U.S. Hemp Roundtable

U.S. Hemp Guidance Program

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1 GROWER

1.1 GENERAL TERMS & DEFINITIONS

The following Definitions and Interpretations apply to such terms when used in this U.S. Hemp Guidance 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 industrial 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 industrial 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 industrial hemp, including those that may not appear in the finished batch of the industrial hemp.

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

Hemp refers to cannabis varieties and any part of the plant, whether growing or not, containing a delta-9 tetrahydrocannabinol (THC) concentration of no more than three-tenths of one percent (0.3%) on a dry weight basis.

Industrial Hemp is 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 industrial 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 be related to the quality of an industrial 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 of microorganisms of public health concerns.

1.2 REGISTRATION/APPLICATION/NOTIFICATION

Prior to the Industrial Hemp Grower planting any seed, a license or agreement with the State must be obtained. The following information is required to make the application before a license will be issued: (Each State may have different regulations – refer to application – See Kentucky Hemp Policy Guide as an example)

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 purpos-of industrial hemp
- In the case of a plant breeder, the variety of industrial 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, 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 a licensee
- Any change in the mailing address of the licensee
- Any change in the ownership of the land used to cultivate industrial hemp
- Any change to the approved cultivar being sown or, in the case of a plant breeder, to the variety of industrial hemp being sown;
- Any genetic modification.

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

1.3 PERSONNEL

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.

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 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, industrial 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

1.3.1 U.S. HEMP GUIDANCE - GROWER - PERSONNEL CHECKLIST				
√ if Applicable		YES	NO	NOTES
	Are the supervisors qualified for their responsibilities by training, education or experience?			
	Do the employees performing the growing, processing, packaging and labeling tasks, have the proper training necessary to perform the tasks?			
	Are contamination and hygienic measures in place to exclude personnel who might be a source of contamination?			
	Are personnel excluded from operations if they have, an illness, infection, open lesion, or any other abnormal source of contamination?			
	Do employees notify their supervisor if there is a possible health condition as described above?			
	Do personnel wear outer garments in a manner that protects against the contamination?			
	Do operating personnel maintain adequate personal cleanliness?			
	Are hand washing facilities available and used?			
	Do operating personnel remove or cover unsecured jewelry etc. to prevent them from falling into hemp products or causing harm?			
	Are gloves used when appropriate?			
	Are caps, shoes and head covering used when appropriate?			
	Is the appropriate Personal Protective Equipment (PPE) used as needed?			
	Are there adequate and appropriate first aid equipment available?			
	Is there adequate bathrooms and changing rooms?			
	Are the OSHA warnings and signs visible?			
	Has there been adequate training?			
	If applicable is the PPE and trains available for the pesticide applicators?			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

1.3.2 U.S. HEMP GUIDANCE – GROWER – BEST MANAGEMENT PRACTICES CHECKLIST			
	YES	**NO**	**NOTES**
Are you using the best soil available?			
Have you Soil tested for macro and micro nutrients?			
Have you used the appropriate Growth Medium for intended purposes?			
Has the licensee determined the concentration of THC in the hemp?			
Is seed planted listed on the license?			
Is the entire hemp plant used as licensed?			
Do you properly use pre- plant weed control?			
Do you have a Germination Certificate from the seed supplier			
Did you use the proper Certified Seed suitable for location?			
Did you use the proper seed treatment?			
Do you have a site history?			
Do you have a water quality report or history?			
Did you use fertilizer to target desired yield per acre according to soil test?			
Did you use animal manure for fertilizer or biomass purposes?			
Did you plant by optimum seeding date?			
Did you plant at the optimum rate of seeds per acre?			
Have samples of the industrial hemp been collected in accordance with the Guidance Procedures?			
Has the equipment used to sow, harvest and transport the hemp been thoroughly cleaned to prevent contamination?			
Are you prepared to harvest when the plant is ready?			
Have you complied with the drying procedures			
Do you have sufficient and proper storage facilities or adequate transportation equipment available?			
Is the biomass sold to a licensed person or entity according the Guidance Procedures?			
Is the biomass packaged, labeled, and transported according to the Transportation Guidance Procedures?			
Has any loss or theft been reported according to the license requirements?			
Are the records being kept according to the Guidance Procedures for Record Retention?			

Grower Signature_____ **Date** _____

Printed Name_____ **Farm location or identifier**_____

1.3.3 U.S. HEMP GUIDANCE - GROWER - FACILITY & BIOSECURITY AWARENESS CHECKLIST				
A.	**Facility Security (physical security of buildings and grounds)**			
√ if Applicable	**Is the facility using:**	**YES**	**NO**	**NOTES**
	Security lighting			
	Perimeter fencing			
	Controlled gate access			
	Off-hours security guard			
	Electronic motion detectors			
	Door alarms			
	Video cameras			
	Adequate indoor lighting			
	Alarms linked to an off-site security system			
	Door hardware is of industrial design			
	Guards are installed on exterior ladders			
	Exit doors and gate are electronically/mechanically secured			
	Entry and discharge points of exterior tanks are padlocked when not in use			
	All vehicles parked outside are locked			
	Empty/loaded containers are parked inside			
	Law enforcement patrol over company premises on regular but unpredictable basis			
	Employees reporting any suspicious behaviors			
	Restricted access to computer process control and data systems			
	Safeguard of data systems using data security program			
	Backup of all data and processes at an off-site place			
B.	**Visitor Policy**			
√ if Applicable	**Is the facility using:**	**YES**	**NO**	**NOTES**
	Company representative for visitor to check in with			
	Signs informing visitors where to report			
	Specific area for visitor parking			
	Records of visitors (include name, company, arrival and departure, and purpose of visit)			
	Visitor badges/identification cards			
	Company representative to escort visitor all the time			
	Restricted access to key manufacturing areas			
C.	**Distribution**			
√ if Applicable	**Is the facility implementing the following:**	**YES**	**NO**	**NOTES**
	Bulk containers are inspected prior to loading for foreign and/or suspicious material			

	Verify that all customer pick-up drivers are representatives of the customer			
	The product stream is inspected visually			
	Container access points are secured after loading			
	Seal numbers are documented on the shipping papers			
	Shipping documents are used to identify the contents of each compartment			
	Shipping log is maintained			
	Bio-sanitation program is implemented			
	Procedures exist to disinfect vehicles and drivers			
D.	**Housekeeping**			
√ if Applicable	**Is the facility implementing the following:**	**YES**	**NO**	**NOTES**
	Written housekeeping program for all areas of the facility			
	Written pesticide and rodenticide program			
E.	**Emergency Response**			
√ if Applicable	**Is the facility implementing the following:**	**YES**	**NO**	**NOTES**
	Employees are adequately trained to respond to a crisis as calmly and safely as possible			
	Current inventory of all hazardous and flammable products			
	A plan to provided MSDS to emergency response teams etc.			
	A list of emergency contacts is posted			
	An action plan to deal with suspicious devices or substances			
	Evacuation plan in case of fire and explosions is published			
	Establish and maintain an up-to-date employee roster and visitor log to facilitate personnel head count at any time			
	Disaster Preparedness Plan			
	A weapons security program			
	Conduct evacuation and respond drill periodically			
	Post a site plan depicting escape routes, fire-fighting and rescue equipment			

Signature: _____ **Date:** _____

Printed Name: _____ **Company:** _____

Facility Location: _____

1.4 SAMPLING AND HANDLING HEMP FOR THC & CBD

1.4.1 Definitions

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

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 possession 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.

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 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 part (d) –(f).
    iii. For ground plant or ground floral material Post-Harvest Samples:
        7. 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).
        8. Sample material from bag or container.
        9. Sample from a minimum of four locations within the containers from a given harvest.
        10. Place the complete sample in a plastic sample container.
        11. Seal the plastic sample container.
        12. Complete sampling procedures in part (d) –(f).
    iv. For Post-Harvest Samples in other forms (e.g., trimmed floral material, or floral material and stems, etc.):
        13. Ensure that the entire harvest is accounted for and in the same form (i.e., all harvested material must be uniform).
        14. Randomly collect at least one cup of material by volume.
        15. Place the complete sample in a paper bag or plastic container and seal the container, as appropriate.
        16. Complete sampling procedures in part (d) –(f).
    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. Industrial 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. Industrial 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 TESTING AND HEMP CANNABINOID QUANTIFICATION:

1.5.1 Potency

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.

OR have 3rd party methods accredited as a testing laboratory to International Organization for Standardization (ISO) 17025 by a third-party accrediting body such as the American Association for Laboratory accreditation (A2LA) or assured Calibration and Laboratory Accreditation Select Services (ACLASS).

Cannabinoids potency methods must be able to determine the concentration of target cannabinoids to effectively distinguish cannabis as either 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 may be subject to FDA and state regulations regarding harmful substances and contaminants.

Guidance for contaminants in cannabis products (heavy metals, microbiology, pesticides and residual solvents) has been published in the American Herbal Pharmacopoiea (AHP) Cannabis monograph.

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

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

In addition, the American Herbal Products Association has resources available regarding Regulatory Information, testing botanical products for purity, Good Agriculture and Collection Practices, cGMP SOP templates, and other Technical Guidance that can be utilized to develop testing programs.

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 and repeating during a short time period. Expressed as the repeatability standard deviation (SD_r); or % repeatability relative standard deviation ($\%RSD_r$).

Reproducibility.—The standard deviation or relative standard deviation calculated from among-laboratory data. Expressed as the reproducibility standard deviation (SD_R); or % reproducibility relative standard deviation ($\%RSD_R$).

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

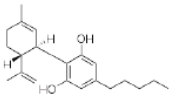
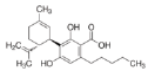
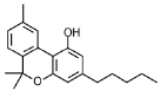
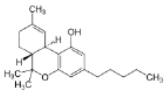
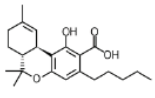
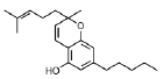
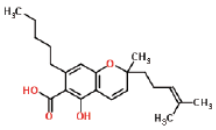
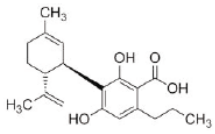
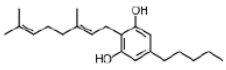
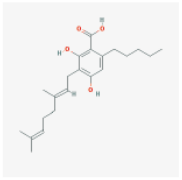
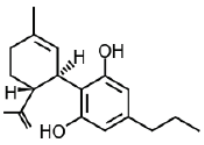
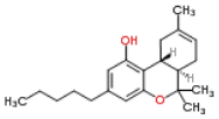
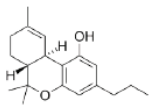
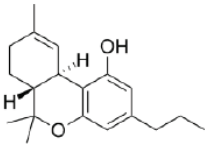
Common name	Abbreviation	IUPAC name	CAS No.	Molecular structure	Reference material
Cannabidiol	CBD	2-[(1*R*,6*R*)-6-Isopropenyl-3-methylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol	13956-29-1		Restek Cerilliant Sigma-Aldrich API Standards Echo Pharm Lipomed AG
Cannabidiolic acid	CBDA	2,4-Dihydroxy-3-[(1*R*,6*R*)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-6-pentylbenzoic acid	1244-58-2		Cerilliant USP Restek Lipomed AG Echo Pharmaceutical
Cannabinol	CBN	6,6,9-Trimethyl-3-pentyl-benzo[c]chromen-1-ol	521-35-7		Cerilliant Restek
Tetrahydro-cannabinol	THC	(−)-(6a*R*,10a*R*)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6*H*-benzo[c]chromen-1-ol	1972-08-3		Cerilliant USP Echo Pharmaceuticals
Tetrahydro-cannabinolic acid	THCA	(6a*R*,10a*R*)-1-hydroxy-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6h-benzo[c]chromene-2-carboxylic acid	23978-85-0		Cerilliant USP Echo Pharmaceuticals

Table 2. Additional, desirable cannabinoids

Name	Abbreviation	IUPAC name	CAS No.	Molecular structure	Reference material
Cannabichromene	CBC	2-Methyl-2-(4-methylpent-3-enyl)-7-pentyl-5-chromenol	20675-51-8		Cerilliant Sigma Aldrich Echo Pharmaceuticals
Cannabichromenic acid	CBCA	5-Hydroxy-2-methyl-2-(4-methyl-3-penten-1-yl)-7-pentyl-2*H*-chromene-6-carboxylic acid	20408-52-0		No reference material
Cannabidivarinic acid	CBDVA	2,4-Dihydroxy-3-[(1*R*,6*R*)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-6-propylbenzoic acid	31932-13-5		Cerilliant
Cannabigerol	CBG	2-[(2*E*)-3,7-dimethylocta-2,6-dienyl]-5-pentyl-benzene-1,3-diol NIST: 1,3-Benzenediol, 2-(3,7-dimethyl-2,6-octadienyl)-5-pentyl	25654-31-3 NIST: 2808-33-5		Cerilliant Lipomed AG Echo Pharmaceuticals SPEX Certiprep Tocris (UK)
Cannabigerolic acid	CBGA	3-[(2*E*)-3,7-dimethylocta-2,6-dienyl]-2,4-dihydroxy-6-pentylbenzoic acid	25555-57-1		Cerilliant Echo Pharmaceuticals SPEX Certiprep
Cannabidivarin	CBDV	2-((1*S*,6*S*)-3-methyl-6-(prop-1-en-2-yl)cyclohex-2-enyl)-5-propylbenzene-1,3-diol	24274-48-4		Cerilliant SPEX Certiprep
$^{\Delta 8}$Tetrahydro-cannabinol	$^{\Delta 8}$THC	6,6,9-Trimethyl-3-pentyl-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol	5957-75-5		Cerilliant SPEX Certiprep
Tetrahydro-cannabivarin	THCV	6,6,9-Trimethyl-3-propyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromen-1-ol	28172-17-0		Cerilliant USP
Tetrahydrocannabivarin acid	THCVA		28172-17-0		No reference material

1.6 STORAGE AND DISTRIBUTION

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

1.6.1 U.S. HEMP GUIDANCE - GROWER - STORAGE & DISTRIBUTION CHECKLIST				
√ if Applicable		YES	NO	NOTES
	Is the industrial hemp and hemp products stored or warehoused under appropriate conditions?			
	Are the storage conditions sufficient to prevent adulteration?			
	Are the storage conditions sufficient to prevent changes in specifications of the hemp products?			
	Is the material used in-process held under adequate conditions to prevent changes in the components or ingredients?			
	Are the packaging materials stored and held in conditions to prevent deterioration?			
	Are the labels and labeling materials stored and held in conditions to prevent deterioration?			
	Is the hemp distribution plan adequate to preserve the quality of the hemp products?			
	Is the hemp distribution plan adequate to assure that the hemp products are shipped to the intended place and to the intended recipient?			
	Is the Storage of hemp and hemp products properly labeled at all times to prevent contaminations and unintended comingling?			
	Is the Storage of hemp and hemp products properly labeled to indicate a hold or available for release?			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

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 industrial 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 industrial hemp is imported, purchased or sold,
- Variety of industrial 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 industrial hemp imported, purchased, or sold,
- Date of planting and harvest,
- Date of each pesticide, herbicide, fungicide and fertilizer application if any,
- Destination of the industrial hemp that is sold, - name and address of the purchaser and the country, to which it is exported,
- Date that each shipment of industrial 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.

1.7.1 U.S. HEMP GUIDANCE – GROWER - RECORD RETENTION CHECKLIST				
√ if Applicable	***ALL RECORDS ARE TO BE KEPT FOR 5 YEARS***			
	DO THE RECORDS INCLUDE THE FOLLOWING?	**YES**	**NO**	**NOTES**
	Source of industrial hemp seed including			
	Name, address and country of origin			
	Name and license of person who sold the seed			
	Form of the industrial hemp seed			
	Variety of the seed			
	Quantity of the seed			
	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			
	Date of planting			
	Date of harvesting			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

2 PROCESSOR

2.1 GENERAL TERMS & DEFINITIONS

The following Definitions and Interpretations apply to such terms when used in this U.S. Hemp Guidance 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 industrial 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 industrial 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 industrial hemp, including those that may not appear in the finished batch of the industrial hemp.

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

Hemp refers to cannabis varieties and any part of the plant, whether growing or not, containing a delta-9 tetrahydrocannabinol (THC) concentration of no more than three-tenths of one percent (0.3%) on a dry weight basis.

Industrial Hemp is 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 industrial 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 be related to the quality of an industrial 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 of microorganisms of public health concerns.

2.2 REGISTRATION/APPLICATION/NOTIFICATION

Prior to the Industrial Hemp Processor processing any seed or hemp product, a license or agreement with the State must be obtained. The following information is required to make the application before a license will be issued: (Each State may have different regulations – refer to application – See Kentucky Hemp Policy Guide as an example)

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 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 on licensee
- Any change in the mailing address of the licensee
- Any change in the ownership of the land used to cultivate industrial hemp
- Any change to the approved cultivar being sown or, in the case of a plant breeder to the variety of industrial hemp being sown;

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

2.3 PERSONNEL GUIDANCE

Qualified employees who 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.

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, industrial 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.

2.3.1 U.S. HEMP GUIDANCE - PROCESSOR- PERSONNEL CHECKLIST				
√ if Applicable		YES	NO	NOTES
	Are the supervisors qualified for their responsibilities by training, education or experience?			
	Do the employees performing the growing, processing, packaging and labeling tasks, have the proper training necessary to perform the tasks?			
	Are contamination and hygienic measures in place to exclude personnel who might be a source of contamination?			
	Are personnel excluded from operations if they have, an illness, infection, open lesion, or any other abnormal source of contamination?			
	Do employees notify their supervisor if there is a possible health condition as described above?			
	Do personnel wear outer garments in a manner that protects against the contamination?			
	Do operating personnel maintain adequate personal cleanliness?			
	Are hand washing facilities available and used?			
	Do operating personnel remove or cover unsecured jewelry etc. to prevent them from falling into hemp products or causing harm?			
	Are gloves used when appropriate?			
	Are caps, shoes and head covering used when appropriate?			
	Is the appropriate Personal Protective Equipment (PPE) used as needed?			
	Are there adequate and appropriate first aid equipment available?			
	Is there adequate bathrooms and changing rooms?			
	Are the OSHA warnings and signs visible?			
	Has there been adequate training?			
	If applicable is the PPE and trains available for the pesticide applicators?			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

2.4 EMPLOYEE TRAINING

A. 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 GMP requirements are conducted no less frequently than a yearly basis. All personnel are trained to follow 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.
    Personnel with less than the required qualifications or experience should be provided with a training program designed to make up deficiencies.

5. 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.
6. 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.
7. 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.
8. Visitors or untrained personnel should not be permitted into production, storage or QC areas without training.
9. 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.

2.4.1 U.S. HEMP GUIDANCE – PROCESSOR – NEW EMPLOYEE TRAINING CHECKLIST

EMPLOYEE INFORMATION

Name:	Start Date:
Position:	Manager:

FIRST DAY

Provide New Employee Handbook

- ❑Safety Manual
- ❑Smoking Policy
- ❑Emergency Procedures - 29 CFR 1910.38
  - ❑Emergency Contact Numbers
  - ❑Evacuation Signal and Communication- 29 CFR 1910.165
  - ❑Meeting Location
  - ❑Safety Equipment
  - ❑First Aid -29 CFR 1910.151
  - ❑Hazardous Waste and Spills -29 CFR 1910.120
  - ❑Fire, Weather, etc.
- ❑Hazard Communication(MSDS/Labels) -29 CFR 1910.1200
- ❑PPE Requirements (Ear, Eye, Face, Hand, Head)-29 CFR 1910.95;29 CFR 1910.132
- ❑Lock-out/Tag-out - 29 CFR 1910.147
- ❑Designated Confined Spaces - 29 CFR 1910.146
- ❑Accident Reporting Procedures
- ❑Manlifts- 29 CFR 1910.68
- ❑Access to Employee Exposure and Medical Records -29 CFR 1910.20
- ❑Accident Prevention, Signs, Tags - 29 CFR 1910.145

Review Key Policies	❑Company Mission Statement ❑Vacation and Sick Leave ❑Leaves of Absence ❑Holidays ❑Time and Leave Reporting ❑Overtime ❑Performance Review ❑Uniform ❑Environmental Policy ❑Right to Know	❑Personal Conduct Standards ❑Progressive Disciplinary Actions ❑Security ❑Confidentiality ❑Safety ❑Emergency Procedures ❑Visitors ❑Email and Internet Use ❑Anti-Harassment ❑

ADMINISTRATIVE PROCEDURES

General Administrative Procedures	❑Office/Desk/WorkStation ❑Keys ❑ Mail (Incoming and Outgoing) ❑Shipping (FedEx, DHL, UPS) ❑Time Card (Clock-in/Clock-out)	❑Telephones ❑OfficeSupplies ❑ID Cards ❑Purchase Requests

FACILITY TOUR			
Introduction to Department Staff and Key Personnel			
Tour of Facility	❑Restrooms ❑Fax Machines ❑Copy Machines	❑Bulletin Board ❑Parking ❑Printers	❑Break Room ❑Office Supplies ❑Janitorial Closet
Safety Equipment	❑First Aid Kits ❑Fire Alarms ❑PPE ❑Fall Protection	❑Eyewashes ❑Safety Showers ❑Fire Extinguisher	❑Fire Hoses ❑Spill Kits ❑Emergency Lights
Operations	❑Quality Lab ❑Scale House ❑Receiving ❑Silos ❑Liquid Storage	❑Production Floor ❑Packaging ❑Bulk Load-Out	❑Maintenance Shop ❑Boiler Room ❑Air Compressor ❑Rail Yard

The items checked above have been explained by my manager and I understand this information.

Employee Name (print) _____ (Sign and Date) _____

I have met with this employee and discussed this information with him/her.

Manager Name (print) _____ (Sign and Date) _____

POSITION INFORMATION
Introduction to other employees **Review Initial Job Assignments and Training Plans** **Review Job Description and Performance Expectations and Standards** **Review Job Schedule and Hours** **Review Payroll Timing, Time Cards (if applicable), and Policies and Procedures**

COMPUTERS			
Automation System	❑Login ❑Data Entry ❑Security Policy	❑Process Areas ❑Parameters ❑Alarms	❑Reports ❑Disposal
Hardware and Software	❑Email ❑Intranet ❑Software Policy	❑Office System ❑Data on Shared Drives	❑Databases ❑Internet

SAFTEY TRAINING TOPICS		Date Completed	Employee Initial	Trainer Initial
X Required	Topic			
	Housekeeping – Preventing Fires and Dust Explosions -			
	Cutting and Welding – Hot Work Permits - 29 CFR			
	Slips, Trips and Falls			
	Blood Borne Pathogens - 29 CFR 1910.1030			
	Electrical Safety/Arc Flash (Tools, SOPs, Barriers,			
	Compressed Air			
	Respiratory Protection- 29 CFR 1910.134			
	Portable Ladders - 29 CFR 1910.25-26			
	Permit Required Confined Space – Entrant - 29 CFR			
	Permit Required Confined Space – Attendant- 29 CFR			
	Permit Required Confined Space – Supervisor - 29 CFR			
	Powered Trucks – Forklifts- 29 CFR 1910.178			
	Rail Yard Safety and Rail Car Moving Equipment			
	Loading Tractor Trailers – Dock Plates, Jack Stands,			
	Portable Fire Extinguishers- 29 CFR 1910.157			
	Fire Detection, Extinguishing, Alarms - 29 CFR			
	Storage and Handling of Liquefied Petroleum Gases - 29			
	Asbestos - 29 CFR 1910.1001			

OPTIONAL TRAINING TOPICS		Date Completed	Employee Initial	Trainer Initial
Optional	Topic			
	Basic First Aid and Cardiac and Pulmonary			

QUALITY MANAGEMENT SYSTEMS		Date Completed	Employee Initial	Trainer Initial
X Required	Topic			
	Mission Statement			
	Standard Operating Procedures for Manufacturing			
	Quality Manual, GMPs and/or Food Safety Plan			
	Specifications and COA			
	Supplier and Component Qualification			
	Master Manufacturing Record			
	Batch Manufacturing Record			
	Packaging Record			
	Storage and Transportation Records			
	Material Approval			
	Measurement and Quality Control			
	Complaints			
	CAPA/AER/Recall			
	Bioterrorism Act			

REGULATIONS – AIR and WATER		Date Completed	Employee Initial	Trainer Initial
Required	**Topic**			
	Spill Prevention and Counter Control (SPCC) ❑Preventing Spills ❑Unloading Liquid Ingredient Tankers ❑Spill Response ❑Emergency Numbers			
	Air Permit Emission Sources ❑Boilers ❑Bag Filters ❑Cyclones			
	National Pollutant Discharge Elimination System Permit –			
	Storm Water Plan (Best Management Practices and			

EMPLOYEE DEVELOPMENT		Date Completed	Employee Initial	Trainer Initial
X Required	**Topic**			
	Time Management			
	Conflict Resolution			
	Interviewing Skills			
	Performance Reviews			
	Progressive Discipline			
	Operator Certifications			
	Pest Control			
	Pesticide License			
	Mentor			
	First Week Review			

PREVENTIVE MAINTENANCE and HOUSEKEEEPING		Date Completed	Employee Initial	Trainer Initial
Required	**Topic**			
	Lock-out/Tag-out Procedures ❑Equipment Numbers ❑Motor Control Center (MCC) Box Labels			
	Fall Protection			
	Electrical Safety ❑PPE ❑Arc Flash ❑Clothing			
	Cleaning Magnets			
	Greasing Bearings			

	Work Orders ❑Time ❑Cost ❑Parts and Vendors ❑History Tracking			
	Housekeeping Areas ❑Priority Areas ❑Assigned Areas ❑Compressed Air Policy			
	Pest Control Program (Internal and/or External)			
STANDARD OPERATING PROCEDURES		Date Completed	Employee Initial	Trainer Initial
Required	**Topic**			
	Sampling			
	Packaging			
	Receiving			
	Storage and Transportation			
	Cleaning & Sanitation			
	Hygiene			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

2.4.2 U.S. HEMP GUIDANCE – PROCESSOR – EMPLOYEE TRAINING CHECKLIST/ANNUAL RECERTIFICATION

EMPLOYEE INFORMATION

Name:	Recertification Date:
Position:	Manager:

SAFETY TRAINING TOPICS		Date Completed	Employee Initial	Trainer Initial
X Required	**Topic**			
	Housekeeping – Preventing Fires and Dust Explosions			
	Cutting and Welding – Hot Work Permits			
	Slips, Trips and Falls			
	Blood Borne Pathogens			
	Electrical Safety/Arc Flash (Tools, SOPs, Barriers, Clothing)			
	Compressed Air			
	Respiratory Protection			
	Portable Ladders			
	Permit Required Confined Space – Entrant			
	Permit Required Confined Space – Attendant			
	Permit Required Confined Space – Supervisor			
	Powered Trucks – Forklifts-			
	Rail Yard Safety and Rail Car Moving Equipment			
	Loading Tractor Trailers – Dock Plates, Jack Stands, Wheel Chocks			
	Portable Fire Extinguishers			
	Fire Detection, Extinguishing, and Alarms			
	Storage and Handling of Liquefied Petroleum Gases			
	Asbestos			

QUALITY MANAGEMENT		Date Completed	Employee Initial	Trainer Initial
X Required	**Topic**			
	Mission Statement			
	Standard Operating Procedures for Manufacturing			
	Quality Manual, GMPs and/or Food Safety Plan			
	Specifications and COA			
	Supplier and Component Qualification			
	Manufacturing			
	Packaging			
	Storage and Transportation Records			
	Material Approval			
	Measurement and Quality Control			
	Complaints			
	CAPA/Recall/AER			
	Bioterrorism Act			

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REGULATIONS – AIR & WATER		Date Completed	Employee Initial	Trainer Initial
X Required	**Topic**			
	Spill Prevention and Counter Control (SPCC) ❑Preventing Spills ❑Spill Response ❑Emergency Numbers			

STANDARD OPERATING PROCEDURES – JOB SPECIFIC		Date Completed	Employee Initial	Trainer Initial
X Required	**Topic**			
	Sampling			
	Receiving			
	Processing			
	Packaging			
	Labeling			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

2.5 PHYSICAL PLANT AND GROUNDS

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

Facilities shall be such to 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 use.

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 industrial hemp.

Facility maintenance shall include facilities in repair sufficient to prevent industrial 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 need to be free from microorganisms and that are safe and adequate under the conditions of use.

Pest control includes not allowing animals or pests in any area of your 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 industrial 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, attract pests or become a source of contamination.

Grounds shall be maintained to protect against contamination of industrial 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 industrial hemp products
- Adequately operating waste treatment and disposal.

2.5.1 U.S. HEMP GUIDANCE - PROCESSOR - PHYSICAL PLANT AND GROUNDS CHECKLIST				
√ if Applicable		YES	NO	NOTES
	Are the facilities used in the processing, packaging, labeling, or storage of industrial hemp adequate in size, construction, and design?			
	Do the facilities provide adequate space for the equipment and materials necessary for normal operations?			
	Are the facilities adequate for maintenance, cleaning, and sanitizing and to prevent contamination?			
	Does the equipment adequately control temperature and humidity?			
	Are the fans / air-blowing equipment adequate for use?			
	Do the aisles or working spaces between equipment and walls permit all persons to perform their duties?			
	Is there adequate light in all areas as needed?			
	Are the facilities maintained to protect against contamination of industrial hemp?			
	Are the cleaning compounds, sanitizing agents, pesticides, and other materials free from microorganisms and adequate under the conditions of use?			
	Is pest control sufficient to exclude all animals or pests in any areas except Guard or working dogs?			
	Are insecticides, fumigants, fungicides, herbicides, or rodenticides, used with care and in the intended manner?			
	Is the water supply safe and sanitary, and at suitable temperatures, and pressure as needed?			
	Is the plumbing of adequate size and installed and maintained to satisfy operational needs?			
	Does the floor drainage prevent contamination of industrial hemp products or components?			
	Is the sewage disposal adequate for operational needs and bathrooms?			
	Are hand-washing facilities available to ensure that employee's hands are not a source of contamination?			
	Is the trash disposal sufficient to minimize odors, and not attract pests or become a source of contamination?			
	Are the grounds maintained to protect against contamination of industrial hemp?			
	Is the equipment stored and litter and waste removed to prevent pests?			
	Is the grass mowed and weeds cut to prevent pests a place for breeding?			
	Are the roads, yards, and parking lots maintained to prevent contamination of industrial hemp products?			
	Is the waste treatment and disposal operating adequately?			
	Does the Facility have adequate bathrooms and changing rooms?			

Signature: _____ **Date:** _____

Printed Name: _____ **Company:** _____

Facility Location: _____

2.5.2 U.S. HEMP GUIDANCE - PROCESSOR - FACILITY & BIOSECURITY AWARENESS CHECKLIST				
A.	**Facility Security (physical security of buildings and grounds)**			
√ if Applicable	**Is the facility using:**	**YES**	**NO**	**NOTES**
	Security lighting			
	Perimeter fencing			
	Controlled gate access			
	Off-hours security guard			
	Electronic motion detectors			
	Door alarms			
	Video cameras			
	Adequate indoor lighting			
	Alarms linked to an off-site security system			
	Door hardware is of industrial design			
	Guards are installed on exterior ladders			
	Exit doors and gate are electronically/mechanically secured			
	Entry and discharge points of exterior tanks are padlocked when not in use			
	All vehicles parked outside are locked			
	Empty/loaded containers are parked inside			
	Law enforcement patrol over company premises on regular but unpredictable basis			
	Employees reporting any suspicious behaviors			
	Restricted access to computer process control and data systems			
	Safeguard of data systems using data security program			
	Backup of all data and processes at an off-site place			
B.	**Visitor Policy**			
√ if Applicable	**Is the facility using:**	**YES**	**NO**	**NOTES**
	Company representative for visitor to check in with			
	Signs informing visitors where to report			
	Specific area for visitor parking			
	Records of visitors (include name, company, arrival and departure, and purpose of visit)			
	Visitor badges/identification cards			
	Company representative to escort visitor all the time			
	Restricted access to key manufacturing areas			
C.	**Distribution**			
√ if Applicable	**Is the facility implementing the following:**	**YES**	**NO**	**NOTES**
	Bulk containers are inspected prior to loading for foreign			

	and/or suspicious material			
	Verify that all customer pick-up drivers are representatives of the customer			
	The product stream is inspected visually			
	Container access points are secured after loading			
	Seal numbers are documented on the shipping papers			
	Shipping documents are used to identify the contents of each compartment			
	Shipping log is maintained			
	Bio-sanitation program is implemented			
	Procedures exist to disinfect vehicles and drivers			
D.	**Housekeeping**			
√ if Applicable	**Is the facility implementing the following:**	**YES**	**NO**	**NOTES**
	Written housekeeping program for all areas of the facility			
	Written pesticide and rodenticide program			
E.	**Emergency Response**			
√ if Applicable	**Is the facility implementing the following:**	**YES**	**NO**	**NOTES**
	Employees are adequately trained to respond to a crisis as calmly and safely as possible			
	Current inventory of all hazardous and flammable products			
	A plan to provided MSDS to emergency response teams etc.			
	A list of emergency contacts is posted			
	An action plan to deal with suspicious devices or substances			
	Evacuation plan in case of fire and explosions is published			
	Establish and maintain an up-to-date employee roster and visitor log to facilitate personnel head count at any time			
	Disaster Preparedness Plan			
	A weapons security program			
	Conduct evacuation and respond drill periodically			
	Post a site plan depicting escape routes, fire-fighting and rescue equipment			

Signature: _____ **Date:** _____

Printed Name: _____ **Company:** _____

Facility Location: _____

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 PCQI training required under the Food Safety Modernization Act (FSMA) are required to administer food safety programs.

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
        c. 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 this guidance documents.

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 establish 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.

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 for why meeting in-process specifications, in combination with meeting component specifications, will help ensure that the identity, purity, strength, and composition.

Guidance Requirements for Industrial Hemp Laboratory Operations

Industrial 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; and

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 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 3rd party laboratory using highly precise methods such as Nuclear Magnetic Resonance (NMR).

2.6.1 U.S. HEMP GUIDANCE – PROCESSOR – QUALITY MANAGEMENT SYSTEMS CHECKLIST				
Quality management systems must be developed and implemented for manufacturing, packaging, labeling, and holding operations, as well as laboratory operations related to processing.				
√ IF Applicable	**Specifications must be established for each component of a finished hemp product DO YOU HAVE**	**YES**	**NO**	**NOTES**
	Identity specification to ensure purity, strength and composition?			
	Limits on the 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?			
√ IF Applicable	**For the in-process production DO YOU HAVE**	**YES**	**NO**	**NOTES**
	In-process specifications where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the hemp products?			
	Documentation for meeting the in-process specifications, in combination with component specifications, to ensure that the specifications are met for the identity, purity, strength, and composition of the hemp products?			
	Do you have limits on the type of contamination that may adulterate or may lead to adulteration of the finished batch of the hemp product?			
√ IF Applicable	**Specifications must be established for each finished hemp product. DO YOU HAVE**	**YES**	**NO**	**NOTES**
	Specifications for hemp product labels and for packaging that may come in contact or quality of the hemp product?			
	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.			
	Specifications to provide sufficient assurance that the product received is adequately identified and is consistent with your purchase order.			
	Specifications for the packaging and labeling of the finished hemp products, including specifications that ensure the use of the specified packaging and the specified label.			
	Written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

2.6.2 U.S. HEMP GUIDANCE – PROCESSOR – QUALITY MANAGEMENT SYSTEMS PERSONNEL CHECKLIST				
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.				
√ IF Applicable	**Do your Quality management personnel perform the following operations?**	**YES**	**NO**	**NOTES**
	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?			
	Reviewing and approving the documentation setting forth the basis for qualification of any supplier?			
	Reviewing and approving the documentation setting forth the basis for why meeting in-process specifications, in combination with meeting component specifications, will help ensure that the identity, purity, strength, and composition?			
	Approve the Use of criteria for establishing appropriate specifications?			
	Approve the Use of sampling plans for obtaining representative samples?			
	Approve the Components, packaging, and labels for In-process materials?			
	Approve the Components, packaging, and labels for Products received for packaging or labeling?			
	Approve the Use of criteria for selecting appropriate examination and testing methods?			
	Approve the Use of criteria for selecting standard reference materials used in performing tests and examinations?			
	Approve the Use of test methods and examinations in accordance with established criteria?			
	Do the Quality management personnel review and approve the documentation of this guidance documents?			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

2.6.3 U.S. HEMP GUIDANCE – PROCESSOR – LABORATORY OPERATIONS CHECKLIST				
Industrial 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.				
√ IF Applicable	**Laboratory facilities shall be available to perform whatever testing and examinations are necessary, and produce results that are scientifically valid, with acceptable sensitivity and specificity, according to published or commonly accepted method performance requirements**	**YES**	**NO**	**NOTES**
	Test Hemp finish products and components used to determine that they meet specifications?			
	Test to meet In-process specifications as specified in the master manufacturing record?			
	Verify that the laboratory examination and testing methodologies are appropriate for their intended use, according to requirements established in ISO 17025, or consistent with published method performance requirements			
	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?			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

2.7 INDUSTRIAL HEMP GUIDANCE – 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:
    a. Meeting product specifications with valid tests and verifications for materials
    b. Ensuring the integrity of product and packaging
    c. Ensuring all documentation establishes traceability from raw materials to customer deliver, including orders, delivery notes, product labels, specifications and test results.

F. Material specifications include, where applicable
    1. Standard product name to be used in production documents, and compendia name if applicable
    2. Supplier’s product code and trade names
    3. Supplier’s name and address
    4. A unique reference code for the material specification and approval date
    5. Tests and limits for identity, purity, physical and chemical characteristics, microbiological standards (where appropriate) and assay or potency.
    6. Details of, or reference to the test methods to be used by the manufacturer;
    7. Approved or certified supplier(s) of the material;
    8. Type of packaging, storage conditions and precautions;
    9. Physical appearance and characteristics
    10. Precautions or reference to appropriate parts of a standard procedure; and
    11. 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.

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 possession 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.

2.8.2 Sampling Timeline and Grower Responsibilities

d. The grower shall refer to the jurisdiction having authority to determine a timeline.
e. During the sampling, the grower or an authorized representative shall be present at the growing site.
f. 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

e. Adequate personal protective equipment shall be used.
f. Proper equipment shall be used to prevent cross contamination.
g. The material selected for Pre-Harvest Sampling will be determined by the grower. Cuttings will be collected to make one representative sample.
h. 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

f. Samples will be taken for drying and storage.
g. Samples should be arranged in a single layer for drying.
h. Drying oven will be used when possible.
i. Samples in the oven will be left in the labeled sample bag.
j. 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

f. 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.
g. Adequate personal protective equipment shall be used.
h. Proper equipment shall be used to prevent cross contamination
i. 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
j. 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.
    viii. 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.

ix. 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 part (d) –(f).

x. For ground plant or ground floral material Post-Harvest Samples:
    7. 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).
    8. Sample material from bag or container.
    9. Sample from a minimum of four locations within the containers from a given harvest.
    10. Place the complete sample in a plastic sample container.
    11. Seal the plastic sample container.
    12. Complete sampling procedures in part (d) –(f).

xi. For Post-Harvest Samples in other forms (e.g., trimmed floral material, or floral material and stems, etc.):
    13. Ensure that the entire harvest is accounted for and in the same form (i.e., all harvested material must be uniform).
    14. Randomly collect at least one cup of material by volume.
    15. Place the complete sample in a paper bag or plastic container and seal the container, as appropriate.
    16. Complete sampling procedures in part (d) –(f).

xii. A separate sample must be taken for each plot designated for Post-Harvest Sampling.

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

xiv. Label the sample container with a sample ID.

2.8.6 Handling Procedures of Post-Harvest Samples

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

f. Industrial 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.

g. Industrial 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.

h. 100% of post-harvest samples will be tested.

2.9 TESTING AND HEMP CANNABINOID QUANTIFICATION:

2.9.1 Potency

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:

c) List only four compounds: THC, THCA, CBD, and CBDA as the main analytes of interest, with the other 10 listed in the SMPR optional.
d) List all target plant parts of hemp (flower, leaf, stalk, seed) and oils/extracts.

Cannabinoids potency methods must be able to determine the concentration of target cannabinoids to effectively distinguish cannabis as either 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 may be subject to FDA and state regulations regarding harmful substances and contaminants.

Guidance for contaminants in cannabis products (heavy metals, microbiology, pesticides and residual solvents) has been published in the American Herbal Pharmacopoiea (AHP) Cannabis monograph.

> The American Herbal Products Association has developed several guidance documents for determining the purity of botanical products, and many of these are generally consistent with AHP and other guidances for food and dietary supplement products.
> Limits for the following contaminants are listed in the following references:
> Heavy metals: AHP Cannabis Monograph/AHPA Guidance Document*
> Microbiology: AHP Cannabis Monograph**
> Pesticides: AHP Cannabis Monograph/FDA PAM
> Solvents: AHP Cannabis Monograph/USP <467>
> 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.

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 and repeating during a short time period. Expressed as the repeatability standard deviation (SD_r); or % repeatability relative standard deviation ($\%RSD_r$).

Reproducibility.—The standard deviation or relative standard deviation calculated from among-laboratory data. Expressed as the reproducibility standard deviation (SD_R); or % reproducibility relative standard deviation ($\%RSD_R$).

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

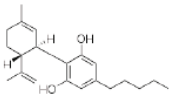
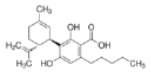
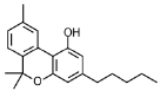
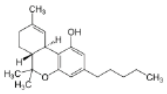
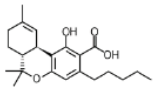
Common name	Abbreviation	IUPAC name	CAS No.	Molecular structure	Reference material
Cannabidiol	CBD	2-[(1*R*,6*R*)-6-Isopropenyl-3-methylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol	13956-29-1		Restek Cerilliant Sigma-Aldrich API Standards Echo Pharm Lipomed AG
Cannabidiolic acid	CBDA	2,4-Dihydroxy-3-[(1*R*,6*R*)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-6-pentylbenzoic acid	1244-58-2		Cerilliant USP Restek Lipomed AG Echo Pharmaceutical
Cannabinol	CBN	6,6,9-Trimethyl-3-pentyl-benzo[c]chromen-1-ol	521-35-7		Cerilliant Restek
Tetrahydro-cannabinol	THC	(−)-(6a*R*,10a*R*)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6*H*-benzo[c]chromen-1-ol	1972-08-3		Cerilliant USP Echo Pharmaceuticals
Tetrahydro-cannabinolic acid	THCA	(6a*R*,10a*R*)-1-hydroxy-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6h-benzo[c]chromene-2-carboxylic acid	23978-85-0		Cerilliant USP Echo Pharmaceuticals

Table 2. Additional, desirable cannabinoids

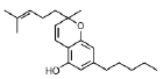
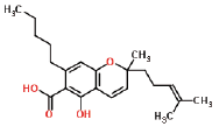
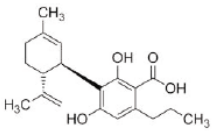
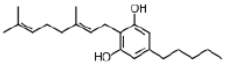
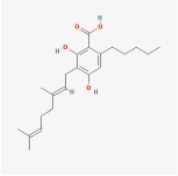
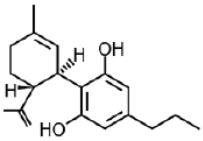
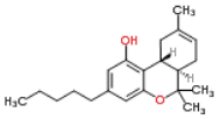
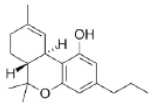
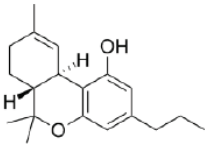
Name	Abbreviation	IUPAC name	CAS No.	Molecular structure	Reference material
Cannabichromene	CBC	2-Methyl-2-(4-methylpent-3-enyl)-7-pentyl-5-chromenol	20675-51-8		Cerilliant Sigma Aldrich Echo Pharmaceuticals
Cannabichromenic acid	CBCA	5-Hydroxy-2-methyl-2-(4-methyl-3-penten-1-yl)-7-pentyl-2*H*-chromene-6-carboxylic acid	20408-52-0		No reference material
Cannabidivarinic acid	CBDVA	2,4-Dihydroxy-3-[(1*R*,6*R*)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-6-propylbenzoic acid	31932-13-5		Cerilliant
Cannabigerol	CBG	2-[(2*E*)-3,7-dimethylocta-2,6-dienyl]-5-pentyl-benzene-1,3-diol NIST: 1,3-Benzenediol, 2-(3,7-dimethyl-2,6-octadienyl)-5-pentyl	25654-31-3 NIST: 2808-33-5		Cerilliant Lipomed AG Echo Pharmaceuticals SPEX Certiprep Tocris (UK)
Cannabigerolic acid	CBGA	3-[(2*E*)-3,7-dimethylocta-2,6-dienyl]-2,4-dihydroxy-6-pentylbenzoic acid	25555-57-1		Cerilliant Echo Pharmaceuticals SPEX Certiprep
Cannabidivarin	CBDV	2-((1*S*,6*S*)-3-methyl-6-(prop-1-en-2-yl)cyclohex-2-enyl)-5-propylbenzene-1,3-diol	24274-48-4		Cerilliant SPEX Certiprep
$^{\Delta 8}$Tetrahydro-cannabinol	$^{\Delta 8}$THC	6,6,9-Trimethyl-3-pentyl-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol	5957-75-5		Cerilliant SPEX Certiprep
Tetrahydro-cannabivarin	THCV	6,6,9-Trimethyl-3-propyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromen-1-ol	28172-17-0		Cerilliant USP
Tetrahydrocannabivarin acid	THCVA		28172-17-0		No reference material

Table 3. Method performance requirements (part 1) for cannabinoids in Table 2

Parameter	Requirement
Limit of quantitation (LOQ; %)	≤0.1
Analytical range, %	0.1–ca. 50[a]

[a] 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

	Range, %		
Parameter	0.1–1	>1–25	>25–ca. 50
Recovery, %	95–105	97–103	98–102
RSD_r, %	≤5	≤4	≤ 2
RSD_R, %	≤7	≤5	≤ 3

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.

Refer to Annex F: *Development and Use of In-House Reference Materials* in Appendix F: *Guidelines for Standard Method Performance Requirements*, *Official Methods of Analysis of AOAC INTERNATIONAL* (20th Ed.), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_f.pdf)

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 D: *Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis*, *Official Methods of Analysis of AOAC INTERNATIONAL* (20th Ed.), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_d.pdf)

Appendix F: *Guidelines for Standard Method Performance Requirements*, *Official Methods of Analysis of AOAC INTERNATIONAL* (20th Ed.), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_f.pdf)

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.

Approved by the AOAC Stakeholder Panel on Strategic Food Analytical Methods (SPSFAM) on March 13, 2017. Final Version Date: March 13, 2017.

2.10 EQUIPMENT AND UTENSILS

Equipment and multi-use utensils shall be designed, and built, to be suitable for its 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 industrial hemp from contaminations.

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 industrial hemp, or contact surface is not contaminated.

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

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

Equipment shall be properly calibrated according to the manufactures specifications.

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

Utensils intended for one-time use, (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 used.

2.10.1 U.S. HEMP GUIDANCE - PROCESSOR – EQUIPMENT CHECKLIST				
√ if Applicable		YES	NO	NOTES
	Is the equipment and multi-use utensils designed, and built for its intended use?			
	Is the equipment able to be adequately cleaned and properly maintained?			
	Is the equipment designed and build so that use will not result in the contaminations?			
	Is the equipment Installed and maintained to facilitate cleaning?			
	Is the equipment maintained to protect industrial hemp from contaminations?			
	Does the Equipment have a certificate of Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)?			
	Does the freezer, refrigerator, and all cold storage equipment have a working thermometer?			
	Is the compressed air or other gases used in such a way that the hemp, or contact surface is not contaminated?			
	Are the instruments and controls used in processing, packaging or labeling for testing hemp products calibrated to assure accuracy?			
	Are the automated, or electronic equipment used to manufacture, package, label, or hold industrial hemp, designed to ensure that hemp product specifications are consistently met?			
	Are the automated, mechanical, and electronic equipment (including software for a computer controlled process) used and operated by trained personal for proper use?			
	Are the utensils intended for one-time use, (paper cups, and paper towels etc.) stored in appropriate containers; and disposed of to prevent contamination?			
	Are the cleaning materials approved and properly labeled and stored and used under their conditions of used?			
	Is the Equipment properly calibrated according to the manufactures specifications?			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

2.11 PRODUCTION AND PROCESS CONTROL

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

Quality Management Systems in the manufacturing, packaging, labeling, and holding of industrial hemp shall ensure the quality of the industrial hemp is packaged and labeled 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 parts of the process where control is necessary to ensure the quality of the hemp products.
- For each batch or lot of finished industrial hemp products a sample shall be taken to verify, if necessary, that the batch meets its product specifications.

2.11.1 U.S. HEMP GUIDANCE - PROCESSOR - PRODUCTION & PROCESS CONTROL CHECKLIST				
√ if Applicable		YES	NO	NOTES
	Is there a process control plan?			
	Is the process control system designed and operating for intended use of processing hemp?			
	Are there written definitions and specifications for processing hemp?			
	Do you have specifications for packaging?			
	Do you have specifications for labeling?			
	Do you have quality management personal?			
	Does the quality management personal review and approve the in-process documentation for all hemp processing?			
	Does the in-process production control ensure that only specified components and ingredients are used?			
	Does the in-process production control ensure that the specified components and ingredients are limited to specifications only?			
	Is each lot or batch given a separate identity as a lot or batch number?			
	Can the lot or batch number be traced to processing or manufacturing record?			
	Is there a sample taken for each lot or batch of hemp processed?			
	Is the sample retained?			
	Is there a processing or manufacturing record?			
	Are there Labeling Operation procedures for packaging industrial hemp products			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

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 the Hemp Guidance

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 Supplement Facts 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;
    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;
        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.

2.12.1 US HEMP GUIDANCE – PROCESSOR - PRODUCTION AND PROCESS CONTROL SYSTEMS MASTER MANUFACTURING RECORD				
1. A written master manufacturing record must be produced for each hemp product that is manufactured, to ensure uniformity in every individual finished batch. 2. The master manufacturing record must identify specifications in the manufacturing process where control is necessary to ensure the quality as specified. 3. Establish controls and procedures to ensure that each batch of product meets the specifications identified in accordance the Hemp Guidance				
√ IF Applicable	**These Master Records must be kept. DO YOU HAVE**	**YES**	**NO**	**NOTES**
	The name of the product to be manufactured and the strength, concentration, weight, or measure of each hemp product for each batch size?			
	A complete list of components to be used?			
	An accurate statement of the weight or measure of each component to be used?			
	The identity and weight or measure of each hemp product ingredient that will be declared on the Supplement Facts label?			
	The identity of each ingredient that will be declared on the ingredients list of the hemp product?			
	A description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label?			
√ IF Applicable	**Written instructions, including the following – DO YOU HAVE**	**YES**	**NO**	**NOTES**
	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?			
	Procedures for sampling and a cross-reference to procedures for tests or examinations?			
	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?			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

2.13 Packaging and Labeling Industrial 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 guidelines 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:

1. This product should be used with caution when driving motor vehicles or operating heavy machinery.
2. Use this product under the guidance of a physician if you have a medical condition, are pregnant or lactating
3. Keep out of the reach of children.
4. 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 industrial hemp products.

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

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

Packaged and labeled industrial hemp shall be documented through distribution.

Packaging, labeling, and other related operations shall ensure that the quality of the industrial 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 industrial 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 industrial hemp from a finished batch of industrial hemp.

Representative samples of each batch of the packaged and labeled industrial 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.
Management 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 an industrial 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.

Hold packaging material and labels under conditions that will protect against contamination and deterioration.

2.13.4 U.S. HEMP GUIDANCE - PROCESSOR - PACKAGING AND LABELING CHECKLIST				
√ if Applicable		YES	NO	NOTES
	Is there a packaging and labeling plan to examine all incoming components and ingredients?			
	Does the packaging and labeling plan determine that the product received meets the appropriate product description?			
	Does the packaging and labeling plan determine the container damage or contamination?			
	Do the packaging and labeling operations ensure the quality of the industrial hemp products?			
	Are the issuance and use of packaging and labels to the proper personal controlled and recorded?			
	Are the packaging and labels for each lot or batch of hemp documented to that the packaging and labels conform to the manufacturing record?			
	Are the packaged and labeled hemp products documented through distribution?			
	Are the packaging and labeling equipment cleaned and sanitized as appropriate?			
	Does the packaging and labeling equipment protect hemp against all contamination?			
	Are sanitary handling procedures being used?			
	Is there physical or spatial separation of packaging and label operations implemented?			
	Are all containers identified that are set aside and held in unlabeled condition for future use?			
	Is a lot or batch number on each package of hemp?			
	Is a representative sample of each batch of the packaged and labeled hemp product kept to determine whether the product meets specifications?			
	Is obsolete or incorrect material properly disposed of to prevent future use?			
	Are records kept of the written procedures for packaging and labeling operations?			
	Do quality control procedures determine whether the received product meets the product specification?			
	Is there an approval process for the components for use in the packaging and labeling of hemp product?			
	Do the quality control procedures Identify each unique lot within each shipment of components received so that it can be tracked through the packaging, labeling, marketing and distribution processes?			
	Is the storage of components under conditions that will protect against contamination and deterioration?			
	Is there a representative sample of each lot?			
	Are the packaging materials and labels held under conditions that will protect against contamination and deterioration?			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

2.14 Storage and Distribution

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

2.14.1 U.S. HEMP GUIDANCE - PROCESSOR - STORAGE AND DISTRIBUTION CHECKLIST				
√ if Applicable		YES	NO	NOTES
	Is the industrial hemp and hemp products stored or warehoused under appropriate conditions?			
	Are the storage conditions sufficient to prevent adulteration?			
	Are the storage conditions sufficient to prevent changes in specifications of the hemp products?			
	Is the material used in-process held under adequate conditions to prevent changes in the components or ingredients?			
	Are the packaging materials stored and held in conditions to prevent deterioration?			
	Are the labels and labeling materials stored and held in conditions to prevent deterioration?			
	Is the hemp distribution plan adequate to preserve the quality of the hemp products?			
	Is the hemp distribution plan adequate to assure that the hemp products are shipped to the intended place and to the intended recipient?			
	Is the Storage of hemp and hemp products properly labeled at all times to prevent contaminations and unintended comingling?			
	Is the Storage of hemp and hemp products properly labeled to indicate a hold or available for release?			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

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:

   i. Identify those responsible for initiating, managing and investigating a product withdrawal or recall;
   ii. Describe the procedures to be implemented by site management;
   iii. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident.
   iv. 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.

2.15.1 U.S. HEMP GUIDANCE – PROCESSOR - PRODUCT COMPLAINTS ADVERSE EVENTS, AND RECALLS CHECKLIST				
Quality Management operations for Product Complaints must include reviewing and approving decisions about whether to investigate a product complaint, review and approve the findings and follow-up action of any investigation performed.				
√ IF Applicable	**The following Product Complaint, Adverse Event, and Recall records must be kept.**	**YES**	**NO**	**NOTES**
	Do you have written procedures for the quality management operations, when a product complaint is received?			
	Do the procedures include a review and making a disposition decision for approving or rejecting any reprocessing;			
	Do you have written documentation that quality management personnel performed the review, approval, or rejection?			
	Does the documentation include the Date that the review, approval, or rejection was performed.			
	Does it include signature of the person performing the review, approval, or rejection			
	Does it include documentation of any material review and disposition decision and follow-up of the material involved in the complaint?			
	Does the documentation include the appropriate batch production record?			
	And Identification of the specific deviation or the unanticipated occurrence			
	And description of your investigation into the cause of the deviation from the specification or unanticipated occurrence			
	And evaluation of whether or not the deviation 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;			
	Identification of the action(s) taken to correct, and prevent a recurrence of, the deviation or the unanticipated occurrence			
	An explanation of what you did with the component, hemp products, packaging, or label;			
	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			
	Documentation of all quality investigations and corrective actions exists			
	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			
	A record of destruction of material, if disposition action includes destruction of material.			
	A record exists for all adverse events and recalls.			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____

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 industrial 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 meet requirements that
   a. are equivalent to those set out in these Guidelines and
   b. ensure that the viable grain will not produce a plant containing more than 0.3% THC w/w in its leaves and flowering heads.

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 industrial 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 industrial 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 industrial hemp is to be imported, the quantity (weight) of each form, the type of packaging, the variety of industrial hemp, if applicable, the country of origin of each form of the industrial 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 industrial 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 industrial hemp shall ensure that a copy of the import permit is attached to the shipment of the industrial hemp.

2.16.2 Export

A. (1) An exporter who applies for a permit to export industrial 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 industrial 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 industrial hemp is to be exported, the quantity of each form, the variety of industrial hemp, if applicable, the country of origin of each form of the industrial 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 industrial 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 industrial hemp shall ensure that a copy of the export permit is attached to the shipment of the industrial hemp.

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

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 industrial hemp seed (imported or purchased or grown), name and address and the country of origin.
- Form in which the industrial hemp is imported or processed.
- Quantity of each form of industrial hemp imported, purchased or sold.
- Destination of the industrial hemp that is sold, name and address of the purchaser and the country, to which it is exported.
- Date that each shipment of industrial hemp is sent or received.
  - Name of the carrier,
  - Results of any tests,
  - Quantity shipped,
- Written procedures of production processes.
- 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.

2.17.1 U.S. HEMP GUIDANCE – PROCESSOR - RECORD RETENTION CHECKLIST				
√ if Applicable	***ALL RECORDS ARE TO BE KEPT FOR 5 YEARS***			
	DO THE RECORDS INCLUDE THE FOLLOWING?	**YES**	**NO**	**NOTES**
	Name, address and country of origin?			
	Name and license of person who grew or sold the seed?			
	Form of the industrial hemp is imported or processed?			
	Quantity of the hemp imported, purchased or sold?			
	Written procedures for processing?			
	Written procedures for packaging and labeling?			
	Processing records including components, ingredients, time, and lot or batch number?			
	Packaging records including labels?			
	Destination of hemp sold, name, address?			
	Date of shipment, name of carrier?			
	Quantity of hemp shipped?			
	Results of any and all tests?			
	All available all images of products and labels?			
	Any and all certification documents?			

Signature: _____ **Date:** _____

Printed Name: _____ **Company/Location:** _____