it could be FDA, USDA, county or city.

Certified seed means seed for which a certificate or any other instrument has been issued, by an agency authorized under the laws of a state, territory, or province to certify seed and which has standards and procedures approved by the United States Secretary of Agriculture to ensure the genetic purity and identity of the seed certified.

Plot means a contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of hemp throughout the area.

ppm means parts per million.

ppb means parts per billion.

Post-harvest sample means a sample taken from the harvested hemp material from a particular plot’s harvest. The entire plot’s harvest must be in the same form (e.g., intact-plant, flowers, ground materials, etc.), homogenous, and not mixed with non-hemp materials or hemp materials from another plot.

Pre-harvest sample means a composite, representative portion from plants in a hemp plot collected in accordance with the procedures as defined by the state providing authority.

Processing means converting an agricultural commodity into a marketable form.

Prohibited variety means a variety or strain of Cannabis excluded from the state providing authority.

Sample means a sufficient amount of material that is representative of the population from which it is taken. A sample may be a particular plant part, including inflorescence (flower), leaf, stalk or seed, or it may be a processed product (oil, extract, powder. Samples must be dried to a sufficiently low moisture content so as not to harbor growth of microorganisms.

Seed source means the origin of the seed or propagules as determined by the state providing authority.

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6 Cannabidiol.
7 U.S. Food & Drug Administration.
8 U.S. Department of Agriculture.
2.8.2 Sampling Timeline and Grower Responsibilities

a. The grower shall refer to the jurisdiction having authority to determine a timeline.
b. During the sampling, the grower or an authorized representative shall be present at the growing site.
c. Floral materials harvested for phytocannabinoid extraction shall not be moved beyond the processor, nor commingled, nor extracted, until test results are complete.

2.8.3 Pre-Harvest Sampling Procedure

a. Adequate personal protective equipment shall be used.
b. Proper equipment shall be used to prevent cross contamination.
c. The material selected for pre-harvest sampling will be determined by the grower. Cuttings will be collected to make one representative sample.
d. Refer to the authority having jurisdiction to determine adequate number of samples and proper locations. In the absence of jurisdictional requirements, the following guidance is given.
   i. Clip the top 12 inches of hemp plant's primary stem, including female floral material.
   ii. Take cuttings from at least five (5) hemp plants within the plot.
   iii. Place the complete sample in a paper bag.
   iv. Seal the bag by folding over the top once and staple the bag shut.
   v. A separate sample must be taken from each non-contiguous plot of a given variety.
   vi. A separate sample must be taken for each variety.
   vii. Samples shall be secured in a paper bag (to allow for air-drying during transport).
   viii. Label the sample container with a sample ID.

2.8.4 Handling Procedures of Pre-Harvest Samples

a. Samples will be taken for drying and storage.
b. Samples should be arranged in a single layer for drying.
c. Drying oven will be used when possible.
d. Samples in the oven will be left in the labeled sample bag.
e. If selected for testing, the entire sample will be sent to a testing lab for analysis.

2.8.5 Post-Harvest Sampling Procedures for Floral Material

a. Refer to the authority having jurisdiction to determine adequate number of samples and proper locations. In the absence of jurisdictional requirements, the following guidance is given.
b. Adequate personal protective equipment shall be used.
c. Proper equipment shall be used to prevent cross contamination.
d. The plot selected for sampling shall be designated by the pre-harvest sample results. The material selected for post-harvest sampling from this plot will be determined by the grower. All post-harvest samples of floral material shall be taken from the designated harvested plot materials in the form (intact-plant, flowers, ground materials, etc.) in which the material will be sent to the processor.
e. Grower must inventory the entire harvest to determine the form in which it exists and follow the protocol as appropriate in part (a), (b), or (c) below.
i. If, upon inventory, the grower determines that the entire harvest is not in a homogenous form (intact-plant, flowers, ground materials, etc.), it must be determined to take additional samples or other course of action or take the pre-harvest results.

ii. For intact-plant post-harvest samples:
   1. Ensure that the entire harvest is accounted for and in the same form (i.e., intact-plants).
   2. Clip the top 12 inches of hemp plant, primary stem, including female floral material.
   3. Take cuttings from at least five (5) non-adjacent hemp plants within the harvest’s storage/drying area.
   4. Place the complete sample in a paper bag.
   5. Seal the paper bag by folding over top once and stapling to keep closed.
   6. Complete sampling procedures in parts (d) and (e) above.

iii. For ground plant or ground floral material post-harvest samples:
   1. Ensure that the entire harvest is accounted for and in the same form (i.e., all harvested material whether whole plant or floral material only must be ground with no intact plants or whole flowers remaining from that harvest).
   2. Sample material from bag or container.
   3. Sample from a minimum of four (4) locations within the containers from a given harvest.
   4. Place the complete sample in a plastic sample container.
   5. Seal the plastic sample container.
   6. Complete sampling procedures in parts (d) and (e) above.

iv. For post-harvest samples in other forms (e.g., trimmed floral material, or floral material and stems, etc.):
   1. Ensure that the entire harvest is accounted for and in the same form (i.e., all harvested material must be uniform).
   2. Randomly collect at least one cup of material by volume.
   3. Place the complete sample in a paper bag or plastic container and seal the container, as appropriate.
   4. Complete sampling procedures in parts (d) and (e) above.

v. A separate sample must be taken for each plot designated for post-harvest sampling.

vi. Samples shall be labeled and prepared for transport to the lab.

vii. Label the sample container with a sample ID.

2.8.6 Handling Procedures of Post-Harvest Samples

a. The entire sample will be sent to the testing lab for analysis.

b. Hemp crops generated from certified seed will incur pre-harvest testing of at least five percent (5%) of growing plots per variety, per seed source.

c. Hemp crops from planting materials other than certified seed will incur pre-harvest testing of at least fifty percent (50%) of growing plots per variety, per seed source.

d. 100% of post-harvest samples will be tested.
2.9 Testing and Hemp Cannabinoid Quantification:

2.9.1 Potency / Cannabinoid Quantification

To ensure that methods measuring cannabinoids are fit for purpose, laboratories should adopt the attached SMPR 2017.002 approved by Cannabis stakeholders with AOAC, except for the following revisions:

a. List only four compounds: THC, THCA, CBD, and CBDA as the main analytes of interest, with the other 10 listed in the SMPR optional.

b. List all target plant parts of hemp (flower, leaf, stalk, seed) and oils/extracts.

Cannabinoid potency methods must be able to determine the concentration of target cannabinoids to effectively distinguish Cannabis as either legal hemp or marijuana. Specifically, methods must be accurate and precise at concentrations that bracket 0.3% THC.

2.9.2 Purity & Contaminants

Hemp products intended for human consumption or topical use may be subject to FDA and state regulations regarding harmful substances and contaminants.

Guidance for contaminants (heavy metals, microorganisms, pesticides and residual solvents) has been published in the American Herbal Pharmacopoeia (AHP) Cannabis monograph and the American Herbal Products Association (AHPA) Guidance Policies.

Limits for the following contaminants are listed in the following references:

- Heavy metals: AHP Cannabis Monograph/AHPA Guidance Document*
- Microbiology: AHP Cannabis Monograph**/AHPA Guidance Document
- Pesticides: AHP Cannabis Monograph/FDA PAM/AHPA Guidance Document
- Solvents: AHP Cannabis Monograph/USP <467>/AHPA Guidance Document

Note: * AHPA guidance does not include the stricter limits for lead consumption required in the state of California under Proposition 65

** Microbiology limits are based on products consumed orally.

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9 AOCA International (Association of Analytical Communities); SMPR is standard method performance requirements.
AOAC SMPR® 2017.002

Standard Method Performance Requirements (SMPRs) for Quantitation of Cannabinoids in Dried Plant Materials

Intended Use: Consensus-Based Reference Method

1 Purpose

AOAC SMPRs describe the minimum recommended performance characteristics to be used during the evaluation of a method. The evaluation may be an on-site verification, a single-laboratory validation, or a multi-site collaborative study. SMPRs are written and adopted by AOAC stakeholder panels composed of representatives from the industry, regulatory organizations, contract laboratories, test kit manufacturers, and academic institutions. AOAC SMPRs are used by AOAC expert review panels in their evaluation of validation study data for methods being considered for Performance Tested Methods® or AOAC Official Methods of Analysis®, and can be used as acceptance criteria for verification at user laboratories.

2 Applicability

The method will be able to identify and quantify individual cannabinoids (as listed in Tables 1 and 2) in dried plant materials.

3 Analytical Technique

Any analytical technique(s) that measures the analytes of interest and meets the following method performance requirements is/are acceptable.

4 Definitions

Dried plant materials.—Dried whole or milled flower plant material from Cannabis sativa and its hybrids.

Limit of quantitation (LOQ).—The minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

Quantitative method.—Method of analysis which response is the amount of the analyte measured either directly (enumeration in a mass or a volume), or indirectly (color, absorbance, impedance, etc.) in a certain amount of sample.

Repeatability.—Variation arising when all efforts are made to keep conditions constant by using the same instrument and operator and repeating during a short time period. Expressed as the repeatability standard deviation (SD); or % repeatability relative standard deviation (%RSD).

Reproducibility.—The standard deviation or relative standard deviation calculated from among-laboratory data. Expressed as the reproducibility standard deviation (SDr); or % reproducibility relative standard deviation (%RSDr).

Recovery.—The fraction or percentage of spiked analyte that is recovered when the test sample is analyzed using the entire method.

5 Method Performance Requirements

See Tables 3 and 4.

### Table 1. Required cannabinoids

<table>
<thead>
<tr>
<th>Common name</th>
<th>Abbreviation</th>
<th>IUPAC name</th>
<th>CAS No.</th>
<th>Molecular structure</th>
<th>Reference material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannabidiol</td>
<td>CBD</td>
<td>2-[1(1R,6R)-6-isopropenyl-3-methylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol</td>
<td>13956-29-1</td>
<td><img src="image" alt="Molecule" /></td>
<td>Restek, Cerilliant, Sigma-Aldrich, Echo Pharm, Lipomed AG</td>
</tr>
<tr>
<td>Cannabidiolic acid</td>
<td>CBDA</td>
<td>2,4-Dihydroxy-3-[1(1R,6R)-3-methyl-6-prop-1-en-2-yloxyhex-2-en-1-yl]-6-pentylbenzoic acid</td>
<td>1244-58-2</td>
<td><img src="image" alt="Molecule" /></td>
<td>Cerilliant, USP, Restek, Lipomed AG, Echo Pharmaceutical</td>
</tr>
<tr>
<td>Cannabinol</td>
<td>CBN</td>
<td>6,6,9-Trimethyl-3-pentyl-benzo[c]chromen-1-ol</td>
<td>521-35-7</td>
<td><img src="image" alt="Molecule" /></td>
<td>Cerilliant, Restek</td>
</tr>
<tr>
<td>Tetrahydro-cannabinol</td>
<td>THC</td>
<td>(−)-6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromene-1-ol</td>
<td>1972-08-3</td>
<td><img src="image" alt="Molecule" /></td>
<td>Cerilliant, USP, Echo Pharmaceuticals</td>
</tr>
<tr>
<td>Tetrahydro-cannabinolic acid</td>
<td>THCA</td>
<td>(6aR,10aR)-1-hydroxy-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromene-2-carboxylic acid</td>
<td>23978-85-0</td>
<td><img src="image" alt="Molecule" /></td>
<td>Cerilliant, USP, Echo Pharmaceuticals</td>
</tr>
<tr>
<td>Name</td>
<td>Abbreviation</td>
<td>IUPAC name</td>
<td>CAS No.</td>
<td>Molecular structure</td>
<td>Reference material</td>
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<td>-------------------------------------</td>
</tr>
<tr>
<td>Cannabichromene</td>
<td>CBC</td>
<td>2-Methyl-2-(4-methylpent-3-enyl)-7-pentyl-5-chromenol</td>
<td>20675-51-8</td>
<td></td>
<td>Certilliant Sigma Addich</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Echo Pharmaceuticals</td>
</tr>
<tr>
<td>Cannabichromenic acid</td>
<td>CBCA</td>
<td>5-Hydroxy-2-methyl-2-(4-methyl-3-penten-1-yl)-7-pentyl-2H-chromene-6-carboxylic acid</td>
<td>20408-52-0</td>
<td></td>
<td>No reference material</td>
</tr>
<tr>
<td>Cannabidivarinic acid</td>
<td>CBDVA</td>
<td>2,4-Dihydroxy-3-[(1R,6R)-3-methyl-6-prop-1-en-2-y]cyclohex-2-en-1-yl]-6-propylbenzoic acid</td>
<td>31932-13-5</td>
<td></td>
<td>Certilliant</td>
</tr>
<tr>
<td>Cannabigerol</td>
<td>CBG</td>
<td>2-[(2E)-3,7-dimethylocta-2,6-dienyl]-5-pentyl-benzene-1,3-diol</td>
<td>26564-31-3</td>
<td></td>
<td>Certilliant Lipomed AG</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NIST, 1,3-Benzendiol,</td>
<td></td>
<td></td>
<td>Echo Pharmaceuticals</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2-(3,7-dimethyl-2,6-octadienyl)-5-pentyl</td>
<td>NIST, 2809-39-3</td>
<td></td>
<td>SPEX Certiprep Tocris (UK)</td>
</tr>
<tr>
<td>Cannabigerolic acid</td>
<td>CBGA</td>
<td>3-[(2E)-3,7-dimethylocta-2,6-dienyl]-2,4-dihydroxy-6-pentylbenzoic acid</td>
<td>25555-57-1</td>
<td></td>
<td>Certilliant Echo Pharmaceuticals</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SPEX Certiprep</td>
</tr>
<tr>
<td>Cannabidivarin</td>
<td>CBDV</td>
<td>2-[(1S,6S)-3-methyl-6-(1-prop-1-en-2-yl)cyclohex-2-enyl]-5-propylbenzene-1,3-diol</td>
<td>24274-48-4</td>
<td></td>
<td>Certilliant SPEX Certiprep</td>
</tr>
<tr>
<td>4-Tetrahydro-cannabinol</td>
<td>4^THC</td>
<td>6,6,9-Trimethyl-3-pentyl-6a,7,10,10a-tetrahydrobenzo[c] chromen-1-ol</td>
<td>5957-75-5</td>
<td></td>
<td>Certilliant SPEX Certiprep</td>
</tr>
<tr>
<td>Tetrahydro-cannabinvarin</td>
<td>THCV</td>
<td>6,6,9-Trimethyl-3-propyl-6a,7,8,10a-tetrahydro-8H-benzo[c] chromen-1-ol</td>
<td>28172-17-0</td>
<td></td>
<td>Certilliant USP</td>
</tr>
<tr>
<td>Tetrahydrocannabinvarin acid</td>
<td>THCVA</td>
<td></td>
<td>28172-17-0</td>
<td></td>
<td>No reference material</td>
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Table 3. Method performance requirements (part 1) for cannabinoids in Table 2

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limit of quantitation (LOQ, %)</td>
<td>≤0.1</td>
</tr>
<tr>
<td>Analytical range, %</td>
<td>0.1–ca. 50a</td>
</tr>
</tbody>
</table>

* Lower concentrations may be acceptable as applicable for cannabinoids listed in Table 2.

Table 4. Method performance requirements (part 2) for cannabinoids in Table 2

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.1–1</td>
</tr>
<tr>
<td>Recovery, %</td>
<td>95–105</td>
</tr>
<tr>
<td>RSD, %</td>
<td>≤5</td>
</tr>
<tr>
<td>RSDw, %</td>
<td>≤7</td>
</tr>
</tbody>
</table>

6 System Suitability Tests and/or Analytical Quality Control

Suitable methods will include blank check samples, and check standards at the lowest point and midrange point of the analytical range.

7 Reference Material(s)

See Tables 1 and 2 for sources of reference materials.


8 Validation Guidance

Method performance should be demonstrated with homogeneous samples. Inherent variation in the plant may preclude or limit homogeneity for the following reasons: (a) they are resinous; cannabinoids are concentrated in the resin, which can clump during grinding; (b) between-flower variation can be high; grinding multiple flowers can impact the homogeneity; (c) grinding can introduce heat, which will cause degradation of cannabidiolic acids into neutral forms, resulting in less accurate results. Grinding would be the best option for homogeneous samples, but, in some cases, there are issues with clumped resin, highly variable samples, and additional grinding would impact the results and lead to inaccurate data.


Appendix K: Guidelines for Dietary Supplements and Botanicals, Official Methods of Analysis of AOAC INTERNATIONAL (20th Ed.), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_k.pdf)

9 Maximum Time-to-Result

None.

2.10 EQUIPMENT AND UTENSILS

Equipment and multi-use utensils shall be designed, and built, to be suitable for their intended use and able to be adequately cleaned and properly maintained.

Equipment and utensils shall be designed and built so that use will not result in contaminations.

Equipment shall be installed and maintained to facilitate cleaning the equipment, utensils, and all adjacent spaces.

Equipment shall be maintained to protect hemp from contaminants.

Equipment shall have a certificate of Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ).

Freezer, refrigerator, and other cold storage equipment shall have a working thermometer.

Compressed air or other gases shall be used and be treated in such a way that the hemp or contact surface is not contaminated.

Instruments and controls used in processing, packaging or labeling or testing hemp products shall be calibrated as necessary to assure accuracy.

Automated, or electronic equipment used to manufacture, package, label, or hold hemp shall be designed to ensure that hemp product specifications are consistently met.

Equipment shall be properly calibrated according to the manufacturer’s specifications.

Automated, mechanical, and electronic equipment (including software for a computer-controlled process) shall be used and operated by trained personnel for proper use.

Utensils intended for one-time use, (e.g. paper cups, and paper towels, etc.) shall be stored in appropriate containers and disposed of to prevent contamination.

Cleaning materials shall be approved and properly labeled for intended use and safe under their conditions of use.
2.11 PRODUCTION AND PROCESS CONTROL

Production and in-process control system shall be designed to ensure that the hemp is manufactured, packaged, labeled, and held in a manner that will ensure the quality of the hemp and that the hemp is packaged and labeled as specified in the manufacturing record.

Specifications shall be made for any part of in the manufacturing process where control is necessary and limits are set to ensure the quality and consistency of the hemp products.

In-process production shall have established in-process specifications for any part in the manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the hemp products and, as necessary, for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the hemp product.

Production documentation shall be made for meeting the in-process specifications.

Quality control personnel shall review and approve the in-process documentation.

Product definitions and specifications shall be established for all hemp products for identity, purity, strength, and composition of the hemp product.

Product specifications shall also include the packaging and labeling requirement of the finished packaged and labeled hemp.

Labeling operations procedures shall be made for packaging hemp products.

Quality Management Systems in the manufacturing, packaging, labeling, and holding of hemp shall ensure the quality of the hemp is as specified in the manufacturing record.

Quality control procedures shall include:

- Verify the identity of any component that is to be used in the production or processing of the hemp products.
- Maintain documentation of verification.
- Monitor each in-process part of the process where control is necessary to ensure the quality of the hemp products.
- For each batch or lot of finished hemp products, a sample shall be taken to verify, if necessary, that the batch meets its product specifications.
2.12 PRODUCTION AND PROCESS CONTROL SYSTEMS MASTER MANUFACTURING RECORD

A. A written master manufacturing record must be produced for each unique formulation of a hemp product that is manufactured, and for each batch size, to ensure uniformity in the finished batch from batch to batch.

B. The master manufacturing record must:

1. Identify specifications for the points, steps, or stages in the manufacturing process where control is necessary to ensure the quality and labeled as specified in the master manufacturing record; and
2. Establish controls and procedures to ensure that each batch of product that is manufactured meets the specifications identified in accordance with Guidance Procedures.

C. The master manufacturing record must include:

1. The name of the product to be manufactured and the strength, concentration, weight, or measure of each hemp product for each batch size;
2. A complete list of components to be used;
3. An accurate statement of the weight or measure of each component to be used;
4. The identity and weight or measure of each hemp product ingredient that will be declared on the label and the identity of each ingredient that will be declared on the ingredients list of the hemp product;
5. A description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label; and
6. Written instructions, including the following:

   a. Specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the hemp product and that the hemp product is packaged and labeled as specified in the master manufacturing record;
   b. Procedures for sampling and a cross-reference to procedures for tests or examinations; and
   c. Specific actions necessary to perform and verify points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the hemp product and that the hemp product is packaged and labeled as specified in the master manufacturing record.
2.13 PACKAGING AND LABELING HEMP

Packaging and Labeling products received, but not processed, shall have a control system to examine each container to determine that the appropriate product was received, content labeled, and that the container had no damage, contamination or deterioration of the components.

2.13.1 Labeling Practices

All products labeled for consumer use shall be labeled according to FDA regulations for foods or dietary supplements, as applicable.

All labeling and marketing must be legible and clearly identifiable.

All claims must be truthful and not misleading.

All ingredients added to the product must be declared.

No products may have labels or marketing that claim to diagnose, treat, prevent or cure any disease.

All products intended to support the structure or function of the body must include the following disclaimer: “This product is not intended to diagnose, treat, cure or prevent any disease.”

All products containing measurable amounts of cannabinoids should include proper warnings and cautions, such as the following:

- This product should be used with caution when driving motor vehicles or operating heavy machinery.
- Use this product under the guidance of a physician if you have a medical condition, are pregnant or lactating.
- Keep out of the reach of children.
- This product meets federal requirements for hemp products, however consumption may be flagged by some drug tests.

2.13.2 Guidance for Packaging and Labeling Operations

Packaging and labeling operations shall be such that the condition of the packaging will ensure the quality of the hemp products.

Issuance and use of packaging and labels shall be controlled and recorded.

Packaging and labels for each lot or batch of hemp shall be documented to determine whether the packaging and labels conform to the manufacturing record.

Packaged and labeled hemp shall be documented through distribution.

Packaging, labeling, and other related operations shall ensure that the quality of the hemp products are packaged and labeled as specified in the manufacturing record, including the following:

- Cleaning and sanitizing all filling and packaging equipment, as appropriate.
- Protecting hemp from contamination, including airborne contamination.
- Using sanitary handling procedures.
- Establishing physical or spatial separation of packaging and label operations from operations on other components.
- Identifying containers that are set aside and held in unlabeled condition.
- Assigning a batch, lot number to each lot of packaged and labeled hemp from a finished batch of hemp.

Representative samples of each batch of the packaged and labeled hemp shall be kept to determine whether the product meets specifications.

Suitably disposing of labels and packaging which are obsolete or incorrect to ensure that they are not used in any future packaging and label operations.

Records shall be kept of the written procedures for packaging and labeling operations.

Quality management personnel shall approve the hemp products for final distribution/sale.

### 2.13.3 Quality Control Procedures Shall Include:

Determine whether the received product meets the product specification.

Approval of the components for use in the packaging and labeling of a hemp product.

Identifying each unique lot within each shipment of components received so that it can be tracked through the packaging, labeling, marketing, and distribution processes.

Storage of the components shall be under conditions that will protect against contamination and deterioration.

Collection of a representative sample of each lot of product.

Hold packaging material and labels under conditions that will protect against contamination and deterioration.
2.14 STORAGE AND DISTRIBUTION

Storage of hemp shall be in under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and composition of the components and hemp are maintained.

Storage of hemp and hemp products shall be properly labeled at all times to prevent contamination and unintended commingling.

Storage of hemp and hemp products shall be properly labeled to indicate a hold or available for release.

Storage of material in-process shall be identified under conditions that prevent mix-ups, contamination, and deterioration.

Storage of material in-process shall be held under appropriate conditions of temperature, humidity, and light.

Storage of packaging and labels shall be under conditions adequate to prevent the packaging and labels from being adversely affected.

Distribution of hemp products shall be under conditions that will protect the products against contamination and deterioration.
2.15 QUALITY CONTROL OPERATIONS RELATED TO PRODUCT COMPLAINTS, ADVERSE EVENTS, AND RECALLS

Quality control operations for product complaints, adverse events, and recalls must include reviewing and approving decisions about whether to investigate a product complaint and reviewing and approving the findings, and follow-up action of any investigation performed.

The following records must be kept:

A. Written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision and written procedures for approving or rejecting any reprocessing.

B. Written documentation, at the time of performance, that quality control personnel performed the review, approval, or rejection requirements by recording the following:
   1. Date that the review, approval, or rejection was performed; and
   2. Signature of the person performing the review, approval, or rejection.

C. Documentation of any material review and disposition decision and follow-up. Such documentation must be included in the appropriate batch production record and must include:
   1. Identification of the specific deviation or the unanticipated occurrence;
   2. Description of your investigation into the cause of the deviation from the specification or the unanticipated occurrence;
   3. Evaluation of whether or not the deviation or unanticipated occurrence has resulted in or could lead to a failure to ensure the quality of the product or a failure to package and label the hemp product as specified in the master manufacturing record;
   4. Identification of the action(s) taken to correct, and prevent a recurrence of, the deviation or the unanticipated occurrence;
   5. Explanation of what you did with the component, hemp products, packaging, or label;
   6. A scientifically valid reason for any reprocessing of a product that is rejected or any treatment or in-process adjustment of a component that is rejected; and
   7. The signature of the individual(s) designated to perform the quality control operation, who conducted the material review and made the disposition decision, and of each qualified individual who provides information relevant to that material review and disposition decision.

D. Product Withdrawal and Recall.

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

1. Identify those responsible for initiating, managing and investigating a product withdrawal or recall;
2. Describe the procedures to be implemented by site management;
3. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident; and
4. Investigation shall be undertaken to determine the cause of a withdrawal, mock recall, or recall and details of investigations and any action taken shall be documented.
2.16 IMPORT / EXPORT

2.16.1 Import

A. A person who is licensed to import seed may import only seed that is of an approved cultivar or, in the case of a plant breeder, seed of a variety of hemp specified on his or her license.

B. (1) When viable grain is imported, the importer shall ensure that each shipment is accompanied by a document, issued by the competent authorities.

(2) Production of viable grain meets requirements that:

a. are equivalent to those set out in these Guidance Procedures; and
b. ensure that the viable grain will not produce a plant containing more than 0.3% THC w/w in any part of the plant.

C. No person shall import seed or viable grain solely for the purpose of conditioning, unless it is of an approved cultivar that will be exported once it has been conditioned.

D. (1) An importer who applies for a permit to import hemp shall submit the following information to the proper authority having jurisdiction:

a. the name, address, and number on the importer’s license;
b. the name and address of the person from whom the hemp is being purchased;
c. the port of entry;
d. the address of the customs office;
e. each mode of transportation;
f. the form in which the hemp is to be imported, the quantity (weight) of each form, the type of packaging, the variety of hemp, if applicable, the country of origin of each form of the hemp, and the countries of transit and transshipment; and
g. a statement certifying that the package and the contents do not contravene any known requirement of the laws of the country from which the hemp is imported, or any country of transit or transshipment.

(2) An import application shall be signed by the applicant or, in the case of a corporation, cooperative, or partnership, one of its officers, directors, or partners, as the case may be, and indicate that all information submitted in support of the application is correct and complete to the best of his or her knowledge.

E. A person who is licensed to import hemp shall ensure that a copy of the import permit is attached to the shipment of the hemp.

2.16.2 Export

A. (1) An exporter who applies for a permit to export hemp shall submit the following information to the jurisdiction having authority:

a. the name and number on the exporter’s license;
b. the name and address of the person to whom the shipment of hemp is to be consigned;
c. the port of exit;
d. the address of the customs office;

e. each mode of transportation;

f. the form in which the hemp is to be exported, the quantity of each form, the
variety of hemp, if applicable, the country of origin of each form of the hemp,
and the countries of transit and transshipment; and


g. a statement certifying that the package and the contents do not contravene any
known requirement of the laws of the country to which the hemp is or is about
to be consigned, or any country of transit or transshipment.

(2) An application shall be signed by the applicant or, in the case of a corporation,
cooperative, or partnership, one of its officers, directors, or partners, as the case may be,
and indicate that all information submitted in support of the application is correct and
complete to the best of his or her knowledge.

B. A person who is licensed to export hemp shall ensure that a copy of the export permit is
attached to the shipment of the hemp.

NOTE: All import and exports must meet the sanitary and phytosanitary requirements of USDA
APHIS\textsuperscript{10} and possibly the country of origin or receipt.

\textsuperscript{10} U.S. Department of Agriculture Animal & Plant Health Inspection Service.
2.17 RECORD RETENTION

Processor, packagers, and labelers shall keep records, electronically or hard copy, that contain the following information for at least five (5) years after process or operations:

- Source of the hemp seed (imported or purchased or grown), name and address and the country of origin
- Form in which the hemp is imported or processed
- Quantity of each form of hemp imported, purchased or sold
- Destination of the hemp that is sold, name and address of the purchaser, and the country to which it is exported
- Date that each shipment of hemp is sent or received
  - Name of the carrier
  - Results of any tests
  - Quantity shipped
- Written procedures of production processes (master manufacturing records, etc.)
- If available, all images of products and labels
- Processing records, including the time the operations were performed, the components, packaging, labels, or products used, and the batch or lot number for the finished product
- Any and all certification documents
- Records kept shall be originals or true copies, such as photocopies, or other accurate reproductions of the original records, or as electronic records
- Results of all tests