

June 1, 2021

The Honorable Tom Vilsack Secretary of Agriculture U.S. Department of Agriculture 1400 Independence Avenue SW Washington, DC 20250

### **RE: Revised Colorado State Hemp Management Plan**

Dear Secretary Vilsack:

Thank you for your recent visit to Colorado. We deeply appreciated you joining us at several locations across our state. As you know, Colorado has been at the forefront of efforts to develop a robust hemp industry since the Colorado Department of Agriculture (CDA) launched a hemp pilot program in 2014. Since then, Colorado has been a national leader in hemp, rapidly scaling up production, launching an innovative certified seed program, diversifying supply chains, and most recently rolling out an initiative to establish a statewide Hemp Center of Excellence.

CDA has strongly advocated for a workable federal regulatory scheme for hemp. After USDA published an Interim Final Rule (IFR) for hemp in January 2020, CDA submitted detailed and comprehensive comments, met with senior USDA officials, and marshalled stakeholder and legislative responses with the goal of improving the outcome of the Final Rule to make it more flexible for hemp producers. In January 2021, USDA responded to these efforts by publishing a vastly improved and revised Final Rule. While CDA will continue to advocate for additional rule revisions to create even more flexibility for producers, we are proud to submit the enclosed Colorado State Hemp Management Plan to USDA for approval.

Although we are submitting a state plan today that we hope USDA will expeditiously approve, we request that USDA continue to review the Final Hemp Rule with an eye toward making it more flexible and practicable for hemp producers in Colorado and across the country.

Thank you for your consideration of our submitted State Plan.

Sincerely,

Jared Polis, Governor Kate Greenberg, Agriculture Commissioner



#### Colorado's Hemp Program

Colorado's citizens voted to pass Amendment 64 to the Colorado Constitution in 2012, which, in part, directed the General Assembly to enact legislation governing the cultivation, processing, and sale of hemp. Legislation adopted in 2013 delegated the responsibility for establishing registration and inspection regulations pertaining to hemp cultivation to CDA. For reference, statutory authority for Colorado's Industrial Hemp Program is set forth in Title 35 Article 61 of the Colorado Revised Statutes (the "Act", Appendix A). CDA has promulgated a comprehensive set of rules to administer and enforce the Colorado Industrial Hemp Regulatory Program Act, which is codified at 8 CCR 1203-23 and is included in Appendix B (the "Rules").

Paired with these measures, the passage of the 2014 Farm Bill, which allowed states that had legalized hemp to implement hemp cultivation pilot programs for research purposes, marked the inception of the hemp industry in Colorado. Since then, Colorado's hemp program has successfully implemented robust requirements for registration, testing, inspection, and enforcement, and has been in place for over five years.

In addition to the other regulatory and statutory measures that aided the success of Colorado's hemp industry, the Colorado General Assembly created the Hemp Advisory Committee (HAC) in 2013. Colo. Session Laws 2013, ch. 342 (enacting SB 14-184). The HAC has helped further establish the country's first regulated hemp industry. The eleven-member committee includes representatives from CDA, the hemp industry, commercial agriculture, higher education, and citizen advocates. Since 2013, the HAC has provided vital input to the Industrial Hemp Regulatory Program. With input from the HAC, CDA developed the elements of its regulatory scheme, including systems for registration, compliance testing, reporting, enforcement, and inspection.

 $<sup>^1</sup>$  As defined in the Colorado Revised Statutes, and in the 2018 Farm Bill, the term "industrial hemp" means the plant species *Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a  $\Delta$ -9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

<sup>&</sup>lt;sup>2</sup> The CDA Industrial Hemp Program's regulatory role is limited to industrial hemp cultivation (growing). The program does not regulate the sale or distribution of industrial hemp. The Colorado Department of Public Health & Environment ("CDPHE"), pursuant to CRS 35-61-108, permits registered persons in the state of Colorado to carry out the processing, sale, and distribution of industrial hemp-based products

<sup>&</sup>lt;sup>3</sup> Hemp FAQ: https://drive.google.com/file/d/1UTKi0RSQUYANd0Q9TAePkBk07jhXWdda/view

<sup>&</sup>lt;sup>4</sup> CDA's current rules, effective March 30, 2019, are undergoing rule-making, consistent with Colorado's Administrative Procedures Act, section 24-4-103, C.R.S. On May 25, 2021, CDA conducted a rule-making hearing, and the proposed rules will be reviewed by the Agricultural Commission on June 9, 2021, for recommendation to the Commissioner to adopt, effective July 30, 2021. The Notice of Public Rulemaking Hearing, along with the proposed changes to the rules, are attached to this document as Appendix B. References to the Rules in this State Plan are to the Rules that will be effective on July 30, 2021, even though they have not been formally adopted as of the date of this submission.

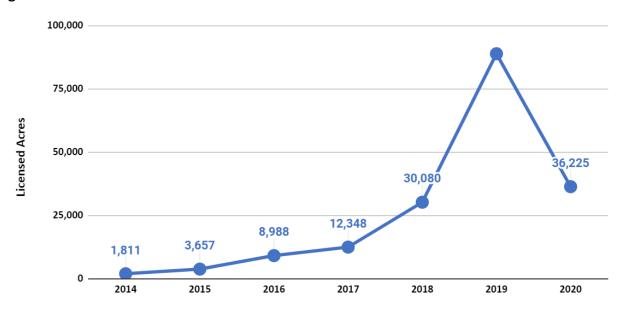


Between 2014 and 2019, CDA continuously revised the Rules to improve registration, data tracking, definitions, and reporting. The Act and Rules are designed with purposeful flexibility to anticipate technology changes, federal regulations, including USDA's Final Rule, "Establishment of a Domestic Hemp Program," 7 CFR Part 990 (the "Final Rule" or "FR"), and future revisions to the FR.

Since late 2019, CDA has operated a custom-developed, secure, online-registration system that stores all registrant information, cultivation location, planting/harvest/testing reports, and enforcement action records.

Importantly, the success of Colorado's hemp program is the result not only of the robust state regulatory environment, but also of the community of hemp cultivators, product manufacturers, and ancillary business operators and stakeholders who have helped drive the growth of the program. In 2014, the first operational year of Colorado's hemp program, 1,811 acres were registered with CDA for hemp cultivation. In the following years, the number of acres registered with CDA for hemp cultivation grew exponentially, as illustrated in Figure 1. However, in 2020 the amount of registered outdoor acreage and indoor square feet significantly declined as a result of over supply and market correction across the industry.

Figure 1.



#### **Colorado Acres Registered for Hemp Cultivation**

As the first state to establish a hemp industry regulatory structure, Colorado rapidly developed into the state with the largest number of acres under hemp cultivation in the nation. Colorado continues to be a national leader in innovative hemp policy and industry



performance by combining its first-mover advantage with its extensive experience regulating, through distinct channels.

The table below, Figure 2, provides information on CDA's Hemp Program registration, registered land area, staff, and budget. By all measures, the program has grown exponentially and CDA's regulatory footprint has expanded along with registrations and acreage. During the 2020 Colorado legislative session, CDA received approval from Colorado's Joint Budget Committee to increase CDA's spending authority in fiscal year 2021 (FY 2020-2021). CDA will continue to grow the regulatory program to scale with the industry.

Figure 2.

CDA Hemp Program Key Indicators, 2014 – 2019

Year	Active Registrants	Registered Acres	Active Registrations	Registered Indoor Sq. Ft.	Dedicated Staff (FTE)*	Annual Expenditure
2014	131	1,811	259	0.3m	N/A	N/A
2015	166	3,657	333	0.6m	N/A	\$322,863
2016	312	8,988	424	1.4m	4.2	\$402,766
2017	404	12,348	539	2.6m	4.4	\$485,425
2018	872	30,080	982	4.6m	4.7	\$492,407
2019	1,947	88,743	2,634	15.4m	7.0	\$573,547
2020	981	36,225	1,254	11m	7.0	\$476,792

\* The hemp program shared staff/budget with the Plant Industry Division in 2014-2015.

Source: Colorado Department of Agriculture.

### **Colorado Hemp Advancement and Management Plan (CHAMP)**

During the 2019 legislative session, Colorado's General Assembly amended the Hemp Regulatory Act to authorize the Commissioner of Agriculture to consult with any stakeholders and to mandate that the Commissioner of Agriculture consult with the industry in drafting any hemp management plan submitted to USDA. C.R.S §35-61-104(6). Colo. Session Laws 2019, ch. 349 (enacting HB 19-1214). In response to this legislative authorization and mandate, the passage of the 2018 Farm Bill, the anticipated publication of the IFR, and Governor Jared Polis's stated priority for Colorado to remain a driving force in hemp production, CDA developed a statewide partnership known as CHAMP in June 2019.

CHAMP represented a broad stakeholder effort. CHAMP included representatives from CDA, the Governor's Office, Department of Public Health and Environment, Department of Revenue, Department of Regulatory Agencies, Office of Economic Development and International Trade, Department of Public Safety, Colorado Commission of Indian Affairs,



Department of Higher Education, local governments, state institutions of higher learning, and industry and ancillary experts. Together this group of stakeholders developed the gold standard in policy for cultivation, testing, research, processing, manufacturing, banking, and marketing for Colorado's hemp industry. The goal of the CHAMP process was to develop a robust and functional hemp supply chain and to establish a strong market for Colorado farming communities.

CDA created CHAMP to ensure that a wide range of stakeholders, including members of the public, would have multiple opportunities to comment on and participate in a variety of hemp topics. Ultimately, the resulting policy recommendations presented in this Plan and in the <a href="CHAMP">CHAMP</a> Report outline the state's ambitions for the hemp industry, representing a consensus of the largest gathering of hemp industry and government stakeholders held in any state to date.

#### **Colorado State Hemp Plan for USDA**

The 2018 Farm Bill and FR require each state or tribe that desires to have primary regulatory authority over the production of hemp within its boundaries to submit a management plan to USDA that outlines how the state or tribe will regulate various aspects of hemp cultivation. After enactment of the 2018 Farm Bill, USDA published nine requirements for states and tribes that intend to develop a hemp regulatory program. In January 2021, USDA issued the FR to further clarify the requirements necessary for USDA to approve such plans.

This section describes how the state of Colorado intends to implement the FR requirements through existing and updated statutory authorities, rules, and procedures. All authorities described in this Plan are either currently in effect or are intended to take effect after USDA approval and before January 1, 2022, and are intended to govern Colorado's hemp industry beginning with the 2022 growing season. Bold text in the sections below represents language taken directly from the FR.

#### 1. Land Registration – 7 CFR 990.3(a)(1)

The FR requires State and Tribal Plans to have practices and procedures to collect, maintain and report Land Used for Production, relates to states' and tribes' registration and record-keeping processes. To maintain a robust, compliant, and transparent hemp industry, a timely record of all land used for hemp cultivation must be maintained:

<sup>&</sup>lt;sup>5</sup> https://www.ams.usda.gov/sites/default/files/media/2018FarmBill.pdf



A State or Tribal plan must include a practice to collect, maintain and report to the Secretary relevant, real-time information for each producer licensed or authorized to produce hemp under the State or Tribal plan regarding:

- (i) Contact information as described in § 990.70(a)(1);
- (ii) A legal description of the land on which the producer will produce hemp in the State or territory of the Indian Tribe including, to the extent practicable, its geospatial location; and
- (iii) The status and number of the producer's license or authorization in a format prescribed by USDA.

#### 7 CFR § 990.3(a)(1) (86 Fed. Reg. 11 p. 5683).

Colorado's Hemp Regulatory Program, C.R.S. § 35-61-101, et seq., (2020), (the "Act") requires that any person "wishing to engage in industrial hemp cultivation ... shall apply to the department for a registration in a form and manner determined by the commissioner prior to planting the industrial hemp." C.R.S. § 35-61-104(1)(a). The Act further requires that such persons must provide to the commissioner "the name and address of the applicant and all key participants and the legal description, global positioning system location, and map of the land area on which the applicant plans to engage in industrial hemp cultivation." *Id.* 

The Act further authorizes the Commissioner of Agriculture ("Commissioner") to promulgate rules "necessary to implement and administer [the Act]." C.R.S. § 35-61-104(5). This rule-making authority permits the Commissioner to enact rules to specify any additional requirements necessary for the applicant to include in a registration. The Commissioner has promulgated such rules, codified at 8 Colo. Code Regs. 1203-23, "Rules Pertaining to the Administration and Enforcement of the Industrial Hemp Regulatory Program Act." Appendix B.

As set forth in the following paragraphs, the Rules regarding registration require registrants to provide all information required in the FR. Further, should any need arise to adjust or amend the information requested from producers, CDA has current rule-making authority that would permit the agency to amend its rules and update its registration requirements. C.R.S. § 35-61-104(5). If CDA promulgates and adopts any amendment to its rules that would modify Colorado's plan, CDA will submit those amended rules to USDA for its approval. Rules 2.1 and 2.2 (Appendix B) establish the information the Commissioner requires from an applicant at the time of application, including those items required in § 990.70(a)(1). Further, Rule 2.14 requires any registrant who makes a change to any of their contact information to update the Commissioner within 10 days of the change.

CDA has always encouraged the development of improved genetics by administering a Certified Seed Program and providing separate requirements for those producing hemp for research purposes. For this reason, CDA plans to continue to offer a separate registration



for those hemp producers cultivating hemp for the purposes of research and development. In addition to institutions of higher learning, CDA will register other public and private producers engaged in doing research and development as long as hemp produced does not enter the stream of commerce. CDA will develop requirements to include providing CDA with the scope of research, a standard operating procedure to include verification of disposal, and disclosing all testing data for periodic auditing by CDA. In addition, CDA requests R&D registrants provide information on intended use, including intended use of harvested crops for testing (e.g., fiber, textile, and seed).

Pursuant to the Rules, CDA requires applicants to complete an annual Registration Application, attached in Appendix C. Historically, a person who desired to register land to cultivate hemp would complete and submit a paper application to CDA for approval. However, as of November 15, 2019, CDA has made the application process available online. This new, online registration process offers CDA the ability to provide real-time updates to USDA as required by 990.70(a)(1) and expedites the data collection process for compliance, enforcement, and reporting.

At the time of application, and pursuant to Rules 2.1 and 2.2, an applicant must describe the type of ownership of any entity, including listing all owners; provide a legal description (Township/Range/Section), including GPS coordinates and a map of the land; describe the size of the operation; provide the intended nature of the cultivation (*e.g.*, indoor or outdoor); and provide the intended seed variety and end use (*e.g.*, fiber, seed, CBD, etc.). The application form further requires full contact information for each hemp producer, as required in 7 CFR § 990.70(a)(1). CDA, therefore, currently collects annual information for each registered grow site; thus, CDA's current procedures exceed the requirements of the FR.

CDA maintains a database that contains current and historical registration data, including the status of any given registration, as well as any changes made since the registration's creation. This database can also link individual registrations to a common registrant. Each registration contains all pre-planting, planting, testing, harvest, and disposal reports. CDA's system is updated in real-time as each registration is processed or amended. CDA has the capability to provide real-time information to USDA upon request and in regular monthly reporting, as required by 990.70(a)(1).

The CDA hemp registration program has been active since 2013, and as all historical records have been retained to date since inception of the program, the program thus exceeds the FR's three-year record retention requirement. CDA will adopt an official procedure noting that "all records must be maintained for not less than three years," which will be effective on or before December 30, 2021. In addition, CDA will require, via Rule, each registrant to maintain a parallel set of all hemp program registration, planting, testing, disposal, land, and employee records for at least three years. This information will be required to be made available to CDA when requested.

<sup>&</sup>lt;sup>6</sup> https://www.colorado.gov/pacific/agplants/commercial-registration-application



#### 2. Sampling and Testing – 7 CFR § 990.3(a)(2)

The FR's sampling and testing rules are set forth at 7 CFR § 990.3(a)(2) and discussed in the FR's summary in Sections II.C and D: State and Tribal Plans; Sampling for Total THC and Testing Laboratories.

A State or Tribal plan must include a procedure for accurate and effective sampling of hemp that includes the requirements in this paragraph (a)(2).

### 7 CFR § 990.3(a)(2) (86 Fed. Reg. 11 p. 5683).

Given Colorado's long-standing history of regulating hemp, the state has established well-defined, efficient, and effective processes for sampling and THC-testing techniques for cultivated hemp.

In 2020, CDA sampled 35 percent of all hemp registrants for both general regulatory compliance and THC analysis. Currently, CDA's process for selecting registrants for sampling is performed with a computerized randomization process. Further, any producers that CDA identifies as high-risk, based on predetermined criteria, are subject to enhanced sampling and testing. The risk factors taken into consideration include:

- Prior testing results above 0.3 percent THC content;
- Prior violations including:
  - Failure to submit planting/harvest reports within the required time frame;
  - o Failure to respond in a timely manner to notice of inspection;
  - o Failure to provide required information or to cooperate with CDA; and
- Complaints made by law enforcement, regulatory agencies, local governments, and/or the public.

While CDA has historically conducted random sampling across all registered lots each year to test for THC compliance, the Commissioner has authority pursuant to the Rules to test all hemp produced within the state—8 CCR 1203-23, (Rules 4.1 and 4.2) (Appendix B). CDA will enhance its well-developed inspection and sampling procedures to comply with the requirements of the FR including performance based sampling (see Appendix E).

CDA will conduct sampling by use of its own sampling staff and by use of authorized sampling agents, consistent with its current practices and procedures, as described more fully in CDA's Sampling Guidelines (Appendix D) to ensure continuity of CDA's practice of accurate, efficient, and effective sampling. CDA will require that all sampling agents, whether CDA staff or private-party sampling agents, complete CDA's hemp-specific sampling training, as set forth in the following paragraphs. CDA will strive to increase its current direct sampling rate towards 100 percent of registrations during the 2021 growing season as well as its direct compliance inspections through its random selection process, as



outlined above, to monitor additional regulatory compliance, including record-keeping and reporting.

CDA will achieve taking a representative sampling of all hemp lots, starting with the effective date of the plan in January 2022. In the 2020 legislative session, Colorado's General Assembly amended the Act to require the Commissioner to create a registration and certification program for authorized samplers. C.R.S. § 35-61-105.5(1). The Commissioner's general rule-making authority to adopt rules "necessary to implement and administer [the Act]" (C.R.S. § 35-61-104(5) provides the authority to adopt rules necessary to establish this certification program. The Commissioner's proposed rules to establish this program are in 8 CCR 1203-2 (Part 4.8), in the attached Appendix B, and will be effective July 30, 2021.

To acquire certification as an authorized sampler, an applicant must register with CDA and complete certification training in accordance with CDA's Hemp Sampling Guidelines (Appendix D). The certification training will permit CDA to ensure that every certified sampler follows CDA's strict sampling guidelines when collecting hemp samples, including procedures related to sample collection, transportation, and documentation. All third-party samplers will also receive training and be required to comply with special chain-of-custody procedures for collection and transfer of hemp samples to eligible laboratories.

Anyone interested in becoming a certified hemp sampling agent will have to meet the following criteria:

- 1. A candidate will be required to participate in an online training program, zoom training or in person training. They will need to review all associated documents including forms, rules and protocols associated with the certified hemp sampling program.
- 2. A candidate will need to receive a score of 80% or higher on a state administered hemp sampler certification exam that will be written by the Hemp Certification Sampling Coordinator.
- 3. A candidate will complete an application, pay an application fee, and sign a conflict of interest document. The conflict of interest statement will state: "As a certified hemp sampling agent, I aver that I do not have an active hemp registration or active economic interest in a hemp registration within the state of Colorado."

Certification will last one year. Appropriate recordkeeping and reporting, adherence to CDA sampling protocol, and other standards provided during the training are required to maintain certification. A certified hemp sampling agent is not authorized to access any fields, buildings or facilities without the presence of the registered producer or the registered producer's appointed representative. A certified hemp sampling agent may not collect or retain any plant material that exceeds the required quantity for sample purposes.

CDA's Hemp Certification Sampling Coordinator will oversee the recruitment, training, testing and certification of all certified hemp sampling agents. He or she will make any



necessary modifications to sample collection guidelines to satisfy state and federal requirements. The Hemp Certification Sampling Coordinator will continuously conduct quality control to ensure sampling is completed in a consistent and uniform manner.

A list of certified hemp sampling agents will be provided on a platform for the hemp producers to choose, or the Colorado Department of Agriculture will choose for them. The Colorado Department of Agriculture will be working in conjunction with the Colorado Department of Public Health and Environment to use only actively licensed, certified labs for THC testing and assist the Colorado Department of Public Health and Environment to conduct quality control measures in laboratory services and ensure testing is consistent and uniform.

Once this program is operational, third-party authorized samplers will collect hemp samples on behalf of CDA and deliver them to certified laboratories for THC testing. CDA will offer sampler certification to qualified agricultural service providers or to other qualified entities and individuals.

All sampler certification information will be maintained in a secure CDA database that will be accessible to USDA upon request, including contact information and documentation of all samples taken and delivered. Initial applicants must pay an application fee to CDA, and CDA will review all certifications annually. Any certified sampler who desires to renew a certification must pay an annual renewal fee to CDA.

As of the writing of this document, there are two DEA-certified labs in Colorado identified on the USDA website. The CDA laboratory is currently ISO 17025 accredited (Appendix F) and has begun the process to obtain DEA certification. Once certified, the CDA lab will become the third DEA-certified testing facility in Colorado. To ensure that the state can sample and test hemp lots for THC, CDA partnered with the Colorado Department of Public Health and Environment (CDPHE) in efforts to create and implement a state-certified laboratory THC testing program.

To acquire hemp-THC-testing certification, an applicant laboratory must be inspected by CDPHE prior to initial certification and annually thereafter. Certification is contingent upon successful on-site inspection, successful participation in proficiency testing, and evidence of ongoing compliance with the applicable requirements.

A certified laboratory must meet all standards of performance, including personnel qualifications, having a standard operating procedure manual, analytical processes, proficiency testing, quality control, quality assurance, security, chain of custody, sample retention, space, records, and results reporting.

CDPHE implemented its rule "Hemp Testing Laboratory Certification," 5 CCR 1005-5, on April 14, 2021. This rule establishes "criteria for the certification of laboratories to test

<sup>7</sup> https://www.ams.usda.gov/rules-regulations/hemp/dea-laboratories?field\_state\_tid=168 (last checked March 4, 2021).



Hemp and hemp-derived products" (*Id.* at Rule 1.2) and complies with the USDA's Laboratory Approval Program described in the FR. The state program ensures that only qualified laboratories that use good laboratory practices, have rigorous quality assurance and control protocols, and use only established methods performed on accepted equipment acquire certification to participate in the program. CDPHE performs regular on-site audits of labs in the program and administers a fee for participation.

CDA will rely upon CDPHE to inspect applicant facilities prior to issuing certifications or renewals to ensure that they meet all USDA and CDA requirements. The program will offer two tiers of approval for hemp THC testing laboratories in Colorado:

- **Certified laboratories**--certification will be granted when laboratories have met all certification requirements of the FR, including ISO/IEC 17025 accreditation and DEA registration; and
- **Conditionally Certified laboratories** will be laboratories that are already CDPHE-certified or have met all CDA and CDPHE certification requirements, but have not received DEA certification prior to January 2023. (5CCR 1005-5 Hemp Testing Lab Certification Rules in Appendix G.)

It is CDA's intention to process all samples for testing through the CDA laboratory or certified laboratories, as described above, where practicable. Therefore, CDA plans to use conditionally approved laboratories, described above, to ensure sufficient testing coverage within the USDA-required timeline.

This approach will permit the state to leverage the considerable investment it has made in certified cannabis and cannabinoid testing capacity and enhance the state's ability to test samples collected from registered hemp lots through the 2021 and 2022 growing seasons.

All participating laboratories will report test results to CDA and USDA electronically in real time starting in the 2022 growing season.

Further, FR section 7 CFR § 990.3(a)(2)(i) states:

(i) Samples from cannabis plants must be collected within 30 days prior to the anticipated harvest, for total delta-9 tetrahydrocannabinol concentration level testing. Samples must be collected by a sampling agent. Producers may not collect samples from their own growing facilities.

7 CFR § 990.3(a)(2)(i) (86 Fed. Reg. 11 p. 5683).

CDA's Rule provides that "[a]t least 30 days prior to harvest, each Commercial Hemp Registrant shall file a Harvest Report, on a form provided by the Commissioner . . . ." Appendix B, p. B-4; 8 CCR 1203-23, Rule 3.3. Failure to comply with the Rule is grounds for disciplinary action. Appendix A p. A-5, C.R.S. § 35-61-107(1)(a). This 30-day requirement



permits CDA to dispatch field inspectors effectively and efficiently to rural and often remote areas of the state to collect samples to comply with CDA's testing requirements.

To achieve the most accurate testing results, CDA or a state-certified sampler, must schedule the testing date based on a producer's submitted Harvest Report. CDA or a state-certified sampler will schedule and conduct sampling within 30 days prior to the anticipated harvest date, consistent with the FR's requirement that samples be collected within "30 days prior to the anticipated harvest." 7 CFR § 990.3(a)(2)(i). For purposes of THC-testing to determine compliance with state and federal law, CDA restricts all sampling either to CDA or to state-certified samplers. Producers may not collect samples from their own growing facilities.

CDA will use its Hemp Sampling Guidelines, Appendix D, both for training and in the field by CDA inspection staff and authorized samplers. The training and operating manual has been updated specifically to provide that:

- Sampling is to be completed within 30 days from harvest;
- Registrants must have all files, including harvest reports with maps, available (authorized agent must be present), at time of inspection. This may be necessary if the registrant fails to provide harvest or updated harvest report; and
- All Cannabis lots not subject to performance based sampling methods within a Registered Land Area must be sampled to ensure compliance with the Hemp Program.

Additionally, if a Registrant needs to amend a reported harvest date, 8 CCR 1203-23, Rule 3.3) (Appendix B) requires that "[a] Registrant must notify the Commissioner immediately of any changes in the reported harvest date(s) in excess of 5 days by submitting an Amended Harvest Report to the Commissioner. If any such changes are made the Commissioner may require additional testing prior to harvest...." This provision in CDA's Rule will aid in compliance with the FR testing requirements.

7 CFR § 990.3(a)(2)(iii) requires that each state establish a proper sampling procedure that ensures that the testing results from each sample are representative of the entire lot.

(iii) The method used for sampling must be sufficient at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level and ensure that a representative sample is collected that represents a homogeneous composition of the lot. Alternatively, States and Tribes may adopt a performance-based method that meets the requirements in paragraphs (a)(2)(iii)(A) and (B) of this section.

7 CFR § 990.3(a)(2)(iii) (84 Fed. Reg. 221 p. 5683).



The CDA Hemp Sampling Guidelines in Appendix D instruct authorized samplers to collect a representative sample of each lot and to adjust their sampling density according to each field. Similar to the FR, CDA currently requires at least one plant per acre, although that can vary by physical characteristics of each field. This method provides sampling sufficient enough to achieve the confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level.

The following sections 7 CFR § 990.3(a)(2)(iv) and (v) provide:

- (iv) During a scheduled sample collection, the producer or an authorized representative of the producer shall be present at the growing site if possible.
- (v) Sampling agents shall be provided with complete and unrestricted access during business hours to all hemp and other cannabis plants (whether growing or harvested), to areas where hemp is grown and stored, and to all land, buildings, and other structures used for the cultivation, handling, and storage of all hemp and other cannabis plants, and all locations listed in the producer license.

7 CFR § 990.3(a)(2)(iv), (v), and (vi) (84 Fed. Reg. 221 p. 5683).

CDA's Rule 4.5 mandates that the Registrant or an authorized representative be "present at the growing operation" during CDA's inspection. *See* 8 CCR 1203-23, Rule 4.4; Appendix B, p. B-6. Rule 4.5 requires that said Registrant or authorized representative, at the time of inspection, must "provide the Department's Inspector with complete and unrestricted access to all Cannabis plants, parts and seeds within a Registered Land Area whether growing or harvested, and all land, buildings and other structures used for the cultivation and storage of Hemp." *Id.* 

The final sampling requirement in this section of the FR provides: "A producer shall not harvest the cannabis crop prior to samples being taken." 7 CFR § 990.3(a)(2)(vi) (84 Fed. Reg. 221 p. 5683) (emphasis added).

In the 2020 legislative session, Colorado's General Assembly amended the Act to prohibit producers from harvesting hemp crops prior to sampling. *See*, C.R.S. § 35-61-105.5(2)(c). Further, CDA's Rules prohibit pre-testing harvest. 8 CCR 1203-23, Rule 4.6.5; Appendix B, p. B-4. As such, any pre-testing harvest or movement of a hemp crop is a violation of state law and subjects the registrant to discipline.

3. Testing Methodology and Non-compliant Hemp – 7 CFR § 990.3(a)(3)



To ensure that all hemp produced is in compliance with federal laws regarding THC content, 7 CFR § 990.3(a)(3) and FR Summary Section II.C and D: Sampling for Total THC and Testing Laboratories require a robust testing procedure.

A State or Tribal plan must include a procedure for testing that is able to accurately identify whether the sample contains a total delta-9 tetrahydrocannabinol content concentration level that exceeds the acceptable hemp THC level. The procedure must include a validated testing methodology that uses post decarboxylation or other similarly reliable methods.

The testing methodology must consider the potential conversion of THCA in hemp into THC and the test result must report the total available THC derived from the sum of the THC and THCA content. Testing methodologies meeting the requirements of this paragraph (a)(3) include, but are not limited to, gas or liquid chromatography with detection. The total THC concentration level shall be determined and reported on a dry weight basis.

#### 7 CFR § 990.3(a)(3) (86 Fed. Reg. 11 p. 5683-5684).

This Plan presents a robust set of protocols for meeting the testing requirements of the FR. CDA's Division of Laboratory Services has developed its Biochemistry Laboratory SOP No.: PT-LBOP-014, titled, "Hemp Sample Preparation," to establish laboratory standard operating procedures (SOP) for hemp sample preparation for THC analysis (Appendix H). This SOP outlines the specific methods to be applied when collecting, drying, sorting, and grinding individual hemp samples.

The CDA Division of Laboratory Services, which houses the CDA Biochemistry Laboratory, has developed its SOP No. PT-METH-031, titled, "Determination of Delta-9-THC in Hemp by Gas Chromatography with Flame Ionization Detection ("GC/FID")." Appendix I. This operating procedure requires that industrial hemp THC testing be conducted with the use of an Agilent 6890N Gas Chromatograph with a Flame Ionization Detector, or equivalent equipment and similarly reliable method, and describes procedures for the THC testing process for hemp plant material. In this document, sample preparation is described in detail, along with the equipment and chemical parameters of the testing process, and reporting requirements and formatting.

All hemp THC testing at the CDA Biochemistry Laboratory is performed using a post-decarboxylation technique (GC/FID), as required by USDA. CDA chose the GC/FID technique because of its efficiency, relative ease of use, accuracy, reliability, and the replicability of results. Approved and conditionally approved laboratories will use GC/FID or other similarly reliable methods. All laboratories will report results to CDA and USDA with THCA, delta-9 THC, total THC and the laboratory-specific margin of uncertainty (MU) on a dry weight basis as required in the FR. The state-certified lab program also outlines



approved testing methodologies (Appendix G, p. 85-96), and provides chain of custody and reporting requirements for THC content (Appendix G, p. 96-97).

As the Colorado hemp program has matured, both CDA and Colorado hemp producers have made significant strides towards improving THC compliance results. Over the past five years the non-compliant rate has been cut by about half, from 31 percent of tested lots in 2014 to 16 percent in 2020, even as the testing rate doubled, and total acreage increased 50-fold.

7 CFR § 990.3(a)(3)(i) requires the following:

Any test of a representative sample resulting in higher than the acceptable hemp THC level shall be conclusive evidence that the lot represented by the sample is not in compliance with this part and shall be disposed of or remediated in accordance with § 990.27.

7 CFR § 990.3(a)(3)(i) (86 Fed. Reg. 11 p. 5684).

Under 7 CFR § 990.27, however, a producer may choose either to conduct on-site destruction of hemp that tests above the acceptable hemp THC limit or to remediate the product.

- (a) Cannabis plants exceeding the acceptable hemp THC level constitute marijuana, a schedule I controlled substance under the Controlled Substances Act (CSA), 21 U.S.C. 801 et seq., and producers must either use a DEA-registered reverse distributor or law enforcement to dispose of non-compliant plants or ensure the disposal of such cannabis plant on site at the farm or hemp production facility.
- (b) Producers must notify USDA of their intent to dispose of or remediate non-conforming plants and verify disposal or remediation by submitting required documentation.
- (c) If a producer elects to perform remediation activities, an additional sampling and testing of the post-remediated crop must occur to determine THC concentration levels.

7 CFR 990.27(a), (b), and (c) (86 Fed. Reg. 11. p. 5688).

The Hemp Sampling Guidelines (Appendix D) describe detailed sample collection procedures for remediation. These guidelines describe remediation as the process of rendering non-compliant cannabis compliant. A producer may remediate by removing and destroying flower material, while retaining stalk, stems, leaf material, and seeds. A producer may also remediate by shredding the entire plant into a biomass-like material and request re-testing by an authorized sampler of the shredded biomass material for



compliance. Producers will be responsible for all remediated sampling and testing costs. By allowing for remediation sampling and testing, CDA reduces the likelihood that usable crops are destroyed when the plant material intended for the stream of commerce tests as compliant.

In the event that a hemp crop conclusively tests higher than the acceptable hemp THC level, a producer must notify the CDA that the crop will be disposed of or remediated accordingly. If the remediated test result remains above the acceptable hemp THC level, CDA will send written correspondence to the producer to describe that the crop has exceeded the acceptable hemp THC level, inform the producer that CDA will notify the USDA of non-compliant hemp, and provide guidance on how to dispose of the hemp crop.

The correspondence explicitly provides that under CDA Rules, a crop that has higher than the acceptable hemp THC level is prohibited from:

- Leaving the registered land area;
- Entering the stream of commerce; and
- Being used for human or animal consumption.

A producer must, prior to destruction or disposal, submit to the Commissioner for review a proposed disposal plan to ensure that destruction of non-compliant hemp is in accordance with USDA and CDA requirements.

CDA's Rules provide that all crops with higher than the acceptable hemp THC level must be destroyed. Appendix B; 8 CCR 1203-23, Rule 4.6.7. Approved disposal methods include disking the crop into the ground, mulching, composting, burning, and burying.

CDA will continue to permit producers to submit video or verifiable photographic evidence to substantiate appropriate disposal of crops whose THC levels exceed the acceptable hemp THC concentration up to 1.0 percent.

CDA requires producers to report, document, and produce evidence of any hemp crop destruction. CDA will also maintain a record of any such destruction and disposal in the hemp registration database and provide monthly reports to USDA during the growing and harvest season describing any lots destroyed for producing non-compliant hemp.

7 CFR § 990.3(a)(3)(ii) provides that "[s]amples of hemp plant material from one lot shall not be commingled with hemp plant material from other lots." 7 CFR 990.3(a)(3)(ii) (86 Fed. Reg. 11 p. 5684) (emphasis added).

The CDA Hemp Sampling Guidelines, Appendix D, provide instructions to field agents on sampling procedures, timing, labeling, sealing, and transporting. To ensure that hemp plant



material samples from one lot are not commingled with samples from other lots, the sealing and transporting section (Appendix D) of this operating procedure states that field agents take the following steps:

- Samples should be placed in provided heavy duty paper bags, stapled, and sealed with evidence tape on the top of the bag.
- Attach initialed and dated map of the field with chain-of-custody or sketch field with sample location on back of chain-of-custody.
- Keep chain-of-custody and map with samples during transfer to the laboratory.

For hemp-testing procedures and measurements, the FR further requires:

Laboratories conducting analytical testing for purposes of detecting the concentration levels of THC shall meet the following requirements:

- (A) Laboratory quality assurance must ensure the validity and reliability of test results;
- (B) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose), and that the laboratory can successfully perform the testing;
- (C) The demonstration of testing validity must ensure consistent, accurate analytical performance;
- (D) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part; and
- (E) Effective disposal procedures for non-compliant samples that do not meet the requirements of this part.
- (F) Measurement of uncertainty (MU) must be estimated and reported with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

#### 7 CFR 990.3(a)(3)(iii) (86 Fed. Reg. 11 p. 5684).

The certification requirements in Appendix G and standard operating procedures in Appendix I will apply for all approved state-certified laboratories used for hemp testing, including ISO 17025 accredited certification, reporting, and GC/FID or other similarly reliable testing methods. Certified labs will meet the DEA registration criteria by December 31, 2022.



The certification and testing procedures in Appendix G ensure that all THC tests are valid, reliable, consistent, accurate, sufficiently sensitive, and replicable, regardless of the laboratory performing the analysis.

The CDA Biochemistry Laboratory (Appendix I) and all state certified laboratories (Appendix G) must have compliant disposal procedures in place.

The CDA testing guidelines (Appendix H) as well as CDPHE Rule (Appendix G, Rule 10) provide a reporting framework for all hemp THC test results that includes a measurement of uncertainty (MU). The test result report also includes accuracy (%A), precision (%CV), level of detection (LoD %), and level of quantitation (LoQ %), which ensure that the analyses and reporting are transparent, accurate, reliable, and replicable. All approved and conditionally approved state-certified laboratories will follow these reporting requirements.

#### 4. Enforcement – 7 CFR § 990.3(a)(5)

7 CFR § 990.3(a)(5), described in FR summary Section II.F: Compliance with Enforcement Procedures Including Determination of Negligence and Annual Inspection of Hemp Producers, requires: "A State or Tribal plan must include a procedure to comply with the enforcement procedures in § 990.6."

Section 990.6, Violations of State and Tribal plans, includes procedures for identifying and correcting producer violations of USDA-approved state hemp production plans, including:

- Defining a negligent violation as:
  - o Failure to obtain a license
  - o Failure to provide legal description of land
  - Failure to obtain a license or other required authorization from state department of agriculture, or
  - Production of cannabis with THC concentration above the acceptable hemp THC level
- Establishing corrective action plans for negligent violations
- Identifying what constitutes a culpable violation
  - Provisions for plan violations by producers with mental state greater than negligence (i.e., culpable)
- Establishing provisions related to any applicant's felony convictions
  - 10-year ineligibility for state or federal felony convictions (Key participants)
- Restricting eligibility of any person who materially falsifies any information contained in an application to produce hemp
- A producer that acquires more than three violations in a 5-year period shall be ineligible to produce hemp for a period of 5 years beginning on the date of the third violation.



### 7 CFR § 990.6(b) (86 Fed. Reg. 11 p.5685).

Under the Act, the Commissioner may deny, revoke, or suspend a hemp registration if a producer "[v]iolates any provision of [the Act] or rules adopted pursuant to [the Act]." C.R.S. § 35-61-107(1)(a). And the Act provides a specific set of unlawful activities that are prohibited, including:

- Cultivating hemp without having a valid registration;
- Harvesting the industrial hemp crop in excess of the time allowed by the commissioner after sampling by an authorized sampler;
- Making false, misleading, deceptive, or fraudulent representations; and
- Refusing to comply with any rules adopted by the commissioner pursuant to the Act or to any lawful order issued by the commissioner.

#### See § 35-61-111(1), C.R.S.

The Rules adopted pursuant to the Act establish additional activities or failures that constitute a violation and that may result in discipline against a producer, or denial of an application for a registration to cultivate hemp, including:

- Failure to fully cooperate and assist CDA in the inspection process;
- Failure to provide any information required or requested by CDA for the purposes of administering the hemp program;
- Providing any false, misleading or incorrect information in application, registration, reporting and/or inspection;
- Failure to report any required information in 8 CCR 1203-23(3), which includes planting report, seed/varietal information, harvest report, and harvest date(s);
- Growing hemp exceeding the acceptable hemp THC level (>0.3 percent by dry weight);
- Failure to pay fees assessed by CDA for inspection and laboratory analysis;
- A state or federal felony conviction relating to a controlled substance within the past ten years, except that a person who was growing hemp in Colorado under a lawfully issued registration to cultivate prior to December 20, 2018, and whose conviction occurred while the person was registered to cultivate hemp and prior to December 20, 2018, shall not be denied a registration. Annex 1, Proposed Rule 6.2.



#### 8 CCR 1203-23, Part 6 (Appendix B).

The Act and the Rules provide the Commissioner with authority to comply with the enforcement procedures of § 990.6. CDA has defined negligent violations and culpable violations in the Rule (8 CCR 1203-23, Rule 6.1.7) and adopted regulations providing for the correction of negligent violations as required by the FR. *See* 8 CCR 1203-23, Rule 6.1.8 (appendix B). By rule, CDA has established that failure to provide a legal description of the land on which the producer intends to produce hemp, failure to obtain a registration for the production of hemp, and production of cannabis above the acceptable hemp THC limit constitute a negligent violation of the Act. 8 CCR 1203-23, Rule 6.1.7; Appendix B. The Rule provides that such offenders must comply with corrective actions required in 8 CCR 1203-23, Part 6.1.7; Appendix B.

Currently, any proven violation that would constitute a negligent violation of the Act under the new CDA rules is noted in the producer's CDA file and taken into consideration when considering future, risk-based compliance inspections. Under the revised rules, a producer commits a negligent violation when conclusive and final test results indicate that a producer has grown cannabis with a THC content over 1.0 percent. The Commissioner may deny, revoke, or suspend any registration if the applicant or registrant commits any violation of the Act or the Rules. C.R.S. § 35-61-107(1)(a).

The Commissioner may also impose a civil penalty, up to \$2,500, for any violation of the Act or the Rules. C.R.S. § 35-61-107(2). For up to three years after the effective date of any suspension, revocation, or relinquishment of a registration, the Commissioner may deny a registration to any person who was previously listed as participating in an entity against which the Commissioner took such disciplinary action. Anyone who has been found, after notice and opportunity for hearing, to have committed three or more negligent violations in any five-year period shall be "ineligible to produce hemp for five years beginning on the date of the third violation." 8 CCR 1203-23, Rule 6.1.9. Further, anyone who has been found, after notice and opportunity for hearing, to have intentionally falsified information in an application shall be ineligible to receive a registration to cultivate hemp in Colorado. Annex 1, Rule 6.10. Finally, applicants who intentionally falsify information may be charged with committing a culpable violation of the Act or the Rules and will be subject to registration suspension and fines of up to \$2,500 per violation and will be reported to state law enforcement officials. C.R.S. § 35-61-107(1)(b).

CDA's Rules set forth specific corrective action for negligent violations that comply with 7 CFR § 990.6(c). Each corrective action issued to a producer will include the following:

- 1. A reasonable date by which the producer shall correct the negligent violation.
- 2. A requirement that the producer periodically report to CDA on the producer's compliance for a period of 2 years following the negligent violation.
- 3. A producer that commits subsequent negligent violations three times in a 5-year period shall be ineligible to produce hemp for a period of 5 years beginning on the date of the third violation.



4. CDA will conduct periodic inspections to ensure compliance with the corrective action plan.

#### See Appendix B, 8 CCR 1203-23, Rule 6.1.8

CDA Rules set forth specific provisions addressing the corrective action taken against a producer who has committed violations of the Act with a culpable mental state greater than negligence to comply with section 990.6(d). If the state determines that the producer has violated the plan with a culpable mental state greater than negligence, CDA will report the producer to the U.S. and Colorado Attorneys General.

To determine whether a person is subject to the felony conviction restrictions, as required by 7 CFR § 990.6(e)(2), the Act requires:

With the submission of an application for registration, each key participant shall submit a complete set of fingerprints to the Colorado bureau of investigation . . . for the purpose of conducting fingerprint-based criminal history record checks. [. . .] The commissioner shall use the information resulting from the fingerprint-based criminal history record check to investigate and determine whether a key participant is qualified to be registered.

C.R.S. § 35-61-104(1)(c)...

The Act includes the procedure for circulating the fingerprints through the Colorado and Federal Bureaus of Investigation. *Id.* 

Under the FR, registration in the hemp program will not be permitted for any key participant who has been convicted of a felony in the past 10 years related to a controlled substance under state or Federal law before, on, or after the enactment of the 2018 Farm Bill. An exception applies to a key participant who was lawfully growing hemp in a state-regulated program under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

#### 5. Disposal or Remediation Notification – 7 CFR § 990.3(a)(6)

7 CFR § 990.(a)(6)3(a)(4), described in the FR, Section II.E: Disposal and Remediation of Non-Compliant Plants, requires:

A State or Tribal plan must include a procedure for the disposal or remediation of cannabis plants if the sample representing that plant tests above the acceptable hemp THC level.



- (i) The disposal method must be conducted either by using a DEA-registered reverse distributor or law enforcement; or on site at the farm or hemp production facility.
- (ii) The State or Tribal plan must include procedures to verify the disposal or remediation of the cannabis plant. This may come in the form of in-person verification by State or Tribal representatives, or alternative requirements that direct growers to provide pictures, videos, or other proof that disposal or remediation occurred successfully. Disposal and remediation means are described at AMS's website.
- (iii) If a producer elects to perform remediation activities, an additional sampling and testing of the post-remediate crop must occur to determine THC concentration levels.

#### 7 CFR § 990.3(a)(6) (86 Fed. Reg. 11 p. 5684).

Under Colorado's hemp program, when a hemp lot conclusively tests higher than the acceptable hemp THC limit, official communication in the form of a letter, generated by CDA, describes the failure and provides disposal requirement options to the producer. Appendix J. Producers growing hemp conclusively testing above acceptable hemp THC limits, as described above, will be notified of a negligent violation, if applicable, in addition to receiving a letter.

All hemp with non-compliant THC levels is required to be disposed of according to the methods described in the letter. If crop destruction is required, CDA will promptly notify USDA of any occurrence of cannabis plants or plant material that exceed the acceptable hemp THC limit and attach records to demonstrate crop destruction is performed pursuant to the requirements set forth for DEA registrants under the Controlled Substances Act (CSA) and Drug Enforcement Administration (DEA) rules. *See also* pp. 15-16 for additional information relevant to implementing the provisions set forth in this part of the FR.

Each month, CDA will submit a hemp disposal report following the format of OMB No. 0581-NEW, AMS-24 (10/2019) that provides verification of compliant disposal. Additionally, the CDA laboratory and all approved and conditionally approved state-certified laboratories will provide the USDA with instant notification of non-compliant lots. In addition, CDA will require commercial and R&D registrants to report destruction to USDA in a disposal report per 7 CFR § 990.70(b).

#### 6. Inspections - 7 CFR § 990.3(a)(7)

7 CFR § 990.3(a)(7), described in IFR summary Section II.F: Compliance with Enforcement Procedures, Including Determination of Negligence and Annual Inspection of Hemp Producers, requires:



A State or Tribal plan must include a procedure for conducting annual inspections of, at a minimum, a random group of producers to verify that hemp is not produced in violation of this part.

#### 7 CFR § 990.3(a)(7) (86 Fed. Reg. 11 p. 5684).

The Rules for hemp inspections are located in Part 4 of 8 CCR 1203-23. Appendix B, p. 16. CDA applies both a random and a risk-based sampling approach to general compliance inspections annually. Each year CDA will conduct sampling and inspection as follows:

- 1. 100 percent of all registrants (not previously exempted from sampling based on alternative protocols) and the lots they are cultivating will be sampled by CDA or third-party samplers with samples submitted to approved testing laboratories to confirm compliance with the acceptable hemp THC limits.
- 2. CDA will randomly select approximately 25 percent of registrants in good standing for a general compliance inspection, which also includes THC sampling to verify any third-party sampler compliance if such sampling has already occurred at the time of the random inspection.
- 3. CDA will follow up on all tips from law enforcement, and for-cause inspections, including sampling and testing. As indicated on page 8, above, under CDA's current protocols, registrants assigned high-risk status are placed on an enhanced inspection schedule.

#### 8 CCR 1203-23, Part 4.

- 4.1 All Registrations are subject to routine inspection and sampling to verify that the total THC concentration of the Cannabis planted within a Registered Land Area does not exceed 0.3% on a dry weight basis. The Commissioner must select 100% of the Registrants for sampling and must take samples not less than 30 days prior to harvest. All lots grown on a registered land area shall be sampled by the Department or Approved Sampler. The Commissioner shall send notification to each Registrant to inform the Registrant of the scope and process by which the inspection will be conducted and require the Registrant to contact the Department within 10 days to set a date and time for the inspection to occur. Failure to contact the Department as required may result in the initiation of disciplinary proceedings pursuant to Part 6 of these Rules against the Registration.
- 4.2 The Commissioner shall also conduct additional inspections and sampling to verify compliance with the reporting requirements of these Rules. A subset of applicants will be randomly selected each year for records audit, inspection of premises, and sampling to ensure compliance with these rules.

In the past, this process has mostly focused on THC sampling, but has been modified to include a general compliance check. Each registrant is notified of their selection status for an inspection shortly after CDA receives the registrant's harvest report. For each selected



registrant, CDA informs the registrant of the scope and process by which the inspection will be conducted and requires the registrant to contact CDA within 10 days of notification to schedule the inspection. In addition to any routine inspection and sampling under Rule 4.1, the Commissioner may inspect and take samples from any Registered Land Area during normal business hours without advance notice if there is reason to believe a violation of the Act or these Rules may be occurring or has occurred. The Commissioner may also conduct such additional inspection and sampling to verify compliance with the reporting requirements of these Rules. (Rule 4.2)

During the inspection, the registrant or an authorized representative is required to be present at the registered premises. The registrant or authorized representative must provide the CDA Inspector or an authorized third party sampler with complete and unrestricted access to all hemp plants and seeds whether growing or harvested, all land, buildings and other structures used for the cultivation and storage of hemp, and all documents and records pertaining to the registrant's hemp growing business. For audit purposes, CDA requires all hemp growers to maintain all documents related to their participation in the hemp program for no less than three years.

#### 7. Producer Information Sharing – 7 CFR § 990.3(a)(8)

7 CFR § 990.3(a)(8) and FR Section II.G, Information Sharing, require states to define procedures for sharing registration details with the USDA:

A State or Tribal plan must include a procedure for submitting the report described in § 990.708 to the Secretary by the first of each month. [...] All such information must be submitted to the USDA in a format that is compatible with USDA's information sharing system.

#### 7 CFR § 990.3(a)(8) (86 Fed. Reg. 11 p. 5684).

Under Colorado's Rules, the information described above is collected in each registration application for both individuals and business entities alike. The CDA Registration Application is attached in Appendix C, and all applicants submit the type of ownership and all owners, a legal description (Township/Range/Section), GPS coordinates, and a map of the land, size and nature of the cultivation (*i.e.*, indoor or outdoor), intended seed variety

<sup>&</sup>lt;sup>8</sup> 7 CFR § 990.70 includes requirements for a monthly producer report for all new and existing licensee or licensed business entity contact information, including full name of the individual or business, license or authorization identifier, business address, telephone number, and email address (if available), key employees; license status; report period (i.e., month). The section also requires a monthly disposal report documenting the licensees, location, acreage, disposal agent and disposal completion date. The annual report requires total acreage planted, harvested and destroyed. The test results report must include producer and lot identifying information; lab identifying and certification information; date of test, indication if retest required; and the test result.



and end use (*i.e.*, fiber, seed, CBD, etc.). Full contact information for each hemp producer is also included in this form. CDA maintains this information in a continuously-updated, secure database that contains current and historical data on all registrations, changes, plantings, harvests, and violations. *See* page 7 above for additional information.

Pursuant to the requirement in 7 CFR § 990.3(a)(8), CDA will submit the information described in 7 CFR § 990.70 to the Secretary in a monthly report, following the format of USDA document OMB No. 0581-NEW, AMS-23 (10/2019). This monthly report will be automatically generated by the CDA data management and reporting system and will include all new or revised hemp producer registration information, including all new and updated contact information, registered land area and license identifier, and status for all registered hemp producers. Additional reports will be regularly filed by CDA with USDA for disposal, testing results (both filed monthly), and an annual report. CDA will incorporate this provision in the rule.

#### 8. Certification of Resources – 7 CFR § 990.3(a)(9)

7 CFR § 990.3(a)(9), described in IFR summary Section II.H: Certification of Resources, requires:

The State or Tribal government must certify that the State or Indian Tribe has the resources and personnel to carry out the practices and procedures described in paragraphs (a)(1) through (9) of this section.

#### 7 CFR § 990.3(a)(9) (86 Fed. Reg. 11 p. 5684).

In accordance with this requirement, CDA provides a Letter of Certification signed by the Commissioner. Appendix K. CDA also has six years of historical operational data demonstrating the resources available to CDA, specifically for the hemp program oversight.

In fiscal year 2020-2021, CDA has 6.3 full time equivalent (FTE) staff directly working on the hemp program and 3.5 FTE laboratory staff. Twenty field inspectors are seasonally available for hemp-related operations on a full-time basis. In 2018, the program became entirely funded by registration and other administrative fees.

The Governor's Office and CDA are committed to providing all necessary resources to the hemp program to keep Colorado and its hemp producers in a leading position.

#### 9. Law Enforcement Information - 7 CFR § 990.3(a)(10)

7 CFR § 990.3(a)(10) requires:

The State or Tribal plan must include a procedure to collect and share information with USDA to support the information sharing requirements in 7



U.S.C. 1639q(d). The State or Tribal government is responsible for reporting the information identified in paragraphs (a)(10)(i) through (iii) of this section with AMS.

#### 7 CFR § 990.3(a)(10) (86 Fed. Reg. 11 p. 5684).

The information described in 7 U.S.C. 1639q(d) is collected in each registration application for both individuals and business entities. *See* Appendix C. Each applicant must submit full contact information and a legal description of the land (Township/Range/Section) where the applicant intends to produce hemp.

As discussed on page 7, above, CDA maintains a database that contains real-time data on all current and historical registrations, including current license status and any amendments. CDA will include this information to the USDA in the regular report. In addition, CDA will require each registrant to report this information directly to FSA. CDA will amend its rules to require that producers report specific information to FSA. The amendment will have:

#### 8 CCR 1203-23 Part 3 (Proposed)

- 3.11 All producers licensed to produce hemp shall report to the USDA Farm Service Agency (FSA) and shall provide at minimum:
  - 3.11.1 Street address and geospatial location for each lot or greenhouse where hemp will be produced. If an applicant operates in more than one location, that information shall be provided for all production sites.
  - 3.11.2 Acreage dedicated to the production of hemp, or greenhouse or indoor square footage dedicated to the production of hemp.

(d) Information sharing for law enforcement

<sup>&</sup>lt;sup>9</sup> 7 U.S.C. 1639q(d):

<sup>(1)</sup> In general The Secretary shall—

<sup>(</sup>A) collect the information described in paragraph (2); and

<sup>(</sup>B) make the information collected under subparagraph (A) accessible in real time to Federal, State, territorial, and local law enforcement.

<sup>(2)</sup> Content. The information collected by the Secretary under paragraph (1) shall include—

<sup>(</sup>A) contact information for each hemp producer in a state or the territory of an Indian tribe for which—

<sup>(</sup>i) a State or Tribal plan is approved under section 1639p(b) of this title; or

<sup>(</sup>ii) a plan is established by the Secretary under this section;

<sup>(</sup>B) a legal description of the land on which hemp is grown by each hemp producer described in subparagraph (A); and

<sup>(</sup>C) for each hemp producer described in subparagraph (A)—

<sup>(</sup>i) the status of—

<sup>(</sup>I) a license or other required authorization from the state department of agriculture or Tribal government, as applicable; or

<sup>(</sup>II) a license from the Secretary; and

<sup>(</sup>ii) any changes to the status.



## 3.11.3 License or registration number.



# **APPENDICES**



## **Table of Contents:**

Appendix A: Title 35, Article 61, Colorado Revised Statutes	3
Appendix B: 8 CCR 1203-23 Rules Pertaining to the Administration and Enforcement of Industrial Hemp Regulatory Act	the 16
Appendix C: CDA Commercial Hemp Registration Application, 2021	32
Appendix D: Hemp Sampling Guidelines and Remediation Sampling	46
Appendix E: Performance Based Sampling Plan	59
Appendix F: CDA Testing Laboratory ISO Certification	65
Appendix G: Colorado Department of Public Health and Environment Hemp Testing Laboratory Certification, 5 CCR 1005-53	70
Appendix H: CDA Hemp Sample Preparation Standard Operating Procedure/Analysis of Moisture Content in Hemp Using the Mettler Toledo HE73 Moisture Analyzer	98
Appendix I: CDA Hemp THC Testing Standard Operating Procedure	111
Appendix J: Notification of Hemp Lot Exceeding Acceptable Total THC and Remediation/Disposal Form	126
PlanAppendix K: Letter of Certification	132



# Appendix A: Title 35 Article 61, Colorado Revised Statutes<sup>1</sup>

<sup>1</sup> source 2021 West Law



#### C.R.S.A. § 35-61-101 Formerly cited as CO ST § 25-18.7-101

### §35-61-101. Definitions

Effective: September 14, 2020

As used in this article 61, unless the context otherwise requires:

- (1) "Acceptable hemp THC level" means when the application of the measurement of uncertainty to the reported delta-9 THC content concentration level on a dry weight basis produces a distribution or range that includes three-tenths of a percent or less.
- (1.3) "Authorized sampler" means an employee of the Colorado department of agriculture or a registrant who has been authorized by the commissioner to collect and handle industrial hemp samples.
- (1.5) "Certified seed" means seed certified by a seed certifying agency pursuant to article 27 of this title 35 and includes foundation and registered seed.
- (2) "Certifying agency" means the seed certification service of the authorized board of governors of the Colorado state university system or the authorized seed certifying agency of another state.
- (3) "Commissioner" means the commissioner of agriculture.
- (4) "Committee" means the industrial hemp advisory committee established in section 35-61-103.
- (5) "Delta-9 tetrahydrocannabinols" or "delta-9 THC" has the same meaning as "tetrahydrocannabinols" as set forth in section 27-80-203(24). Delta-9 THC is the primary psychoactive component of cannabis. For purposes of this article 61, the terms "Delta-9 THC" and "THC" are interchangeable.
- (6) "Department" means the department of agriculture.
- (7) "Industrial hemp" or "hemp" means the plant Cannabis sativa L. and any part of the plant, including the seeds of the plant and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of no more than three-tenths of one percent on a dry-weight basis.
- (7.3) "Key participant" means a sole proprietor, a partner in a partnership, or a person with executive managerial control in a corporation. A person with executive managerial control includes persons such as a chief executive officer, chief operating officer, or chief financial officer. "Key participant" does not include non executive managers such as farm, field, or shift managers.
- (7.7) "Measurement of uncertainty" means the parameter associated with the results of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement.



- (8) "Person" means any individual, natural person, corporation, company, limited liability company, partnership, association, or other legal entity.
- (9) "Total THC" means the molar sum of THC and tetrahydrocannabinolic acid (THCA).

C.R.S.A. § 35-61-102 Formerly cited as CO ST § 25-18.7-102

### § 35-61-102. Industrial hemp--permitted growth by registered persons

Effective: September 14, 2020

- (1) Notwithstanding any other provision of law to the contrary, a person who holds a registration issued pursuant to section 35-61-104 may engage in industrial hemp cultivation for commercial purposes.
- (2) Notwithstanding any other provision of law, a person registered pursuant to section 35-61-104 is not subject to any civil or criminal actions for engaging in the activities described in subsection (1) of this section if the person is acting in compliance with this article.

C.R.S.A. § 35-61-103 Formerly cited as CO ST § 25-18.7-103

# § 35-61-103. Industrial hemp advisory committee--appointments--duties--coordination with commission

- (1)(a) The industrial hemp advisory committee is hereby established. The state agricultural commission created in section 35-1-105 shall appoint an advisory committee to advise the commissioner on matters regarding the regulation of industrial hemp production and to assist the commissioner in promulgating rules to carry out this article 61. The commission shall appoint ten members to the industrial hemp advisory committee as follows:
- (I) One member with experience in industrial hemp regulation;
- (II) One member who is a farmer from a cooperative;
- (III) One member who is a commercial farmer;
- (IV) One member with experience in seed development and genetics;
- (V) One member representing the hemp manufacturing industry;
- (VI) One member representing small hemp businesses;



- (VII) Repealed by Laws 2020, Ch. 194 (S.B. 20-197), § 3, eff. Sept. 14, 2020.
- (VIII) One member who is a citizen advocate for industrial hemp;
- (IX) One member who is a representative from a research institution of higher education;
- (X) One member who is a representative from the cannabinoid industry; and
- (XI) One member who represents certified seed growers.
- (b) The term of office of members of the committee is three years; except that the members appointed pursuant to subsections (1)(a)(I) and (1)(a)(V) of this section serve initial two-year terms to ensure staggered terms of office.
- (c) Each committee member holds office until his or her term of office expires or until a successor is duly appointed. If a vacancy occurs on the board, the appointing authorities shall appoint a new member meeting the qualifications of the member vacating the position to serve the remainder of the unexpired term of the member.
- (d) Members of the committee shall serve without compensation but are entitled to reimbursement for actual and necessary travel and subsistence expenses incurred in the performance of their official duties as members of the committee.
- (2) The committee shall provide advice to the commissioner, review proposed rules, and recommend new rules or changes to existing rules.
- (3) Repealed by Laws 2020, Ch. 194 (S.B. 20-197), § 3, eff. Sept. 14, 2020.
- (4) The committee shall meet at least once a year.

C.R.S.A. § 35-61-104

# § 35-61-104. Registration--cultivation of industrial hemp--research and development growth--hemp management plan--rules

- (1)(a) A person wishing to engage in industrial hemp cultivation shall apply to the department for a registration in a form and manner determined by the commissioner prior to planting the industrial hemp. The application must include the name and address of the applicant and all key participants and the legal description, global positioning system location, and map of the land area on which the applicant plans to engage in industrial hemp cultivation. The applicant shall also submit to the department the fee required by section 35-61-106(2). Application for registration pursuant to this section is a matter of statewide concern.
- (b) Repealed by Laws 2019, Ch. 350 (S.B. 19-220), § 3, eff. May 29, 2019.



- (c) With the submission of an application for registration, each key participant shall submit a complete set of fingerprints to the Colorado bureau of investigation or the department for the purpose of conducting fingerprint-based criminal history record checks. If received by the department, the department shall submit the fingerprints to the Colorado bureau of investigation for the purpose of conducting fingerprint-based criminal history record checks. The Colorado bureau of investigation shall forward the fingerprints to the federal bureau of investigation for the purpose of conducting fingerprint-based criminal history record checks. Upon completion of the criminal history record check, the bureau shall forward the results to the commissioner. The department may acquire a name-based criminal history record check for a key participant who has twice submitted to a fingerprint-based criminal history record check and whose fingerprints are unclassifiable. The commissioner shall use the information resulting from the fingerprint-based criminal history record check to investigate and determine whether a key participant is qualified to be registered. The key participant shall pay the costs associated with the fingerprint-based criminal history record checks.
- (2) If a person applies for registration in accordance with subsection (1) of this section and the commissioner determines that the person has satisfied the requirements for registration pursuant to this article 61, the commissioner may issue a registration to the person.
- (3)(a) A registration issued pursuant to this section is valid for one year from the date of its issuance.
- (b) To continue engaging in industrial hemp cultivation or research and development growth operations in this state after a registration's expiration, a registrant must apply for renewal of its registration in accordance with rules adopted by the commissioner setting forth application renewal and review processes and setting a registration renewal fee.
- (4) If the registrant wishes to alter the land area on which the registrant will conduct industrial hemp cultivation or research and development growth operations, before altering the area, the registrant shall submit to the department an updated legal description, global positioning system location, and map specifying the proposed alterations.
- (5) The commissioner shall adopt rules as necessary to implement and administer this article 61.
- (6) The commissioner or the commissioner's designee shall submit a hemp management plan in accordance with the requirements and timelines prescribed by the secretary of the United States department of agriculture pursuant to the "Agriculture Improvement Act of 2018", Pub.L. 115-334, as amended, for approval by the secretary.
- (7) Except as otherwise prohibited by law, the commissioner may establish separate registration and waiver requirements for research and development cultivation of industrial hemp.

C.R.S.A. § 35-61-104.5

§ 35-61-104.5. Repealed by Laws 2020, Ch. 194 (S.B. 20-197), § 5, eff. Sept. 14, 2020



#### C.R.S.A. § 35-61-105

# § 35-61-105. Report of growth and sales activities--verification of crop content--testing--waiver of concentration limits--rules

Effective: September 14, 2020

- (1) At least annually and more often as required by the commissioner, a person who obtains a registration under this article 61 to engage in industrial hemp cultivation shall file with the department a report that includes the following information:
- (a) Prior to planting, a verification that the crop the registrant will plant is of a type and variety of hemp that will produce a delta-9 tetrahydrocannabinol concentration of no more than three-tenths of one percent on a dry-weight basis; and
- (b) Repealed by Laws 2019, Ch. 350 (S.B. 19-220), § 5, eff. May 29, 2019.
- (c) Any other information required by the commissioner by rule.
- (2) The commissioner, in consultation with the committee, shall adopt rules to establish an inspection program to determine THC concentration. The rules must also establish a process by which a registrant may apply to the commissioner for a waiver from the THC concentration limits above the acceptable hemp THC limit.

C.R.S.A. § 35-61-105.5

### § 35-61-105.5. Authorized samplers--lot sampling--testing laboratories

- (1) The commissioner shall establish a registration and certification program for authorized samplers.
- (2)(a) The commissioner shall develop hemp sampling and testing procedures to sample and test one hundred percent of the hemp lots planted each year. Each registered land area, including each lot within a registered land area, must be inspected and sampled to ensure compliance with all requirements of this article 61 and to determine the total THC content.
- (b) An authorized sampler, or employee of the department, shall collect samples of flower material from all lots grown on the registered land area.
- (c) A registrant shall not harvest the hemp crop prior to samples being collected.
- (d) An authorized sampler shall submit collected samples to a state certified industrial hemp testing laboratory.



#### Formerly cited as CO ST § 25-18.7-104

# § 35-61-106. Industrial hemp registration program cash fund--industrial hemp research grant fund--fees

Effective: September 14, 2020

- (1) There is hereby created in the state treasury the industrial hemp registration program cash fund, referred to in this article as the "fund". The fund consists of fees collected by the commissioner pursuant to subsection (2) of this section and any general fund moneys appropriated to the fund by the general assembly. The moneys in the fund are subject to annual appropriation by the general assembly to the department for the direct and indirect costs associated with implementing this article.
- (2) The commissioner shall collect a fee from persons applying for a registration pursuant to this article 61 based on a fee schedule determined by the commissioner. The commissioner shall set the fee schedule at a level sufficient to generate the amount of money necessary to cover the department's direct and indirect costs in implementing this article 61. The commissioner may also collect any fees necessary to cover the cost of inspection and compliance sampling and testing. The commissioner shall transmit the fees collected pursuant to this section to the state treasurer for deposit in the fund.
- (3) There is hereby created in the state treasury the industrial hemp research grant fund. The fund consists of:
- (a) Repealed by Laws 2020, Ch. 194 (S.B. 20-197), § 8, eff. Sept. 14, 2020.
- (b) Any moneys from foundations, private individuals, or any other funding sources that can be used to expand the scope or time frame of any hemp research authorized pursuant to this article;
- (c) On and after July 1, 2015, up to ten million dollars from the marijuana tax cash fund created in section 39-28.8-501, C.R.S., as enacted by Senate Bill14-215. The moneys in the fund are subject to annual appropriations by the general assembly to the department to establish and administer an industrial hemp research grant program and to conduct hemp research.

C.R.S.A. § 35-61-107

### § 35-61-107. Violations--penalties--denial of registration--application

- (1) The commissioner may deny, revoke, or suspend a registration if the applicant or registrant:
- (a) Violates any provision of this article or rules adopted pursuant to this article;
- (b) Engages in fraud or deception in the procurement of or attempt to procure a registration under this article or provides false information on a registration application; or
- (c) Fails to comply with any lawful order of the commissioner.



- (2) The commissioner may impose a civil penalty, not to exceed two thousand five hundred dollars per violation, on any person who violates this article or any rule adopted under this article.
- (3) The commissioner shall not impose a penalty against a person alleged to have violated this article or a rule adopted under this article until the commissioner has notified the person of the charge and has given the person an opportunity for a hearing pursuant to article 4 of title 24, C.R.S.
- (4) If the commissioner is unable to collect a civil penalty or if a person fails to pay all or a portion of a civil penalty imposed pursuant to this section, the commissioner may bring an action in a court of competent jurisdiction to recover the civil penalty plus attorney fees and costs.
- (5) Cannabis plants exceeding the acceptable hemp THC level must be disposed of in accordance with rules established by the commissioner.
- (6) Notwithstanding any other provision of this article 61, for up to three years after the effective date of the suspension, revocation, or relinquishment of a registration, the commissioner may deny an application for registration if:
- (a) The applicant or any key participant is an individual who was previously listed as participating in an entity pursuant to section 35-61-104 and that individual or entity was subjected to discipline under this article 61: or
- (b) The applicant or any key participant is an entity that lists an individual as participating in the entity pursuant to section 35-61-104 and the individual was previously listed as a participating person or key participant in an entity that was subjected to discipline under this article 61.
- (7) If a person's registration, including any key participant to the registration, is suspended, revoked, or voluntarily relinquished for a violation of this section, the commissioner may deny a new application for registration for that person for up to three years after the effective date of the suspension, revocation, or relinquishment.

## § 35-61-108. Exportation of industrial hemp--processing, sale, manufacturing, and distribution--rules

Effective: June 29, 2020

- (1) Nothing in this article 61 limits or precludes the exportation of industrial hemp in accordance with the federal "Controlled Substances Act", as amended, 21 U.S.C. sec. 801 et seq., federal regulations adopted under the act, and case law interpreting the act.
- (2) The conduct authorized under this section is intended to be consistent with federal law.
- (3) Notwithstanding any other provision of law, a person engaged in processing, manufacturing, selling, transporting, possessing, or otherwise distributing industrial hemp cultivated by a person registered under this article 61, or selling industrial hemp products produced from it, is not subject to



any civil or criminal actions under Colorado law for engaging in such activities. The department may promulgate rules to require approved shipping documentation for the transportation of hemp.

- (4)(a) Because the unprocessed seeds of industrial hemp are included in the definition of "commodity" pursuant to section 35-36-102(7) of the "Commodity Handler and Farm Products Act", part 1 of article 36 of this title 35, a person acting as a commodity handler, as that term is defined in section 35-36-102(8), with respect to the unprocessed seeds of industrial hemp, shall comply with the licensing requirements set forth in part 2 of article 36 of this title 35 and any rules promulgated pursuant to article 36.
- (b) Because industrial hemp is included in the definition of "farm products" pursuant to section 35-36-102(14) of the "Commodity Handler and Farm Products Act", article 36 of this title 35, a person acting as a dealer, small-volume dealer, or agent, as those terms are defined in section 35-36-102, with respect to industrial hemp, shall comply with the licensing requirements set forth in part 3 of article 36 of this title 35 and any rules promulgated pursuant to article 36.

C.R.S.A. § 35-61-108.5

## § 35-61-108.5. Repealed by Laws 2018, Ch. 302, § 1, eff. July 1, 2019

Effective: July 1, 2019

C.R.S.A. § 35-61-109

§ 35-61-109. Repealed by Laws 2019, Ch. 350 (S.B. 19-220), § 6, eff. May 29, 2019

Effective: May 29, 2019

C.R.S.A. § 35-61-110

## § 35-61-110. Record-keeping requirements

- (1) Each registrant shall maintain records of all hemp plant lots acquired, produced, handled, or disposed of in the form and manner designated by the commissioner. The producer shall retain the records for three years.
- (2) The commissioner may request all reports and records required as part of registration, including confidential data or business information including but not limited to information constituting trade secrets or disclosing a trade position, financial condition, or business operations. The commissioner after receipt shall keep the reports and records in the commissioner's custody or control. Confidential business information may be shared with applicable federal, state, or local law enforcement in compliance with this article 61.



- (3)(a) The commissioner may deny access to personal information about persons involved with the cultivation of industrial hemp if the commissioner reasonably believes dissemination of such information will cause harm to such persons.
- (b) On the grounds that disclosure would be contrary to the public interest, the commissioner may deny access to the following:
- (I) Specific operational details of industrial hemp operations that constitute confidential commercial data pursuant to section 24-72-204. Such operational details include:
- (A) Ownership, numbers, field locations, and movements of crops;
- (B) Financial information;
- (C) The purchase and sale of crops;
- (D) Account numbers or unique identifiers issued by government or private entities; and
- (E) Operational protocols.
- (II) Information related to confidential business information that:
- (A) Would identify a person or field location; or
- (B) Contains confidential data, including records of ongoing investigations that pertain to industrial hemp cultivation; except that records of investigations must not be withheld if the investigation has concluded and the person being investigated is found by the commissioner to have violated any provision of this title 61 that pertains to industrial hemp.
- (4) If the commissioner denies access to information pursuant to subsection (3)(a) or (3)(b) of this section, the commissioner shall redact the confidential information and make the remaining portions of the record available for disclosure. If the commissioner is unable to redact the record within the time limits established in section 24-72-203(3), the time limits are waived and the commissioner shall redact the information and provide the redacted record as soon as is practicable.
- (5) Nothing in this article 61 authorizes the commissioner to obtain information not otherwise permitted by law.
- (6) Nothing in this article 61:
- (a) Precludes a person in interest from accessing his or her own information;
- (b) Prevents the commissioner from releasing biological industrial hemp samples to an authorized external entity for scientific testing, so long as the testing entity agrees to maintain the confidentiality of the information it receives:
- (c) Prevents the commissioner from disclosing information that is otherwise permitted or required to be disclosed; or



- (d) Applies when the commissioner determines that disclosure of industrial hemp cultivation information is necessary to prevent or address an immediate threat to the health and safety of a person or animal.
- (7) When disclosing information pursuant to subsection (6)(d) of this section, the commissioner shall release only as much information as is necessary to address the situation.

#### § 35-61-111. Unlawful acts

Effective: September 14, 2020

- (1) Unless otherwise authorized by law, it is unlawful and a violation of this article 61 for any person to:
- (a) Cultivate hemp without having a valid registration from the department;
- (b) Harvest the industrial hemp crop in excess of the time allowed by the commissioner after sampling by an authorized sampler;
- (c) Refuse to comply with a cease-and-desist order issued pursuant to section 35-61-107;
- (d) Refuse or fail to comply with the provisions of this article 61;
- (e) Make false, misleading, deceptive, or fraudulent representations;
- (f) Impersonate any state, county, city and county, or municipal official or inspector; or
- (g) Refuse or fail to comply with any rules adopted by the commissioner pursuant to this article 61 or to any lawful order issued by the commissioner.
- (2) Notwithstanding any provision of law to the contrary, no person is subject to criminal prosecution for:
- (a) Failure to provide a legal description of the land on which the producer produces hemp;
- (b) Failure to obtain a registration pursuant to this article 61 for the production of industrial hemp; or
- (c) Producing cannabis with a THC level above three-tenths of a percent but below a percent as determined by the commissioner through rule.

C.R.S.A. § 35-61-112

§ 35-61-112. Civil penalties



- (1)(a) Any person who violates any provision of this article 61 or any rule adopted pursuant to this article 61 is subject to a civil penalty, as determined by the commissioner.
- (b) Before imposing any civil penalty, the commissioner shall consider the severity of the violation, the amount of harm caused by such a violation, the presence or absence of a pattern of similar violations by the registrant, the effect of the proposed penalty on the ability of the registrant to continue to conduct business, and any other factors deemed to be relevant.
- (c) The maximum penalty imposed by the commissioner must not exceed two thousand dollars per violation per day.
- (2) The commissioner shall not impose any penalty unless the person charged is given notice and an opportunity for a hearing pursuant to article 4 of title 24.
- (3) The department shall transmit any civil penalties or fines collected pursuant to this article 61 to the state treasurer, who shall credit them to the industrial hemp registration program cash fund created pursuant to section 35-61-106.

#### § 35-61-113. Powers and duties of commissioner--rules

- (1) The commissioner may administer and enforce the provisions of this article 61 and any rules adopted pursuant thereto.
- (2) The commissioner may adopt all reasonable rules for the administration and enforcement of this article 61, including but not limited to:
- (a) Minimum standards of the acceptable hemp THC level;
- (b) Maintenance of records concerning all hemp plant lots acquired, produced, handled, or disposed of; and
- (c) Establishment of qualifications for authorized samplers.
- (3) The commissioner may establish the annual date or dates on which registrations issued pursuant to this article 61 expire.
- (4) The commissioner may enter into cooperative agreements with any agency or political subdivision of this state or with any agency of the United States government for the purpose of carrying out the provisions of this article 61, receiving grants-in-aid, and securing uniformity of rules.
- (5) The powers and duties vested in the commissioner by this article 61 may be delegated to qualified employees of the department.



#### § 35-61-114. Inspections--investigations--access--subpoenas

- (1) The commissioner, upon his or her own motion or upon the complaint of any person, may make any investigations necessary to ensure compliance with this article 61.
- (2) Complaints of record and the results of the investigations may, in the discretion of the commissioner, be closed to public inspection, except to the person in interest, as defined in section 24-72-202(4).
- (3) At any reasonable time during regular business hours, the commissioner must be provided free and unimpeded access upon consent or upon obtaining an administrative search warrant to:
- (a) Those portions of all buildings, fields, and other areas in which any industrial hemp lots are handled for the purpose of carrying out any provision of this article 61 or any rule promulgated pursuant to this article 61; and
- (b) All records required to be kept, and the commissioner may make copies of such records for the purpose of carrying out any provision of this article 61 or any rule promulgated pursuant to this article 61.
- (4)(a) Whenever the commissioner has reasonable cause to believe a violation of any provision of this article 61 or any rule made pursuant to this article 61 has occurred and immediate enforcement is deemed necessary, the commissioner may issue a cease-and-desist order, which may require any person to cease violating any provision of this article 61 or any rule made pursuant to this article 61. The cease-and-desist order must set forth the provision alleged to have been violated, the facts alleged to have constituted the violation, and the requirement that the actions be ceased forthwith.
- (b) If any person fails to comply with a cease-and-desist order within twenty-four hours after receipt of the order, the commissioner may bring a suit for a temporary restraining order or injunctive relief to prevent any further or continued violation of such order.
- (5) The commissioner has full authority to administer oaths and take statements; to issue administrative subpoenas requiring the attendance of witnesses before the commissioner and for the production of all books, memoranda, papers and other documents, articles, or instruments; and to compel the disclosure by such witnesses of all facts known to them relative to the matters under investigation. Upon the failure or refusal of any witness to obey an administrative subpoena, the commissioner may petition the district court, and, upon a proper showing, the court may enter an order compelling the witness to appear and testify or produce documentary evidence. Failure to obey



such an order of the court is punishable as contempt of court.

15



Appendix B: Notice of Public Rulemaking Hearing, "Rules Pertaining to the Administration and Enforcement of the Industrial Hemp Regulatory Act," 8 CCR 1203-23, including proposed rule amendments, modifications, and updates.



# NOTICE OF PUBLIC RULEMAKING HEARING FOR AMENDMENTS TO: "Rules Pertaining to the Administration and Enforcement of the Industrial Hemp Regulatory Program Act" 8 CCR 1203-23

Notice is hereby given pursuant to § 24-4-103 C.R.S. that the Department of Agriculture will hold a public rulemaking hearing:

DATE: May 25, 2021 TIME: 1:30 pm

LOCATION: This hearing will be held via Zoom

**CALL INFORMATION: 1-253-215-8782** 

MEETING ID: 875 9859 5656 PASSCODE:944341

In order to maintain a proper hearing record you are encouraged to pre-register by completing this Google form. If you do not have access to Google you may send your name and telephone number to Jenifer.Gurr@state.co.us

Pre-registration is not required to participate in the hearing.

The purposes of these proposed rule revisions are to align Colorado's hemp program with Federal law and Colorado SB 20-197, effective September 1, 2020. Specific changes conform definitions with those in law; identifies additional information to be obtained from registrants; updates program requirements; sets new standards for testing and establishes an authorized sampler program; addresses violations; removes hemp seed certification from the program; and identifies the source of certified testing laboratories. General typographical and grammatical corrections are also proposed.

The statutory authority for these rules is §§ 35-61-104 (5) and 35-61-105(2), C.R.S.

Any interested party may file written comment with the Commissioner's office prior to the hearing, or present at the aforementioned hearing written data, views or arguments. Emailed comments should be sent to the hearing officer at Jenifer.Gurr@state.co.us. A copy of the proposed rule is available on the Department of Agriculture's website at www.colorado.gov/ag or may be obtained by calling

303-869-9004. The proposed rule shall be available for public inspection at the Colorado Department of Agriculture at 305 Interlocken Parkway, Broomfield, Colorado during regular business hours.

Proposed Rule Revisions can be found here.



#### DEPARTMENT OF AGRICULTURE

#### **Plant Industry Division**

RULES PERTAINING TO THE ADMINISTRATION AND ENFORCEMENT OF THE INDUSTRIAL HEMP REGULATORY PROGRAM ACT

8 CCR 1203-23

Pursuant to the provisions and requirements of the Industrial Hemp Regulatory Program Act, Title 35, Article 61, C.R.S., the following Rules are hereby promulgated to regulate the cultivation of Industrial Hemp:

#### **Part 1 DEFINITIONS**

- 1.1 "Act" means the Industrial Hemp Regulatory Program Act, Title 35, Article 61, C.R.S.
- 1.2 "CDA Approved Certified Seed" means Cannabis seed that is approved and labeled by the Department for cultivating Industrial Hemp. "Approved Laboratories" means a laboratory certified by the Colorado Department of Public Health and Environment that meets all standards of performance, personnel qualifications, operating procedures, analytical processes, proficiency testing, quality assurance, ISO accreditation and any other standard required by the Commissioner to meet State and Federal requirements for testing hemp.
- 1.3 "Commercial" means the growth of Industrial. Hemp, for any purpose including engaging in commerce, market development and market research, by any person or legal entity other than an institution of higher education under the pilot program administered by the Department for purposes of agricultural or academic research in the development of growing Industrial. Hemp.
- 1.4 "Commissioner" means the Commissioner of Agriculture AND ANY EMPLOYEE OF THE DEPARTMENT OF AGRICULTURE ASSOCIATED WITH THE Industrial HEMP REGULATORY PROGRAM.
- 1.5 Culpable mental state greater than negligence" means to act intentionally, knowingly, willfully, or recklessly.
- 1.56 "Department" means the Colorado Department of Agriculture.
- 1.67 "Harvest" means the termination of the cultivation process, INCLUDING TAKING CUTTINGS, or the movement of INDUSTRIAL Hemp from a Registered Land Area to another location or movement within a Registered Land Area between indoor and outdoor planting areas.
- 1.78 "Industrial Hemp" means a plant of the genus Cannabis <u>sativa L.</u> and any part of the plant, <u>INCLUDING THE SEEDS OF THE PLANT AND ALL DERIVATIVES, EXTRACTS, CANNABINOIDS, ISOMERS, ACIDS, SALTS, AND SALTS</u>



- **OF ISOMERS,** whether growing or not, containing a **TOTAL** delta-9 tetrahydrocannabinol (THC) concentration of no more than three-tenths of one percent (0.3%) on a dry-weight basis.
- 1.89 "Law Enforcement" means the activities of the federal, state and local Law Enforcement agencies responsible for maintaining public order and enforcing the law.
- 1.10 "Lot" means a contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of cannabis throughout the area.
- 1.11 "Negligence" means the failure to exercise the level of care that a reasonably prudent person would exercise in complying with the regulations set forth in the Industrial Hemp Regulatory Program Act, section 35-61-101, et seq., or the rules adopted pursuant thereto.
- 1.912 "Planting" means the starting of the growing process, including by planting seed, sticking cuttings, tissue culture, the transfer of plants within or moved into a Registered Land Area except for replanting into a larger container within the same independent registered Land Area, and the emergence of volunteer plants that the Registrant intends to cultivate and not destroy.
- 1.103 "Registrant" means any individual or legal entity who holds a valid Registration to grow Industrial Hemp under these Rules and the Industrial Hemp Regulatory Program Act.
- 1.1<u>14</u> "Registration" means authorization by the Commissioner for any individual or legal entity to grow **INDUSTRIAL** Hemp on a Registered Land Area.
- 1.125 "Registered Land Area" means a contiguous land area registered with the Department on which a Registrant plans to cultivate Industrial Hemp. A Registered Land Area may include land and buildings that are not used for cultivation.
- 1.136 "Research and Development" means cultivation of Industrial. Hemp by an institution of higher education or other entity approved under the pilot program administered by the Department for purposes of agricultural or academic research in the development of growing Industrial. Hemp.
- 1.147 "Variety" means a group of plants or an individual plant that exhibits distinctive observable physical characteristic(s) or has a distinct genetic composition.

#### Part 2 REGISTRATION

2.1 Each applicant for a Commercial INDUSTRIAL Hemp Registration SHALL MUST submit a signed, complete, accurate and legible application form provided by the Commissioner at least 30 days-prior to planting which includes the following information:



- 2.1.1 The name and address of the applicant and <u>A LIST OF ALL KEY PARTICIPANTS, INCLUDING THE</u>
  FULL NAME, TITLE, AND EMAIL ADDRESSES FOR EACH KEY PARTICIPANT.
- 2.1.2 Type of entity, such as corporation, LLC, partnership, or sole proprietor, etc. including the entity's employee identification number, the principal business location address, telephone number, and e-mail address (if available).
- 2.1.3 Business name(s) if different from (2.1.1) above. The Secretary Of State Id Number Under Which A Corporate Entity Is Doing Business.
- 2.1.4 The legal description (Section, Township, Range) in which the growing area is located.
- 2.1.5 The global positioning system location coordinates taken at the approximate center of the Registered Land Area.
- 2.1.6 A map of the land area on **THE**-which the applicant plans to cultivate **Industrial** Hemp, showing the boundaries and dimensions of the land area(s), whether in acres or square feet or both as appropriate.
- 2.1.7 By submitting an application the Registrant acknowledges and agrees to the following terms and conditions:
  - 2.1.7.1 Any information provided to the Department may be publicly disclosed and provided to law enforcement agencies without further notice to the Registrant.
  - 2.1.7.2 The Registrant shall allow and fully cooperate with any inspection and sampling that the Department deems necessary.
  - 2.1.7.3 The Registrant shall pay for any inspection and laboratory analysis costs that the Department deems necessary within 30 days of the date of the invoice.
  - 2.1.7.4 The Registrant shall submit all required reports by the applicable due dates specified by the Commissioner.
- 2.1.8 A Registrant must have the legal right to cultivate Industrial. Hemp on the Registered Land Area and the legal authority to grant the Department access for inspection and sampling.
- 2.2 Each applicant for a Research and Development Hemp Registration shall submit a signed, complete, accurate and legible application form provided by the Commissioner at least 30 days prior to planting which includes the following information
  - 2.2.1 The name and address of the applicant.



- 2.2.2 Type of organization.
- 2.2.3 Organization name(s) if different from (2.2.1 above.
- 2.2.4 The legal description (Section, Township, Range) in which the growing area is located.
- 2.2.5 The global positioning system location coordinates taken at the approximate center of the Registered Land Area.
- 2.2.6 A map of the land area on which the applicant plans to cultivate Industrial Hemp, showing the boundaries and dimensions of the land area whether in acres or square feet or both as appropriate.
- 2.2.7 By submitting an application the Registrant acknowledges and agrees to the following terms and conditions:
  - 2.2.7.1 Any information provided to the Department may be publicly disclosed and be provided to law enforcement agencies without further notice to the Registrant.

## sampling

- 2.2.7.2 The Registrant shall allow and fully cooperate with any inspection and that the Department deems necessary.
- 2.2.7.3 The Registrant shall pay for any inspection and laboratory analysis costs that the Department deems necessary within 30 days of the date of the invoice.
- 2.2.7.4 The Registrant shall submit all required reports by the applicable due-dates specified by the Commissioner.
- 2.3 Registrations <del>cannot be assigned or transferred to another business, individual or other enti</del><u>ty a</u>re non-transferable
- 2.4 No **INDUSTRIAL** Hemp plant **SHALL MAY** be included in more than one Registration simultaneously.
- 2.5 No Registered Land Area may contain Cannabis plants or parts thereof that the Registrant knows or has reason to know are of a variety that will produce a plant that when tested will produce more than 0.3% TOTAL DELTA-9 THC concentration on a dry weight basis. No Registrant SHALL MAY use any such variety for any purpose associated with the cultivation of Industrial Hemp.
- 2.6 Each noncontiguous land area on which Industrial Hemp is grown Must have a unique shall require a separate Registration. Any addition to a Registered Land Area Must also have a shall also require a separate Registration.



- 2.7 In addition to the application form, each applicant for a Registration shall must submit the Registration fee set by the Commissioner. If the Registration fee does not accompany the application, the application for Registration will be deemed incomplete.
- 2.8 The annual Registration fee for Commercial production of **Industrial** Hemp **SHALL BE IS** \$500 plus \$5.00/acre outdoors **AND/**or \$3.00/1000 sq. ft. indoors.
- 2:9 The annual Registration fee for production of Industrial Hemp for Research and Development SHALL BE IS \$500 plus \$5.00/acre outdoors AND/or \$3.00/1000 sq. ft. indoors. Application fees for Research and Development registrations may be waived for institutions of higher education.
- 2.10 All Registrations shall be valid for one year from the date of issuance.
- 2.11 All Industrial. Hemp plant material must be planted, grown and harvested under a valid Registration. Any plant material that is not harvested in the Registration period in which it was planted or and any volunteer plants that are not destroyed, must be declared for inclusion in a subsequent Registration.
- 2.12 Any Registrant that wishes to alter the growing area(s) on which the Registrant will conduct Industrial Hemp cultivation for either Commercial or Research and Development purposes shall, before altering the area, submit to the Department an updated legal description, global positioning system location, and map specifying the proposed alterations. Amendments to an existing Registration are limited to changes within the original land area registered, including variety changes, location(s) of varieties, and actual acreage or square feet of each variety planted.
- 2.13 Incomplete applications will not be processed, and application fees will not be refunded if a Registration is not granted.
- 2.14 Any changes to contact information must be provided within 10 days of the change.
- 2.15 No Land area may be included in more than one Registration at the same time.

#### Part 3 REPORTS AND RECORDS REQUIREMENTS

- 3.1 Prior to planting any Cannabis, Commercial INDUSTRIAL Hemp Registrant shall file, on a form provided by the Commissioner, a Pre-Planting Report that includes:
  - 3.1.1 A statement of verification that the Registrant has reasonable grounds to believe that the crop the Registrant will plant is of a type and variety of Cannabis that will produce a **TOTAL DELTA-9** THC concentration of no more than 0.3% on a dry weight basis.



- 3.1.2 A description of the Cannabis varieties to be planted on the Registered Land Area. All plant material to be used for cultivation of Cannabis within a Registered Land Area must be included.
- 3.1.3 A statement of intended end use for all parts of any Cannabis plants grown within a Registered Land Area.
- 3.2 Within 10 days after planting any Cannabis, and /or-within 10 days after emergence of any volunteer Cannabis plants in a Registered Land Area that the Registrant chooses to cultivate and not destroy, each Commercial Registrant shall submit, on a form provided by the Commissioner, a Planting Report that includes:
  - 3.2.1 A list or description of all varieties AND INTENDED USE of Cannabis planted, or of volunteer Cannabis plants that have emerged and are not destroyed, within a Registered Land Area.
  - 3.2.2 The global positioning system coordinates and a map showing the location and actual acreage or square feet of each variety of Cannabis planted, or of volunteer Cannabis plants that have emerged and are not destroyed, within a Registered Land Area.
  - 3.2.3 A Planting Report must be submitted any time Cannabis is planted in, Moved WITHIN or moved into a Registered Land Area, except for replanting into a larger container within the same INDOOR LOCATION REGISTERED LAND AREA.
  - 3.2.4. To qualify for the benefits under Rule 4.6 for CDA Approved Certified Seed or other variety approved by the Department, a Commercial Industrial Hemp Registrant must provide the variety name and seed or plant labeling bag tag distribution number(s) and quantity in pound(s) planted on/or with the Planting Report.
- 3.3 At least 30 days prior to harvest, each Commercial INDUSTRIAL Hemp Registrant shall file a Harvest Report, on a form provided by the Commissioner that includes:
  - 3.3.1 Documentation that the Commercial Registrant has entered into a purchase agreement with an in-state Industrial. Hemp processor. If the Registrant has not entered into such an agreement, the Registrant shall include a statement of intended disposition of its Industrial. Hemp crop.
  - 3.3.2 The harvest date(s) and location of each variety of Industrial. Hemp cultivated within a Registered Land Area.
  - 3.3.3 A Registrant must notify the Commissioner immediately of any changes in the reported harvest date(s) in excess of 5 days by submitting an Amended Harvest Report to the Commissioner. If any such changes are made the Commissioner may require additional testing prior to harvest and may require that the Registrant retain



- possession and control of the **INDUSTRIAL** hemp in its harvested form until such test results are received by the Department.
- 3.3.4 A Registrant is not required to document the removal of Cannabis plants on a Harvest Report provided that the Cannabis plants are destroyed on the Registered Land Area prior to filing a Harvest Report for the remaining Cannabis plants.
- 3.4 Prior to planting, each Research and Development Industrial. Hemp Registrant shall file, on a form provided by the Commissioner, a Pre-Planting Report that includes:
  - 3.4.1 A statement of verification that the Registrant has reasonable grounds to believe that the crop the Registrant will plant is of a type and variety of Cannabis that will produce a TOTAL DELTA-9 THC concentration of no more than 0.3% on a dry weight basis.
  - 3.4.2 A description of the Cannabis varieties to be planted on the Registered Land Area. All plant material to be used for cultivation of Cannabis within a Registered Land Area must be included.
  - 3.4.3 A statement of intended end use for all parts of any Cannabis plants grown within a Registered Land Area.
- 3.5 Within 10 days after planting any Cannabis, and /or WITHIN 10 days after emergence of any volunteer Cannabis plants in a Registered Land Area that the Registrant chooses to cultivate and not destroy, each Research and Development Registrant shall submit, on a form provided by the Commissioner, a Planting Report that includes:
  - 3.5.1 A list or description of all varieties of Cannabis planted, or of volunteer Cannabis plants that have emerged and are not destroyed within a Registered Land Area.
  - 3.5.2 The global positioning system coordinates and a map showing the location and actual acreage or square feet of each variety of any Cannabis planted, or of volunteer Cannabis plants that have emerged and are not destroyed, within a Registered Land Area.
  - 3.5.3 A Planting Report must be submitted any time Cannabis is planted in, moved into or moved within a Registered Land Area, except for replanting into a container of the same size within the same indoor location.
  - 3.5.4 To qualify for the benefits under Rule 4.6 for CDA Approved Certified Seed, a Research and Development Industrial Hemp Registrant must provide the bag tag distribution number(s) and quantity in pound(s) planted on the planting report.
- 3.6 At least 30 days prior to harvest, each Research and Development Industrial Hemp Registrant shall FILE SUBMIT a Harvest Report, on a form provided by the Commissioner that includes:



- 3.6.1 A statement of the intended use of all **Industrial** Hemp cultivated within a Registered Land Area.
- 3.6.2 The harvest date(s) and location of each variety cultivated within a Registered Land Area.
- 3.6.3 A Registrant must notify the Commissioner immediately of any changes in the reported harvest date(s) in excess of 5 days by submitting an Amended Harvest Report to the Commissioner. If any such changes are made the Commissioner may require additional testing prior to harvest and may require that the Registrant retain possession and control of the INDUSTRIAL hemp in its harvested form until such test results are received by the Department.
- 3.6.4 A Registrant is not required to document the removal of Cannabis plants on a Harvest Report provided that the Cannabis plants are destroyed on the Registered Land Area prior to filing a Harvest Report for the remaining Cannabis plants.
- 3.7 Each Commercial and Research and Development Registrant shall report to the Commissioner any changes to information provided in the Registration or any previously submitted reports, including any changes to the purchase agreement or statement of intended disposition, within 10 days of such change.
- 3.8 REGISTRANTS SHALL MAINTAIN RECORDS OF ALL CANNABIS PLANTS ACQUIRED, GROWN, PRODUCED, HANDLED OR DISPOSED OF, INCLUDING THC TEST RESULTS, OF ALL CANNABIS LOTS GROWN WITHIN ALL REGISTERED LAND AREA(s).
- 3.9 REGISTRANTS SHALL RETAIN SUCH RECORDS AND REPORTS FOR THREE YEARS.
- 3.10 ALL RECORDS PERTAINING TO PART 3.8 SHALL BE MADE AVAILABLE FOR INSPECTION BY CDA AND USDA INSPECTORS, AUDITORS, OR THEIR REPRESENTATIVE DURING REASONABLE BUSINESS HOURS.

#### Part 4 INSPECTION AND SAMPLING PROGRAM

All Registrations are subject to routine inspection and sampling to verify that the Delta-9 total THC concentration of the Cannabis planted within a Registered Land Area does not exceed 0.3% on dry weight basis. For Any Registration Issued Pursuant To These Rules, The Commissioner MAY MUST select up to 100% of the Registrants to be inspected For Sampling and MUST TAKE SAMPLES NOT LESS THAN 30 DAYS PRIOR TO HARVEST. All LOTS GROWN ON A REGISTERED LAND AREA SHALL BE SAMPLED BY THE DEPARTMENT OR APPROVED SAMPLER. The Commissioner shall send notification to each Registrant of the scope and process by which the inspection will be conducted and require the Registrant to contact the Department within 10 days to set a date and time for the inspection

25



to occur. Failure to contact the Department as required may result in the initiation of disciplinary proceedings pursuant to Part 6 of these Rules against the Registration.

- 4.2 THE COMMISSIONER SHALL ALSO CONDUCT ADDITIONAL INSPECTIONS AND SAMPLING TO VERIFY COMPLIANCE WITH THE REPORTING REQUIREMENTS OF THESE RULES. A SUBSET OF APPLICANTS WILL BE RANDOMLY SELECTED EACH YEAR FOR RECORDS AUDIT, INSPECTION OF PREMISES, AND SAMPLING TO ENSURE COMPLIANCE OF THESE RULES.
- 4.23 In addition to any routine inspection and sampling under Rule 4.1, the Commissioner may inspect and take samples from any Registered Land Area during normal business hours without advance notice if HE-THE COMMISSIONER has reason to believe a violation of the Act or these Rules may be occurring or has occurred. THE COMMISSIONER MAY ALSO CONDUCT SUCH ADDITIONAL INSPECTION AND SAMPLING TO VERIFY COMPLIANCE WITH THE REPORTING REQUIREMENTS OF THESE RULES.
- 4.34 A Registered Land Area may be subject to inspection and sampling prior to voluntary termination of the Registration before its expiration date.
- During the inspection, the Registrant or authorized representative shall be present at the growing operation. The Registrant or authorized representative shall provide the Department's Inspector with complete and unrestricted access to all Cannabis plants, parts and seeds within a Registered Land Area whether growing or harvested, and all land, buildings and other structures used for the cultivation and storage of Industrial Hemp, and all documents and records pertaining to the Registrant's Industrial Hemp growing business.
- 4.56 All Cannabis PLANTS LOTS NOT SUBJECT TO PERFORMANCE BASED SAMPLING METHODS within a Registered Land Area MAY MUST be sampled to ensure compliance with the INDUSTRIAL Hemp Program.
  - 4.56.1 Individual or composite samples of each variety or Lot of Cannabis Must MAY be sampled from the Registered Land Area at the Department's discretion.
  - 4.<u>56.</u>2 The sampled material will be prepared for testing using protocols approved by the Commissioner.
  - 4.<u>56.</u>3 Quantitative laboratory determination of the <u>Total Delta-9</u> THC concentration on a dry weight basis will be performed according to protocols approved by the Commissioner.
  - 4.56.4 A sample test result with a TOTAL DELTA-9-THC concentration on a dry weight basis greater than 0.3% THC shall constitute evidence that at least one Cannabis plant or part of a plant in the Registered Land Area contains a TOTALDELTA-9-THC concentration on a dry weight basis of more than 0.3% and that the Registrant of that Registered Land Area is therefore not in compliance with the Act. Upon receipt of such a test result, the Commissioner may summarily suspend or revoke the Registration of an INDUSTRIAL Hemp Registrant in accordance with the Act, these Rules and 24-4-104, C.R.S. Sample test results for INDUSTRIAL Hemp Registrations with a TOTALDELTA-9-THC



concentration greater than 0.3% on a dry weight basis may be provided to the appropriate law enforcement agencies.

- 4.6.5 A PRODUCER SHALL NOT HARVEST THE CANNABIS PRIOR TO SAMPLE COLLECTION.
- 4.6.6 HARVESTED PLANT MATERIAL MAY NOT LEAVE THE REGISTERED LAND AREA PRIOR TO RECEIVING SAMPLE RESULTS.
- 4.6.7 Lots tested above the acceptable hemp THC level may not be further handled, processed or enter the stream of commerce and the producer shall ensure the lot is disposed of in accordance with department guidelines.
- 4.6.8 Individual samples of Hemp lots shall not be commingled with other lots during sampling or laboratory analysis.
- 4.6 FIELDS PLANTED WITH CDA APPROVED CERTIFIED SEED MAY BE INSPECTED AND SAMPLED TO CONFIRM CONSISTENCY WITH THE PLANTING REPORT(s). THE DEPARTMENT WILL WAIVE ALL INSPECTION AND/OR SAMPLING COSTS IF NO INCONSISTENCIES OR VIOLATIONS ARE IDENTIFIED.
- 4.7 Fees and Costs
  - 4.7.1 REGISTRANTS SELECTED FOR INSPECTION AND SAMPLING SHALL PAY A FEE OF \$125.00 PER INSPECTION PLUS ALL LABORATORY COSTS. FOR ALL SAMPLING CONDUCTED BY THE DEPARTMENT PURSUANT TO THESE RULES, THE DEPARTMENT WILL CHARGE THE REGISTRANT \$125 PER INSPECTION PLUS ALL LABORATORY COSTS ASSOCIATED WITH THE INSPECTION.
  - 4.7.2 Registrants selected for inspection and sampling shall reimburse the Department for both the fees and costs incurred by the Department within 30 days of the date of invoice.
  - 4.7.3 REGISTRANT IS RESPONSIBLE FOR PAYING ALL FEES TO APPROVED SAMPLERS AND THIRD PARTY LABS

#### 4.8 AUTHORIZED SAMPLERS

- 4.8.1 Any individual acting as an approved sampler must possess a valid sampler registration and certification issued by the commissioner
  - 4.8.1.1 EACH APPROVED SAMPLER SHALL COMPLETE AND FILE WITH THE COMMISSIONER AN APPLICATION ON A FORM FURNISHED BY THE COMMISSIONER WHICH CONTAINS AT A MINIMUM THE FOLLOWING: NAME, ADDRESS, TELEPHONE NUMBER AND ANY OTHER INFORMATION REQUIRED ON THE FORM.
  - 4.8.1.2 Each applicant for an Authorized Sampler Certification shall take a yearly CDA-approved sampler training course And Pass An Examination Administered By The Department.



- 4.8.1.3 THE COMMISSIONER, OR COMMISSIONER'S DESIGNEE SHALL ADMINISTER A GENERAL TRAINING CLASS ON THE AUTHORIZED SAMPLING AND HANDLING TECHNIQUES ACCORDING TO PROTOCOLS APPROVED BY THE COMMISSIONER.
- 4.8.2 THE COMMISSIONER MAY CANCEL AN AUTHORIZED SAMPLER'S REGISTRATION AND CERTIFICATION OR REFUSE TO REGISTER OR CERTIFY ANY PERSON WHO HAS ENGAGED IN ANY OF THE FOLLOWING ACTIVITIES:
  - 4.8.2.1 Consistent disregard for established and approved methods of sampling determined by CDA in the USDA Approved Colorado State Hemp Plan
  - 4.8.2.2 Failing Or Refusing To Disclose A Conflict Of Interest.
  - 4.8.2.3 Tampering with samples to influence testing results.
  - 4.8.2.4 Purposeful commingling of sampled lots

#### Part 5 WAIVER

- 5.1 Notwithstanding the fact that a sample of a Research and Development Registrant's Industrial Hemp tests higher than 0.3% but less than 1.0% total DELTA-9 THC concentration the Registrant shall not be subject to any penalty under the Act or these Rules if:
  - 5.1.1 The sampled Industrial Hemp was grown solely for Research and Development purposes by an individual or entity holding a Research and Development Registration, and the crop is destroyed or utilized on site in a manner approved of and verified by the Commissioner.
  - 5.1.2 Test results from a Research and Development Registrant may, at the Commissioner's discretion, be accepted in lieu of Department sampling.
- 5.2 Notwithstanding the fact that a sample of a Commercial Registrant's Industrial Hemp tests higher than 0.3% but less than 1.0% total DELTA-9 THC concentration the Registrant shall not be subject to revocation or suspension of their Registration if the crop is destroyed or utilized on site in a manner approved of and verified by the Commissioner.
- 5.3 Registrants shall have 10 days from the date of notification of test results higher than 0.3% acceptable hemp DELTA-9 THC concentration level to request a waiver as provided for in Rules 5.1 or 5.2.

#### Part 6 VIOLATIONS/DISCIPLINARY SANCTIONS/CIVIL PENALTIES

6.1 In addition to any other violations of Title 35, Article 61, C.R.S., or these Rules, the following acts and omissions by any applicant or Registrant or authorized representative thereof shall



constitute violations for which civil penalties up to \$2,500 per violation and disciplinary sanctions, including denial of an application or summary suspension or revocation of a Registration, may be imposed by the Commissioner in accordance with §§ 35-61-107 and 24-4-104. C.R.S.:

- 6.1.1 Refusal or failure by an applicant, Registrant or authorized representative to fully cooperate and assist the Department with all aspects of the administration and enforcement of the Act and these Rules, including the application, registration, reporting, inspection and sampling, and waiver processes.
- 6.1.2 Failure to provide any information required or requested by the Commissioner for purposes of the Act or these Rules.
- 6.1.3 Providing false, misleading, or incorrect information pertaining to the Registrant's cultivation of **Industrial** Hemp to the Commissioner by any means, including but not limited to information provided in any application form, report, record or inspection required or maintained for purposes of the Act or these Rules.
- 6.1.4 Failure to submit any required report in accordance with Part 3.
- 6.1.5 Growing Cannabis that when tested is shown to have a **TOTAL DELTA-9** THC concentration greater than 0.3% on a dry weight basis.
- 6.1.6 Failure to pay fees assessed by the Commissioner for inspection or laboratory analysis costs.
- **6.1.7** Negligent Violations Include, But Are Not Limited To:
  - 6.1.7.1 FAILURE TO PROVIDE A LEGAL DESCRIPTION OF THE LAND ON WHICH THE PRODUCER PRODUCES HEMP.
  - 6.1.7.2 FAILURE TO OBTAIN A REGISTRATION OR OTHER REQUIRED AUTHORIZATION FROM THE COMMISSIONER.
  - 6.1.7.3 PRODUCTION OF CANNABIS WITH A TOTAL THC CONCENTRATION EXCEEDING THE ALLOWABLE LIMIT, EXCEPT THAT A PRODUCER WHO HAS MADE REASONABLE EFFORTS TO GROW HEMP AND WHOSE CANNABIS DOES NOT HAVE A TOTAL THC OF MORE THAN 1.0 PERCENT ON A DRY WEIGHT BASIS WILL NOT HAVE COMMITTED A NEGLIGENT VIOLATION.
- 6.1.8 Corrective Actions For Negligent Violations Include But Are Not Limited To:
  - 6.1.8.1 A Date, set by the Commissioner, By Which The Producer Shall Correct The Negligent Violation.



- 6.1.8.2 PERIODIC REPORTING TO THE COMMISSIONER, ON A FORM PROVIDED BY THE COMMISSIONER, ON THE REGISTRANT'S COMPLIANCE WITH THE ACT AND RULES FOR A PERIOD NOT LESS THAN TWO YEARS FROM THE DATE OF THE NEGLIGENT VIOLATION.
- 6.1.8.3 THE COMMISSIONER WILL CONDUCT INSPECTIONS TO DETERMINE WHETHER THE REGISTRANT HAS IMPLEMENTED THE CORRECTIVE ACTION PLAN AS SUBMITTED.6.1.9 EFFECTIVE JANUARY 1, 2022, A PRODUCER THAT NEGLIGENTLY VIOLATES THE PROVISION OF THESE RULES THREE TIMES IN A FIVE YEAR PERIOD SHALL BE INELIGIBLE TO PRODUCE HEMP FOR FIVE YEARS BEGINNING ON THE DATE OF THE THIRD VIOLATION.

#### PART 7 CDA APPROVED CERTIFIED SEED

- 7.1 A VARIETY OF INDUSTRIAL HEMP MAY BE APPROVED BY THE DEPARTMENT AS CDA APPROVED CERTIFIED SEED IF IT IS TESTED BY THE DEPARTMENT AND CONFIRMED TO PRODUCE MATURE PLANTS WITH A DELTA-9 THC CONCENTRATION OF NO MORE THAN 0.3% ON A DRY WEIGHT BASIS IN APPROVED MULTIPLE GEOGRAPHIC TRIALS IN COLORADO.
  - 7.1.1 The genetics of the plant material must be conditionally approved by the Colorado Seed Growers Association ("CSGA") variety review board or the variety review board of the Association Of Seed Certifying Agencies ("AOSCA") prior to the Department's validation of THC level and field observation for trueness to type in seed production fields registered with the CSGA.
  - 7.1.2 The variety must fit the description on the application form as submitted to the CSGA or AOSCA variety review board.
  - 7.1.3 The seed must be produced and certified in accordance with the certification requirements of a CDA approved seed certifying agency.
  - 7.1.4 THE SEED MUST BE LABELED WITH A CDA APPROVED CERTIFIED SEED TAG.
- 7.2 In addition to the Registration fees required by Rules 2.8 and 2.9, all Registrants shall pay to the Department an additional fee established by the Committee, for the purpose of funding the costs of administering the CDA Approved Seed Certification program.
- 7.3 An applicant that submits a variety for approval under the CDA Approved Seed Certification program shall pay the testing costs incurred by the Department and submit such other information as required on a form provided by the Commissioner.
- 7.4 Commercial applications for production fields of CDA approved and conditionally approved certified seed varieties shall be submitted by the Colorado Seed Growers Association members on a form provided by the Commissioner.



## Part 8 Reserved APPROVED LABORATORIES

- 8.1 THE DEPARTMENT WILL MAINTAIN A LIST OF APPROVED HEMP TESTING LABORATORIES THAT ARE CERTIFIED BY THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT.
- 8.2 AUTHORIZED SAMPLERS MUST SUBMIT HEMP SAMPLES FOR OFFICIAL ANALYSIS ONLY TO THOSE APPROVED HEMP TESTING LABORATORIES IDENTIFIED BY THE DEPARTMENT, AS SET FORTH IN RULE 8.1.



# Appendix C: CDA Commercial Industrial Hemp Registration Application, 2021



**REVISED MARCH 2021** 

#### For CDA Office Use Only

Registration Number
Payment Info: 6580
Payment Type Last 4
CR#

Amount Paid \$	
CR#	

#### COMMERCIAL INDUSTRIAL HEMP PROGRAM APPLICATION

Completely fill in the information requested. Incomplete applications will cause delays in processing. Need help? Use the <a href="Step-By-Step Instructions">Step-By-Step Instructions</a> which can be found on the Industrial Hemp web page, under "Forms and Reports". For a guided application and **expedited processing** times you may **Apply Online** instead. The *only* way to speed up processing is to apply Online. Please allow up to 30 days for processing times.

## Step 1. Choose option A or B below.

## A) REGISTERING AS A BUSINESS The business or trade name should be currently registered with the Colorado Secretary of State (SOS) or your state of residence. Please write the business name as registered with the SOS. Business Type: Corporation S-Corp LLC Partnership Co-Op Trade Name Business Name This will be the name that appears on your registration Business ID Number assigned by Colorado Secretary of State\_\_\_\_\_ If out of state, please indicate in which state your business is registered\_\_\_\_\_ (Include a copy of the alternative State's business registration certificate.) Business Federal EIN(Tax ID)Number\_\_\_\_\_\_ B) REGISTERING AS AN INDIVIDUAL/SOLE PROPRIETOR You will also need to complete and submit the attached citizenship verification form (Form 1A). Individual's/Sole ProprietorName\_ This will be the name that appears on your registration **Set a Main Contact** This person can be different from applicant or owner(s) and will be our first contact for all communications. Any change in contact information must be submitted within 10 days. \*Name\_\_\_\_\_\_Title\_\_\_\_ Phone Mobile Phone \*Is this person a "Key Participant" as defined in Step 2 (on the following page)? Yes $\square$ No $\square$ Business Mailing Address\_\_\_\_\_

City\_\_\_\_\_ State\_\_\_\_



## Step 2. Identifying Authorized Persons and Key Participants

CDA will only provide information to those authorized below. By Law, <u>you must also identify each Key Participant.</u> A Key <u>participant means</u>: a sole proprietor, a partner in a partnership, member of an LLC, or a person with executive managerial control in a corporation. A person with executive managerial control includes persons such as a chief executive officer, chief operating officer, or chief financial officer. "Key participan<u>t" does not inclu</u>de non executive managers such as farm, field, or shift managers.. Please note\* The CDA cannot remove "Key participant(s)" from the file without legal documentation once they have been identified as such on this application. Any change in contact information must be submitted within 10 days. Please write clearly!

*Name	Title	
Phone	Mobile Phone	
Email		
*Is this person a "Key Particip	oant" as defined in Step 2? Yes □No □	
*Nama	Title	
Phone	Mobile Phone	
Email		
*Is this person a "Key Particip	pant" as defined in Step 2? Yes □No □	
*Name	Title	
Phone	Mobile Phone	
Email		
*Is this person a "Key Particip	oant" as defined in Step 2? Yes □No □	
*Name	Title	
	Mobile Phone	
Email		
*Is this person a "Key Particip	oant" as defined in Step 2? Yes □No □	
*Name	Title	
Phone	Mobile Phone	
Email		
*Is this person a "Key Particip	oant" as defined in Step 2? Yes □No □	
*Name	Title	
Phone	Mobile Phone	
Email		
*Is this person a "Key Particip	oant" as defined in Step 2? Yes □No □	
*Name	Title	
Phone	Mobile Phone	
Email		
*Is this person a "Key Particip	pant" as defined in Step 2? Yes □No □	

Use additional sheets, if necessary



## **Step 3. Registered Land Area** ALL Fields on this page are required ~

## Aligning with local land use and water rights requirements

proposed land use relative to hen etc). By initialing this statement with local regulations and all nec ditch, or delivered via truck have	erifying regulations with local jurisdictions that may have authority over the up production (including, but not limited to: land owner, city, town, county, HOA, I confirm that the proposed hemp-related land use activities are in compliance essary approvals have been obtained. Any proposed use of water from a well, been verified as legal for such agricultural and/or commercial use by the
	rces. In addition, I understand that application fees paid to the CDA will not be ilure to verify, or violation of, non-CDA requirements: Initial Here:
The Applicant(s) have the legal a	thority to grow hemp on this land area. Initial Here:
include the entire property and the guidance use the Step-By-Step Instrour webpage.  A) PHYSICAL ADDRE  This is the address printed or	on which you plan to engage in Industrial Hemp cultivation. This does not need to area may include land and buildings you are not using for cultivation. For additional actions which can be found on the Industrial Hemp web page. See Mapping Examples on SS  n your registration certificate. It must be descriptive enough to differentiate it from ot a physical address, then please see step-by-step instructions for guidance. Do not enter
a Lot #, parcel #, TBD , etc	
Physical Address City	State C <u>O Zip Code</u>
B) REGISTERED LAN	ID AREA DIMENSIONS
entire property <u>. All areas mu</u>	e dimensions of the property the land area you register sits on if you are not registering the st be contiguous/connected within one boundary line or registered separately. Include all our total acreage, and all indoor hoop houses, greenhouses, or any other indoor space in
Exact Outdoor Acres to Re	gister Exact Indoor Square Feet to Register
	ES at the approximate center of the Registered Land Area (not the property) For help Step by Step Instructions or Page 1 of the Mapping Guide on our webpage.
GPS coordinates of center properties information)	point and within the boundary lines of mapped area (see Page 4 for map
Latitude	Longitude

## D) TOWNSHIP/RANGE/SECTION

Example: 39.918298

Go to <a href="https://www.earthpoint.us/TownshipsSearchByLatLon.aspx">www.earthpoint.us/TownshipsSearchByLatLon.aspx</a> and enter the GPS coordinates from section 3C to get your

Example: -105.112165

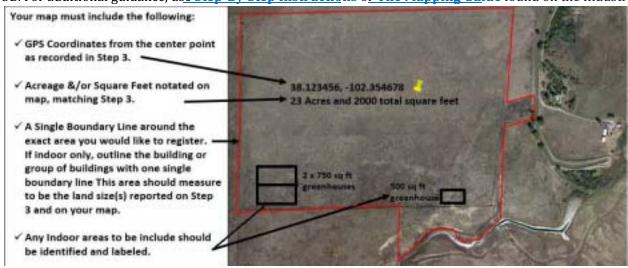


Township, Section and Range.

Township (T)	Range (R)	Section (S)
Example: T1S	Example: R69W	Example: S33

## Step 4. Registered Land Area Map

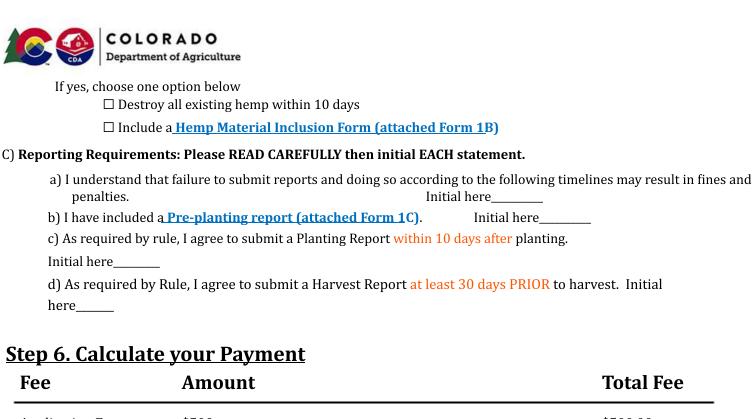
Attach a copy of a photo image map to this application. Surveyor maps and hand drawn maps will not be accepted. Identify and label on your map all indoor hoop houses, greenhouses, or any buildings used for cultivation. This information should match information reported in Step 3. Your mapped acreage and square feet must measure to match what is declared in Step 3B. For additional guidance, use Step-By-Step Instructions or The Mapping Guide found on the Industrial Hemp web page.



## Step 5. Inclusions: Complete each section (A, B, and C) AND initial all 4 in section C.

A) <u>Is this land area</u>	currently registered? $\square$ Yes $\square$ No <b>If</b> No, skip to $\square$	3. If Yes, Complete AT <b>AND then choose</b> AZ or A3
1) Name on	existing registration:	
Registration	#: ExpirationDate:	
valid until c <b>OR</b> 3) □ Close t	urrent registration expires. Continue to use you he current registration. Issue new registration is	upon approval of this application.
	anaging Agent from the existing registrant mus	st sign 3a: cisting registration and as someone with legal authority fo
this l	and area to sign . If you are not, you will need to nendment to Close prior to approval of this app	o contact the current registrant to request that they submi elication. The form can be found on the Industrial Hemp
time	revent having the same Registered Land Are I hereby request that the Colorado Departn Stration #	a included in more than one registration at the same nent of Agriculture close
	orized Agent Printed Nam <u>e</u>	
Auth	orized Agent signature	

B) <u>Is industrial hemp</u>, whether volunteer or otherwise, growing on the land area identified in this application?  $\Box$ Yes  $\Box$  No



Fee	Amount				Total Fee
Application Fee	\$500				\$500.00
Outdoor Acre	\$5.00 per acre	Enter # of Acres	x \$5.00	=	
Indoor Square Foot	\$0.003 per sq. ft.	Enter # of Square Ft	_ x 0.003	=	
		Enter " of Square I t	Total D	ue_	

Must be submitted with application

Date

## Step 7. Sign your Application

Signature

The person who signs for the registration should be someone who has the highest authority for business decisions in regards to this registration. Once registered they cannot be removed from the file, and is the only person that can terminate this registration prior to expiration without additional legal documentation.

I verify that I have reasonable grounds to believe that the crop planted is/will be of a type and variety of Cannabis that will produce a **TOTAL** DELTA-9 THC concentration of no more than 0.3% on a dry weight basis. Initial Here  $_{-}$  [Total  $\Delta$ 9-THC =  $\Delta$ 9-THC + (0.877 x  $\Delta$ 9-THCA). For information on our testing procedures please see our website].

I.	print name) verify that I have read the Rules (Rules Pertaining to the
Administration and Enforcement of the Indu	strial Hemp Regulatory Program Act,) and that I have all the legal and necessary
authority to bind the herein named Registrar	nt in making this application.

Title

## **Step 8. Submit your Application and Payment**

1) Make a copy of your application for your records.



#### 2) Send Application and Payment to

Email industrialhemp@state.co.us

OR Colorado Department of Agriculture
Attn: Industrial Hemp Program
305 Interlocken Parkway
Broomfield, CO 80021

Payment must accompany all applications for processing to begin. Applications received without payment included will be deemed incomplete and may be returned.

If dropping off your application in person it must be complete prior to your arrival, including a check, money order, or the attached payment form (no cash). If you need assistance completing your application, please call the office. We can not review it, or approve it, at the time of a walk-in submission as we process in the order they are received.

## **What to Expect Next**

We do our best to process these quickly. Please allow us up to 30 days to issue your registration prior to attempting to check the status. We'll reach out to you if we need any corrections or further information.

For expedited processing, apply online at Colorado.gov/hemp This is the only way to speed up processing and to pay application fees online. This is the only option for faster processing times.

In the meantime, if you have any questions please view our FAO's or email industrialhemp@state.co.us

## **Step 9. Payment Method (Choose One)**

It is recommended that you encrypt your email when sending account information. Alternatively, you can send this form via US Mail or call to provide this information over this phone. 303-869-9080 or 303-869-9084. Leave a message and allow for 24-48 hours for a return call. See Page 5 for email or mailing address.

Total Amount Due (from Section 6) to be charged to account below  CREDIT CARD PAYMENT  Type of Credit Card □Visa □ MasterCard □ American Express □ Discover  Credit Card Number: Expiration Date: 3 Digit Security Code: Name as it appears the card:	
Type of Credit Card □Visa □ MasterCard □ American Express □ Discover Credit Card Number:Name as it ap	
Credit Card Number <u>:</u> Expiration Date:3 Digit Security Code: Name as it ap	
	ppears on
Billing Address:	
City:State:Zip Code:	
By signing below, I agree that CDA will charge the credit card above the full application amount. In addition, I agadditional non-refundable 2.25% of the total amount due to cover the cost of the credit card transaction and non-refundable processing fee of \$0.75.	
Signature Date	

#### **ELECTRONIC CHECK (ECHECK) PAYMENT**

Some banks put fraud filters on bank accounts to prevent fraudulent charges. Please make sure your bank accepts e- check



Signature\_\_\_\_\_ Date\_\_\_\_



(A) \_\_\_ I am a United States Citizen

#### Form 1A

# Citizen Verification Form TO BE SUBMITTED ONLY IF YOU ARE NOT REGISTERING AS A BUSINESS

All state agencies are required to verify the lawful presence in the United States of all individuals and individuals doing business as sole proprietors who apply for certain public benefits including the license, permit or registration for which you are applying. (Colorado Revised Statutes section 24-76.5-103)

I swear and affirm under penalty of perjury under the laws of the State of Colorado that the information I have provided on this

## STEP 1- CHECK AN OPTION, PROVIDE PERSONAL INFORMATION AND SIGN THE AFFIRMATION.

form is complete and accurate and (CHECK ONE OPTION BELOW):

**(B)** \_\_\_ I am a permanent resident of the United States

(C) I am lawfully present in the United State	es pursuant to federal law			
AND I understand that this sworn statement is recolorado Revised Statutes section 24-76.5-103. I present in the United States prior to receipt of th requires the Colorado Department of Agriculture Department of Homeland Security ("DHS") Citize Entitlement Program. I hereby authorize DHS/CI acknowledge that making a false, fictitious, or fraunder the criminal laws of Colorado as perjury in shall constitute a separate criminal offense each	understand that this state law require is public benefit. I understand that if I is ("CDA") to verify my lawful presence is nship and Immigration Services ("CIS" S to provide CDA with information related under the second degree under Colorado Re	s me to provi am not a Uni n the United ) Systematic Ited to my im n this sworn vised Statute	ide proof that I am lay ted States citizen this States through the fe Alien Verification of amigration status. I fu affidavit is punishabl	wfully law deral rther e
Applicant Signature		Signature	Date	
First Name of Individual/Sole proprietor	Last Name of Individual/Sole propri	etor	Date of Birth	
Provide Business name, if different	2 propri			

#### STEP 2- PROVIDE DOCUMENTATION OF YOUR LAWFUL PRESENCE IN THE UNITED STATES.

ENT	ER YO	UR VAI	LID CO		DO DR UMBE		LICEN	ISE OR	R ID CA	RD
#	#	-	#	#	#	ı	#	#	#	#



## <u>OR</u>

## <u>CHOOSE</u> ONE OF THE FOLLOWING AND <u>PROVIDE A</u> COPY OF THE DOCUMENT.

OF THE DOCUMENT.
presence:
☐ Birth Certificate
US Coast Guard Merchant Mariner card
Native American Tribal Identification Document
Valid I-551 permanent resident card
ions to verify your lawful presence in the US.
ed the following information:
icator
ough CAVE
ough SAVE
ough SAVE
les. Specify the document or combinatio
<del></del>
int'sVerifying the document(s)
through the SAVE program
he applicant's lawful presence in the
_



\_Applicant did not provide the required documentation provided was not complete or accurate. provided was not complete or accurate

\_Other reason, please provide details:\_\_\_\_\_



#### Form 1B

## **Industrial Hemp Material Declaration for Inclusion**

To be submitted only if there is Industrial Hemp currently growing on the SAME land area identified in this application under an existing, valid, registration that will be closed or expiring prior to harvest of that plant material.

This form is for the express purpose of declaring Industrial Hemp for which a planting report has already been submitted under an existing registration for this same land area, and is still currently growing, but will not be harvested before the previous registration for this same land area expires. Industrial Hemp plant material submitted on this form at the time of application will be included in the new registration.

This Report is due with the new registration application.

This form should NOT be used for plant material acquired from a different location, source, or registered land area, other than the land area that is identified in this application.

Previous Registration planted: (Reg		<i>is same land area</i> ) under which the plant mate	erial was
•	-	d area was previously registered:	(Required)
		a area was previously registered.	
Mailing Address			
City	State_	Zip Code	
Business Phone		Cell Phone	
location where it is cur	rently planted an $\underline{a}$ to the map requ	Varieties/Cultivar e variety name, acreage and/or square feet pland the GPS coordinates for that location. (Use a sired with the application, provide a separate	additional sheets if necessary)
Indoor Variety	Square Feet	Description Of Location; i.e. 1000 sq ft greenhouse, 100 sq ft shed in NW corner Provide enough detail to clearly define location.	GPS Coordinates: Latitude and Longitude in decimal degree format from center of varietal grow area
Outdoor Variety	Square Feet	Description Of Location; i.e. 1000 sq ft greenhouse, 100 sq ft shed in NW corner Provide enough detail to clearly define location.	GPS Coordinates: Latitude and Longitude in decimal degree format from center of varietal grow



	area

## **Industrial Hemp Material Declaration for Inclusion**

To be submitted ONLY if there is Industrial Hemp currently growing on the land area identified in this application. This form is for the express purpose of declaring Industrial Hemp where a planting report has been submitted, but that the plant material will not be harvested before the previous registration for this same land area expires. Industrial Hemp plant material submitted on this form at the time of application will be included in the new registration.

## Map:

Map.		
PLEASE WRITE	"INCLUSION FORM MAP" on the top of t	he map in order to differentiate it from the application map.
This map will sh	now planting locations and different vari	ety locations, whereas the application map should not be broken down
	1 1	he Registered Land Area showing the boundaries of the entire grow
area, dimension	s/size of the cultivation area, clearly del	ineating the location of each existing variety within the Registered Land
Area.		
I	(print name), as	(Title of Officer if not sole proprietorship) verify that
		which was not harvested in the previous registration period and should
be included in th	ne subsequent registration for this Regis	tered Land Area.
Cianatura		Data
Signature		Date



# Form 1C

. . 1 137 ...

# **PRE-**PLANTING REPORT

(Planning Report)

Under Rule 3.1 Registrants are required to submit a pre-planting report, prior to planting. This is a "planning" report and only required ONCE per registration period. Not prior to each planting.

Providing the information below on this form and submitting it with this application fulfills the PRE-Planting Report requirement.

\*\*Your intended varieties and intended use can change from what is reported here.\*\*
You will report those changes, and show what you actually end up planting, on your Planting Report within 10 days of planting.
No updated Pre-Planting report is required if the details below change prior to when you plant.

Read the following important notice and then enter initials.

<u>I understand that in addition to this PRE-Planting report, A Planting Report is required within 10 days after planting and a Harvest Report is required at least 30 days prior to Harvest.</u> I also understand that failure to submit these required reports within the required timelines can result in fines and penalties. <u>Initial here</u>

Intended varieties:	
VARIETY NAME	
VARIETY NAME	
<del></del>	
(USE ADDITIONAL SHEETS IF NECESSARY)	
<b>Statement of Intended End Use</b>	
Please check off your intended end use for all plants grown under this registration. (Check all that apply)	
Animal Bedding□ Biofuel□ Cannabinoid Extraction□ Cloning□ Compost□ Cosmetic/Beauty□ Dietary Supplements□	
Fiber□ Food/Drink Additive□ Grain□ Hempcrete□ Insulation□ Polymer□ R&D□ Seed□ Smokable Flower□	
I(Title of Officer, if	
<b>not SoleProprietor)</b> verify that the material and purposes listed in the pre-planting reports are accurate and true to the of my knowledge.	bes
Signature	



# **Appendix D: Hemp Sampling Guidelines**



# Guidance 1

# **Hemp Sampling Guidelines and Remediation Sampling**

### **DESCRIPTION OF PURPOSE OF GUIDELINES**

Trained CDA inspectors as well as Authorized Samplers will collect pre-harvest samples from all lots not subject to performance based sampling on the Registered Land Area from registrations that have submitted planting reports required by CDA. CDA Inspectors will collect post-harvest samples from lots of those registrations where a lot tested above the acceptable total THC level.

# PART I: PRE-HARVEST SAMPLING-AUTHORIZED SAMPLERS

# A. SUPPLY LIST

- Digital scale
- Phone/camera
- Sampling kit
- Pruners/scissors
- Alcohol swabs or equivalent
- Paper towels
- Heavy duty paper bags (medium and large)
- Stapler w/staples
- Plastic bags and plastic zip ties
- Evidence tape
- Sharpies and pens
- Packing tape
- Ruler
- Binder clips
- Boxes for mailing samples

# B. GENERAL INFORMATION

- CDA inspectors and authorized samplers can only inspect and collect samples from Active registrations (or Amend to Close depending) and <u>only</u> from Registered Land Area
- CDA inspectors and authorized sampler needs to ensure that the sample being collected from the lot represents the lot being sampled



Lot: A contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of cannabis through the area

- No commingling of lots; one sample from one lot; collect samples from all lots.
- No commingling of indoor and outdoor hemp, even if same variety
- In the case of very small plantings where individual or a very limited number of hemp plants of a specific lot are present (so few you can easily count them), take a minimum of 3 flowers from 3 different plants (minimum of 1.00 ounce (oz)).

# C. PRE-SAMPLING

- Personal protective equipment (PPE): masks, long pants, long sleeved or short sleeved shirt, closed toe shoes, socks, sunglasses or other eyewear, baseball cap or wide-brim hat
- Ensure that the registration is Active at the time of your visit (contact hemp staff if Amend to Close)
- Have your list of registrations to be sampled, and key participant name and phone number or name and phone number of additional contact
  - The registrant will contact the Authorized Sampler prior to harvest to set date of sampling
  - Sampling must occur within 30 days prior to harvest date
  - If registrant is not cooperative with the Authorized Sampler, the Authorized Sampler must report that to the Department for potential enforcement actions
- Have map of location with GPS coordinates and lot(s); HOP application
- Have Planting and Harvest Reports (from HOP)
- Have Chain of Custody (COC) forms
- Have Sampling Form
- Have sampling kits
- Have disposable tyvek suits, if requested by registrant

# D. SAMPLE NUMBER

Use the following format: yyyymmdd-registrationnumber-01

- Example: sample number 20200807-08-999999-01
  - o The 01 represents that one sample was collected from registration no. 08-999999 on 8-7-2020. The 08 represents the state of Colorado USDA number.
  - o Registrations with multiple lots will have multiple samples collected: 20200807-08-999999-02, etc.
- Write the sample number and collection time (military time) on the heavy duty paper bag
- Multiple cuttings from one lot do not comprise multiple samples; it is one sample with multiple cuttings

# E. SAMPLE COLLECTION FROM EACH LOT



- Ensure registration key participant or additional contact is present during sampling.
  - If key participant, or additional contacts, gives Authorized Sampler approval to meet with someone else other than those people on application, the Authorized Sampler is to request that in writing; write on inspection form that the Authorized Sampler received approval from key participant, or additional contact, and write date, time, and name (first and last) of who you spoke with, and their title
- Ask whether pesticides have been applied; may need to return on different day if an REI
- Complete Sampling Form, sign form, and have key participants or additional contact sign form.
  - If the Authorized Sampler met with someone other than the key participant, or additional contact, write that in the comments and write the name of the person you met with.
  - Email the Sampling Form to the key participant or additional contact
- Set up your cleaning area:
  - put paper towels down on the space; as you remove the items from your sampling kit and clean them, put them on the paper towel
  - not necessary to replace paper towels between lots; replace only when soiled
- Clean pruners/scissors with alcohol swab between lots
- Clean other equipment with alcohol as needed (things get sticky)
- Fill out the COC form
  - A. Collecting the sample
    - Business name, business phone number, mailing address, physical address, email address, name of main contact or additional contact
    - Registration number
    - Sample number (see above)
    - Collection time---use military time
    - Registered Land Area (sq ft and/or acres)
    - Size of lot sampled (sq ft or acres)
    - Number of Cuttings Collected
    - Strain or Variety name: DO NOT PUT N/A, write Unknown
    - Development stage (i.e., flowering or not)
    - GPS coordinates; location name (not address)
    - Comments
    - Print name of inspector
    - Signature of inspector
  - B. Relinquishing the sample
    - Fill out the bottom of the COC for transfer of the sample; either through the mail or directly with the approved lab personnel (see Transport)
- Put on nitrile/latex gloves
  - Change gloves between lots



- DO NOT touch anything else other than the hemp plants and the pruners, writing utensil, etc, otherwise you need to put on new gloves
- When requested by registrant, have a disposable tyvek suit
- View the area that is to be sampled and determine your path (<u>See Table 2</u>); assess the homogeneity of the field/indoor lot and collect from similar looking plants; randomly select the plants and avoid collecting too many flowers from the edges
  - Photograph field or area to be inspected and/or sampled and when finished upload image to registrant's file on G drive
  - Cut 8 inches from the top of flowering cannabis plants (male and female) (i.e., <u>one</u> <u>cutting per plant</u>)
  - For outdoor fields: Using your pruners, acut 8 inches from the top of mature flowering cannabis plants. If no flowers, weigh.
    - o A minimum of 5 cuttings (minimum of 1 ounce (28.35 grams)) is required (<u>See Table 1</u>)
  - For indoor: Using your pruners, cut 8 inches from the top of 3 mature flowering cannabis plants per 1000 sq ft (i.e., 3 cuttings per 1000 sq ft) (a minimum of 1.00 ounce (28.35 grams). If no flowers, weigh.
    - o When requested, the registrant may provide sterile pruners when concerned about contaminants being introduced
    - o In the event pruners are provided by the registrant, please note this on the Sampling Form
- Place each cutting into the heavy duty paper bag until the required number is achieved. Use multiple paper bags when needed for large acreages or indoor
- Fold paper bag
  - At your cleaning area, staple the fold in 1-3 locations
- Put evidence tape over the fold of stapled paper bag
- Using the Sharpie, write the sample number and collection time on the heavy duty paper bag (Collection time on paper bag must match collection time on COC)

When multiple paper bags are used for the same lot, additionally identify them as bag 1 of 3, 2 of 3, etc. and <u>write the same sample number on each bag</u>

- Sketch your path on the field map, or sketch a map
  - staple the map to the COC form and using a binder clip attach the sheets to the heavy duty paper bag that has the sample
- Place the sample in box or tote for storage until mailed or delivered to approved labs or Department Lab
- Remove nitrile/latex gloves and dispose of them in a trash bag
- Clean everything you used (pruner, stapler, evidence tape, etc.) with alcohol swabs

# F. TRANSPORT



- Keep the COC and map with sample during transfer to approved labs or Department Lab
- Keep heavy duty paper bags out of the sun and as cool as possible during transport
- When you are dropping off the samples at approved lab, fill out the bottom of the COC form
  - who relinquished, date, time, and reason for sample transfer
  - approved lab staff will fill in "who received"
- When dropping off samples at approved labs or mailing samples (USPS) to approved labs, follow their procedures
- If mailing samples, place samples in a plastic bag to mitigate odors; use zip tie on plastic bag
- Please immediately notify Michael Roll or Brian Koontz if problems arise during shipping.

# G. AFTER SAMPLE COLLECTION

• Inform the Department when sampling is concluded at a registration

### H. HEMP PROGRAM CONTACTS

- Contact Michael Roll for:
  - Questions about the sampling
  - Questions from the registrant about why they were sampled

Michael Roll - Hemp Sampling Certification Coordinator 303-869-9000 (office) 720-955-8840 (cell)

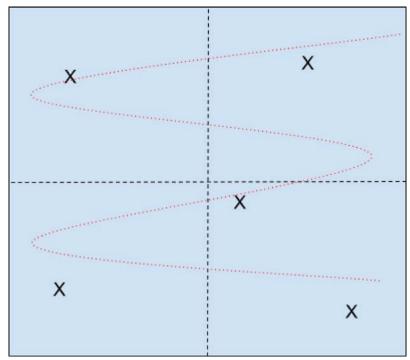


Table 1. Cuttings per Area

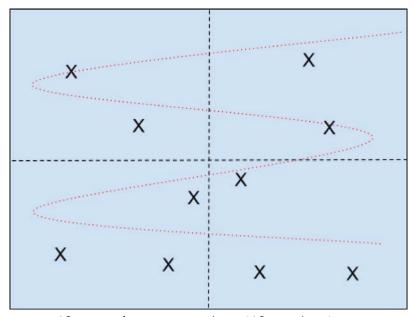
Acres Planted	Number of Plants (cuttings)	Acres Planted	Number of Plants (cuttings)
1000 sq ft; < 1 acre	3	91-95	73
1-5	5	96-100	76
6-20	1 cutting per acre	101-105	78
21-25	24	106-110	81
26-30	28	115-120	86
31-35	32	121-125	89
36-40	36	126-130	91
41-45	40	131-135	94
46-50	43	136-140	96
51-55	47	141-145	98
56-60	51	146-150	101
61-65	54	151-155	103
66-70	57	156-160	105
71-75	61	161-165	107
76-80	64	166-170	109
81-85	67	171 and greater in increments of 5 acres	add 2
86-90	70		



**Table 2.** Sampling patterns.



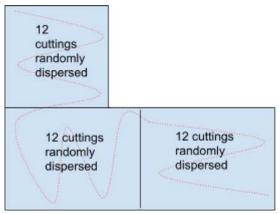
1 acre plot same variety (5 cuttings)



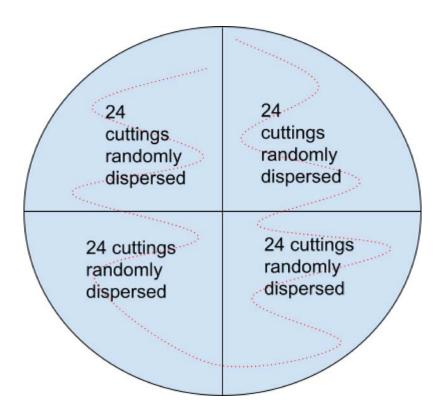
10 acre plot same variety (10 cuttings)



**Table 2.** Sampling patterns cont'd.



40 acre plot same variety (36 cuttings)



140 acre plot same variety (96 cuttings)



### PART II: HEMP REMEDIATED LOT SAMPLING GUIDELINES - CDA INSPECTORS

#### A. GENERAL INFORMATION

- A key participant or additional contact must be present
- No co-mingling of post-harvest lots; one sample from one post-harvest lot
- Personal protective equipment (PPE): mask, long pants, long sleeved shirt, closed toe shoes, socks, nitrile gloves, sunglasses or other eyewear, baseball cap or wide-brim hat
- Have your list of registrations to be sampled, and main contact name and phone number OR name and phone number of authorized person
  - After the Registrant is notified that test results are non-compliant, the Inspector shall email the Registrant informing them that a post-harvest remediation sample will be collected from the harvested non-compliant hemp lot(s).
  - The inspector shall make an appointment with the Registrant in a timely manner to collect that sample. Once the Department receives the Registrant's Disposal or Remediation Form, an inspector will collect a post-harvest sample within 10 business days.
- Have map of location with GPS coordinates of the registered land area
- Have Final Report (i.e., Certificate of Analysis)
- Have Chain of Custody forms
- Sampling kit stocked with supplies

#### B. SAMPLE LOCATION

• Within the registered land area, collect the sample from the non-compliant lot(s) of lot remediated by either blending the entire biomass or removing and destroying flower material.

# C. SAMPLE NUMBER

Use the following format: yyyymmdd-registration number-01P

- Example: sample number 20200807-08-999999-01P
  - The 01 represents that one sample was collected from registration no. 999999 on 8-7-2020. The 08 represents the state of Colorado USDA number. P means post-harvest.
  - Registrations with multiple post-harvest lots will have multiple samples collected: 20200807-08-999999-02P, etc.

# D. REMEDIATED CROP SAMPLE COLLECTION FROM EACH NON-COMPLIANT LOT



- Post-harvest samples are to be collected from non-compliant hemp only (pre-harvest hemp that tested greater than 0.3% and less than 1% THC) that includes total blended biomass with flowers or biomass after all flowers are removed.
- No commingling of remediated lots is allowed.
- Set up your cleaning area: put paper towels down on the space; as you remove the items from your kit and clean them, put them on the paper towel
  - not necessary to replace paper towels between lots; replace only when soiled
- Have nitrile disposable gloves
- Have paper bags
- Have trash bag(s)
- Clean pruners with alcohol swab between lots
- Clean Sharpie (external and with lid off) with alcohol swab between lots
- Clean writing utensil with alcohol swab between lots and other supplies as needed
- Have scale; clean the scale surfaces with alcohol swab between lots
- Have single-use disposable scoops
- Fill out Chain of Custody form
- Collecting the sample
  - o Business name, business phone number, mailing address, physical address, name of key participant or authorized agent and/or who you met with
  - o Registration number
  - o Sample number (yyyymmdd-registrationnumber-01P)
  - o Collection date and time (military time)
  - o Indoor or Outdoor
  - o Location of the storage/drying area (Barn, garage, greenhouse, etc.)
  - o Strain/variety name; development stage (i.e., dry intact plant; ground plant or ground floral material; trimmed floral material, or floral material and stems)
  - o Comments: post-harvest sample and any other information
    - o Print name of inspector
    - o Signature of inspector
  - 1. Relinquishing the sample
    - o Fill out the bottom of the Chain of Custody for transfer of the sample; either through the mail or directly with Department Lab personnel or certified lab (see Transport)
- Using the Sharpie, write the sample number and collection time on the paper bag
- Put on nitrile gloves and any other PPE mentioned above
  - Change gloves between lots
  - DO NOT touch anything else with your hands other than the hemp plants and the pruners, writing utensil, etc., otherwise you need to put on new gloves
- View the dry plant material to be sampled; assess the homogeneity of it; ensure all the harvested plant material is accounted for; ensure that the post-harvest plant



material is the same plant material that was sampled pre-harvest; randomly select the dry plant material

- 1. For intact-plant post harvested plant material with no flowers:
  - For plants harvested from indoor or outdoor fields: Cut 8 inches from the top of the plant material from randomly selected remediated plants of the non-compliant lot. Be consistent with the number of cuttings as were from the pre-harvest sample (number of cuttings per area). Use pruners to cut stalks
  - Place the cuttings in the paper bag
  - Fold the paper bag and staple
  - Put evidence tape over the stapled part of the paper bag
  - Write the sample number and collection time (military time) on the paper bag
  - Using a binder clip, clip the Chain of Custody form to the paper bag
  - Place the paper bag sample in box or tote
  - Remove nitrile gloves and dispose of them in trash bag
  - Clean pruners with alcohol swab
  - Clean everything you used (pruner, scale, evidence tape, etc.) with alcohol swabs
- 2. For post-harvested homogenized plant material
  - Tare the scale to 0.00 oz; place paper bag on scale; tare again
  - Use the disposable scoop to collect dry plant material and place in paper bag
  - Weigh the paper bag as you go to collect 1.00 oz of dry plant material
  - Write the weight on the Chain of Custody form in "comments"
  - Fold the paper bag and staple
  - Put evidence tape over the stapled part of the paper bag
  - Write the sample number and collection time (military time) on the paper bag
  - Using a binder clip, clip the Chain of Custody form to the paper bag
  - Place the paper bag sample in box or tote
  - Remove nitrile gloves and dispose of them in trash bag
  - Place used scoop in trash bag
  - Clean everything you used (pruner, scale, evidence tape, etc.) with alcohol swabs

# E. TRANSPORT

- Keep Chain of Custody with sample during transfer to Department Lab
- Keep paper bags out of the sun and as cool as possible during transport
- If you are dropping off the sample at the Department Lab, fill out the bottom of the Chain of Custody form
  - who relinquished, date, time, and reason for sample transfer
  - Lab staff will fill in "who received"



- If you are mailing the sample, fill out the bottom of the Chain of Custody form
  - who relinquished, date, time, and reason for sample transfer (once the Department Lab receives the sample, Lab staff will fill in "who received")
  - place samples in a plastic bag to mitigate odors; use zip tie on plastic bag
  - <u>DO NOT</u> put the COC forms in the plastic bag; put them in the box but outside the plastic bag. Attach the COC to the plastic bag with a binder clip if more than one sample in the box
  - Use US Postal Service boxes (Regional A and/or Regional B, or appropriate size box) or any box you choose. Mail samples to the Department Lab and keep your mailing receipt, for tracking purposes:

Colorado Department of Agriculture Kristi McCallum Laboratory Services 300 S. Technology Ct. Broomfield, CO 80021

Return Address:
Brian Koontz, Program Manager
Colorado Department of Agriculture
305 Interlocken Pkwy
Broomfield, CO 80021

• Please follow this procedure when <u>dropping off samples at the Lab</u>:

Inspectors bringing hemp to the laboratory will come through the warehouse door and enter the BCL Sample receiving room.

They will pick up the phone in sample receiving and call Caroline at 303-869-9222.

They will tell Caroline that they are here with "Hemp samples" and Caroline will page the BCL.

Someone from BCL will come to the sample receiving area to receive the samples. This is all written out and posted in the BCL Sample receiving room.

• Please immediately notify Margaret Foderaro or Brian Koontz if problems arise during shipping.



# **Appendix E: Performanced Based Sampling Plan**



# Guidance 2

# **Performanced Based Hemp Sampling Protocol**

CDA's Hemp Sampling Guidelines (Appendix D) adopts USDA performance sampling approach where the method of sampling ensures a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level and ensure that a representative sample is collected that represents a homogeneous composition of the lot. The performance-based sampling methods meet the following criteria as described in (a)(2)(iii)(A) and (B) of section §990.3. These are:

- (A) The alternative sampling method is included in the State's hemp plan and will be reviewed and approved by USDA.
- (B) The alternative method will ensure, at a confidence level of 95 percent, that the cannabis plants tested with the alternative method will not test above the acceptable hemp THC level. The alternative method includes the following factors:
  - (1) A producer who used certified seed that have demonstrated consistently acceptable THC level under Colorado conditions;
  - (2) A producer who has registered for R&D and is conducting research on hemp;
  - (3) A producer who has consistently produced compliant hemp plants at least for three consecutive growth cycles; and
  - (4) A producer who grows immature plants including clones and microgreens who will not have mature plants will be subjected to alternate sampling protocols.

Performance based sampling does not prevent CDA from conducting random records inspections or sampling and testing of any hemp crops from licensee/registrants of the hemp program. CDA reserves the right to conduct a records inspection, sample, and test any hemp lot at any time to ensure compliance with the acceptable hemp THC level. Based on testing data for a period of two years, CDA will reassess all performance based sampling.

Performance based sampling will include different sampling frequencies and requirements for the following categories of hemp producers:

# 1. Producers Using Certified Seed or Certified Clones With Consistent THC Levels

CDA has conducted certified seed trials since 2014 and included clones in 2020. Twenty two varieties of hemp seed and two varieties of clones consistently provide total THC results of less than 0.3% in test plots located in various regions of Colorado. Because CDA has used scientific methods to test hemp crops produced from certified seed and clone to ensure at a confidence level of 95 percent that no more than one percent (1%) of the plants in the lot would exceed the acceptable hemp THC level, CDA will apply an alternative sampling plan to these crops. Table 1 below.

To qualify for alternative sampling methods, producers must provide CDA the following in addition to information required in 7 CFR 990.3(a)(1). These are:

- a) Producer must provide to CDA copies of all certified seed label(s) and invoices of all purchased certified seed to in order to verify size of certified lots and that certified production is not supplemented with non-certified genetics in the planting report.
- b) Hemp crops produced from certified hemp seeds or clones may not be subject to testing of each lot. Instead, certified seed or clone lots will be tested every other year. If a certified hemp seed or clone variety



is found to exceed the acceptable total THC concentration, that producer must have the specific variety tested at every growth cycle until the acceptable total THC concentration is achieved.

c) CDA will randomly select lots produced with certified seed or clone for sampling for a period of two years and evaluate total THC results in order to determine effectiveness of this alternative sampling method.

# 2. Production For Research And Development

To qualify for alternative sampling methods, producers must provide to CDA the following in addition to information required in 7 CFR 990.3(a)(1) including:

- a) The hemp producers cultivating for these purposes apply for a research and development hemp registration with CDA per 8 CCR 1203-23, rule 2.2 (see Appendix B).
- b) Provided that the hemp is NOT entering commerce, allow universities and research institutions to self-report results of sampling and testing under the following conditions:
  - i) Results regarding research are shared with the public or published on the research institution website.
  - ii) The research producer provides CDA with the scope and standard operating procedures for production of hemp.
  - iii) The research producer provides CDA with a disposal plan for all hemp produced including photographic evidence for verification.
  - iv) The research producer allows the CDA to inspect or audit the above documentation and testing results on an annual basis.
  - v) Any non-compliant lots of hemp produced by a university research institution (or research institution) shall be disposed of and reported to the department.
- c) Research institutions may not be subject to pre-harvest sampling of hemp crops when they comply with (a), (b), and (c) listed above.
- d) Although university research institutions must be assessed a negligent violation, if tested crops exceed 1.0%, CDA may use discretion in developing corrective action plans and is not required to suspend a research license.
- e) Research institutions shall only be assessed a negligent violation if the THC content of a sample collected by CDA exceeds 1.0% total THC.

# 3. Producer Producing Compliant Hemp Over An Extended Period Of Time

The final rule allows for the consideration of "whether a producer has consistently produced compliant hemp plants over an extended period of time." A hemp producer who has met all three of the below compliance history requirements may not be subject to testing in the current year:

- a) produced hemp for a period of three (3) consecutive growth cycles;
- b) has had their hemp tested by CDA or an authorized sampling agent each of those growth cycles;
- c) all results in each of the previous three (3) growth cycles were below the acceptable hemp THC level (total THC not more than 0.3%); and are growing the same variety(s) or cultivar(s) as in the previous three (3) growth cycles.

# 4. Production Of Microgreens, Greens, Transplants, And Immature Plants

**Hemp Microgreens (definition):** immature hemp seedlings for human consumption that are cut-off above the soil or substrate line and harvested prior to flowering and not more than 14 days after germination. Hemp microgreens are typically between two (2) and three (3) inches in height, but not taller than five (5) inches.



If hemp producers harvest microgreens, the state shall conduct random testing of these plants to include 25% of all lots produced. Due to extremely low levels of cannabinoids in the very immature plants, the sampling and testing of every harvest of every lot is impractical and unnecessary.

Hemp microgreens may not be subject to testing of each lot. The producer shall ensure that the seeds used to produce microgreens are from cannabis varieties that meet the definition of hemp. The producer must obtain written approval from CDA before planting seeds for microgreens. Hemp microgreen operations shall be subject to random inspections and sampling.

**Hemp Greens (definition):** hemp leaves from immature plants germinated from seed and the plants are no more than ten (10) inches tall and are not flowering.

Since the definition of hemp greens involves the leaves of very immature plants (less than 10 inches tall) and not flowering it would be unnecessary to sample every lot of that hemp.

Hemp greens may not be subject to testing of each lot. The producer shall ensure that the seeds used to produce hemp greens are from cannabis varieties that meet the definition of hemp. The producer must obtain written approval from CDA before planting seeds for hemp greens. Lots harvested for hemp greens shall be subject to random inspections and sampling.

**Hemp Transplants (definition):** hemp seedlings, rooted cuttings, immature plants produced from tissue culture, or other means of reproduction, which are not harvested but transplanted into a large container or field to mature for harvest. The movement of transplants from their original location to the crop production location is not considered a harvest.

When hemp transplants move from the greenhouse/indoor facility to either larger pots or the field, this would not be considered a harvest, therefore would not require sampling because the final crop is sampled prior to harvest.

The transfer of hemp transplants to the location at which these plants will grow to maturity and from which these plants will be harvested shall not be considered a harvest. Hemp transplants will not be subject to sampling before the plants are transferred to the location at which these plants will grow to maturity and from which these plants will be harvested. However, the mature crop produced from hemp transplants is subject to sampling and testing.

**Hemp Mother Plants (definition):** immature cannabis plants with a THC concentration of 0.3% or less that are used for cloning purposes.

Hemp mother plants may be sampled any time, but may not be subject to testing in the future if those results are 0.3% THC or less. If the mother plants are of certified seed or clone varieties, they would not need to be sampled when they are harvested or leave the Registered Land Area. Otherwise, different strains of mother plants that are harvested or leave the Registered Land Area must be sampled.

# 5. Production For Grain Or Industrial Uses

If producers are harvesting for grain or fiber, there is less need to sample because these strains of cannabis plants are generally below 0.3% THC. For this reason, these producers will be sampled every other year or growth cycle. Producers growing varieties that test above the allowable total THC concentration will be tested every growth cycle will be required to have subsequent lots of that variety tested every growth cycle and will be



eligible for testing every other year after receiving a test result within the allowable total THC concentration for that variety. In addition, risk-based sampling would apply to producers using strains that have historically tested higher in total THC concentration.

If a producer is sampled and the lot fails the pre-harvest test, the producer would have the option to remediate the lot or destroy it. The remediated lot would be sampled.

Table 1. Certified Seed/Clone Data 2020. All are seed except as noted.

Variety	Intended Use	Location	Percent THC
AV1*	Fiber	ARDEC	0.22
		AVRC	0.47
		SLVRC	0.15
		WCRC	0.14
NWG2463_1	Grain/CBD	ARDEC	0.22
		AVRC	0.12
		SLVRC	0.17
		WCRC	0.22
NWG2730_1	Grain/CBD	ARDEC	0.12
		AVRC	0.14
		SLVRC	0.14
		WCRC	0.25
NWG4000_1	Grain/CBD	ARDEC	.012
		AVRC	0.15
		SLVRC	0.16
		WCRC	0.21
NWG4113_1	Grain/CBD	ARDEC	0.19
		AVRC	0.17
		SLVRC	0.21
		WCRC	.017



1 (clone)	ARDEC	0.09	
		AVRC	0.11
	SLVRC	0.16	
		WCRC	0.26
CJ2 (clone)	CBD	ARDEC	0.29
		AVRC	0.23
	SLVRC	0.29	
	WCRC	0.36**	

<sup>\*</sup> Approved conditionally; mandatory testing in 2021
\*\* Re-analysis performed; 0.32% THC



# **Appendix F: CDA Testing Laboratory ISO Certification**



#### SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

# COLORADO DEPARTMENT OF AGRICULTURE BIOCHEMISTRY LABORATORY 300 South Technology Court

Broomfield, CO 80021 Kristina McCallum Phone: 303-869-9250 Fax: 303-869-9223

CHEMICAL

Valid To: June 30, 2023 Certificate Number: 2851.01

In recognition of the successful completion of the A2LA evaluation process (including an assessment of the laboratory's compliance with the A2LA Food Testing Program Requirements, containing 2018 "AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals"), accreditation is granted to this laboratory to perform the following tests on food products, feed, drugs, food additives, fertilizers, water, soil, vegetation, and swabs:

Test(s)/Matrix(ces) **Test Method/Technology** Determination of Amino Acids in Animal Feed and Pet FF-METH-031 UPLC Food Lysine Methionine Taurine Determination of Glyphosate and AMPA in Vegetation, Soil, and Swabs PT-METH-041 LC-MS/MS Determination of Nitrogen in Fertilizer FF-METH-001 Combustion Determination of Nutritional Elements in Animal Food FF-METH-005 AA Calcium Magnesium Potassium Zinc Determination of Pesticide Residues in Vegetation, Excluding PT-METH-012 LC-MS/MS Cannabis Acetochlor Alachlor Aldicarb Atrazine Avermectin B1a Azadiracthin Azinphos-methyl Azoxystrobin Bifenazate Bifenthrin Boscalid

(A2LA Cert. No. 2851.01) 05/24/2021 Page 1



Determination of Pesticide Residues in Vegetation, Excluding	PT-METH-012 LC-MS/MS
Cannabis (cont'd)	
Carbaryl	
Carboxin	
Chlorpyrifos	
Clofentezine	
Clothianidin	
Coumaphos	
Cyazofamid	
Cyhalothrin	
Cyprodinil	
Diazinon	
Dichlorvos	
Difenoconazole	
Diflubenzuron	
Dimethoate	
Dimethomorph	
Dinotefuran	
Diuron	
Ethoprophos	
Etoxazole	
Fenamidone	
Fenarimol	
Fenbuconazole	
Fenhexamid	
Fenpyroximate	
Flonicamid	
Fluoxastrobin	
Flutolanil	
Fluvalinate	
Formetanate	
Hexythiazox Imazalil Malathion	
Metalaxyl Methiocarb	
Methocarb	
Metolachlor	
Myclobutanil	
Oxamyl	
Permethrin	
Phosmet	
Piperonyl butoxide	
Pirimifos-methyl	
Prallethrin	
Propargite	
Propiconazole	
Pymetrozine	
Pyraclostrobin	
Pyrethrin I	
Pyrethrin II	
Pyrethrins	



Pyridaben
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1		
(A2LA Cert. No. 2851.01) 05/24/2021 Test(s)/Matrix(ces)	Page 2 of 3  Test Method/Technology	
Determination of Pesticide Residues in Vegetation, Excluding Cannabis (cont'd) Pyrimethanil Pyriproxyfen Quinoxyfen Simazine Spinosad Spiromesifen Spirotetramat Tebuconazole Tebufenozide Tetrachlorvinphos Thiabendazole Thiacloprid Thiamethoxam Thiodicarb Triadimefon Trifloxystrobin Triflumizole	PT-METH-012 LC-MS/MS	
Determination of P <sub>2</sub> O <sub>5</sub> in Fertilizer	FF-METH-011 Gravimetric	
Determination of Phosphorus in Animal Food	FF-METH-014 ICP	
Determination of Potash in Fertilizer	FF-METH-028 AA	
Determination of Potash and P <sub>2</sub> O <sub>5</sub> in Fertilizer	FF-METH-002 ICP	
Determination of Protein in Animal Food	FF-METH-012 Combustion	
Determination of Sulfur in Fertilizer	FF-METH-004 Combustion	
Determination of Sulfur in Fertilizer	FF-METH-027 Gravimetric	
Determination of Total Delta-9-THC in Hemp	PT-METH-031 GC-FID	
Determination of Vitamin A in Animal Food	FF-METH-023 HPLC	

(A2LA Cert. No. 2851.01) 05/24/2021 Page 3 of 3



# Accredited Laboratory

A2LA has accredited

# COLORADO DEPARTMENT OF AGRICULTURE BIOCHEMISTRY LABORATORY

Broomfield, CO

for technical competence in the field of

# Chemical Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. This laboratory also meets the requirements of A2LA R204 – Specific Requirements – Food and Pharmaceutical Testing Laboratory Accreditation Program. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).

Vice President, Accreditation



Presented this 24<sup>th</sup> day of May 2021.

Services

For the Accreditation Council

Certificate Number 2851.01

Valid to June 30, 2023

For the tests to which this accreditation applies, please refer to the laboratory's Chemical Scope of Accreditation.



# Appendix G: 5 CCR 1005-5 Hemp Testing Laboratory Certification



#### COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

# **Laboratory Services Division**

# **Hemp Testing Laboratory Certification**

5 CCR 1005-5

### **Rule 1: Authority and Definitions**

# **1.1** Authority

This regulation is established under the authority contained in sections 35-61-105.5(2)(d) and 25-1.5-101(1)(f) et seq., C.R.S.

# 1.2 Scope and Purpose

The purpose of this rule is to establish criteria for the certification of laboratories to test Industrial Hemp and hemp-derived products.

#### 1.3 Definitions

The following terms, whenever used in or referred to in these regulations, shall have the following respective meanings

- 1.3.1 "Acceptability Criteria" means the specified limits placed on the characteristics of an item or method that are used to determine data quality.
- 1.3.2 "Accreditation" means approval by an impartial non-profit organization that operates in conformance with the International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) standard 17011 and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for Testing.
- 1.3.3 "Action Level" means the threshold value that provides the criterion for determining whether a sample passes or fails an analytical test.
- 1.3.4 "Analyte" means the substance of interest in the analysis.
- 1.3.5 "Cannabinoid" means a class of lipophilic molecules that are naturally occurring in cannabis, including Industrial Hemp and marijuana.
- 1.3.6 "CBD" means cannabidiol.
- 1.3.7 "CBDA" means cannabidiolic acid.
- 1.3.8 "Chain of Custody" or "COC" means the chronological documentation that records the sequence of custody, control, transfer, analysis, and disposal of a Sample.



- 1.3.9 "Corrective Action" means a reactive action implemented to eliminate the root cause of a Nonconformance and to prevent recurrence.
- 1.3.10 "Certificate of Analysis" means an official document issued by a certified Hemp Testing Laboratory that shows results of scientific tests performed on a product.
- 1.3.11 "Delta-9 tetrahydrocannabinol" or "delta-9 THC" has the same meaning as "tetrahydrocannabinols" as set forth in section 27-80-203 (24). C.R.S. Delta-9 THC (CAS 1972-08-3) is the primary psychoactive component of cannabis. For the purposes of these regulations, the terms "Delta-9 THC" and "THC" are interchangeable.
- 1.3.12 "Department" means the Colorado Department of Public Health and Environment.
- 1.3.13 "Dry Weight Basis" means the ratio of the amount of moisture in a sample to the amount of dry solid in a sample. A basis for expressing the percentage of a chemical in a substance after removing the moisture from the substance. Percentage of THC on a dry weight basis means the percentage of THC, by weight, in a cannabis item (plant, extract, or other derivative), after excluding moisture from the item.
- 1.3.14"Exclusivity" means the specificity of the test method for validating microbial testing methods. It evaluates the ability of the method to distinguish the Target Organisms from similar but genetically distinct non-target organisms.
- 1.3.15"Hemp Testing Laboratory" means a public or private laboratory certified, or approved by the Department, to perform compliance testing on Industrial Hemp and Industrial Hemp Products.
- 1.3.16 "Inclusivity" means, related to microbiological method validation, the sensitivity of the test method. It evaluates the ability of the test method to detect a wide range of Target Organisms by a defined relatedness.
- 1.3.17 "Industrial Hemp" or "hemp" means the plant Cannabis sativa L. and any part of the plant, including the seeds, all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a Delta-9 tetrahydrocannabinol concentration of no more than 0.3% on a dry-weight basis.
- 1.3.18 "Industrial Hemp Cultivator" means a producer that grows Industrial Hemp under a current registration issued by the Colorado Department of Agriculture.
- 1.3.19 "Industrial Hemp Extract" means an unfinished industrial hemp product or industrial hemp product produced through a solvent or non-solvent based industrial hemp manufacturing process, including but not limited to oils, distillates, resins, and isolates.
- 1.3.20 "Industrial Hemp Manufacturer" means a facility that manufactures, produces, packs, processes (extracts), treats, packages, or holds/warehouses Industrial Hemp Products and unfinished Industrial Hemp Products under a current registration issued by the Colorado



Department of Public Health and Environment.

- 1.3.21 "Industrial Hemp Product" means a finished product containing Industrial Hemp that is for human use or consumption and:
  - a. Is a cosmetic as defined in 25-5-402(6) C.R.S.; or
  - b. Is a dietary supplement as defined in 25-5-426(2)(d) C.R.S.; or
  - c. Is a food as defined in 25-5-402(11) C.R.S.;
  - d. Is a food additive as defined in 25-5-402(12) C.R.S.;
  - e. Contains any part of the hemp plant, including naturally occurring Cannabinoids, compounds, concentrates, extracts, isolates, resins, or derivatives; and
  - f. Contains a Delta-9 THC concentration of no more than 0.3% and
  - g. Is not a drug as defined in 25-5-402(9) C.R.S.
- 1.3.22 "Instrument Detection Limit" (IDL) is the concentration equivalent to a signal, due to the analyte of interest, which is the smallest signal that can be distinguished from background noise by a particular instrument. The IDL should always be below the method detection limit, and is not used for compliance data reporting, but may be used for statistical data analysis and comparing the attributes of different instruments. The IDL is similar to the "critical level" and "criterion of detection" as defined in the literature.
- 1.3.23 "Limit of Detection" (LOD) or detection limit, is the lowest concentration level that can be determined to be statistically different from a blank (99% confidence). The LOD is typically determined to be in the region where the signal to noise ratio is greater than 5. Limits of detection are matrix, method, and analyte specific.
  - Note: For the purposes of laboratory certification, the LOD is approximately equal to the Method Detection Limit (MDL) for those tests which the MDL can be calculated.
- 1.3.24 "Limit of Quantitation" (LOQ), or lower limit of quantitation (LOQ), is the level above which quantitative results may be obtained with a specified degree of confidence. The LOQ is mathematically defined as equal to 10 times the standard deviation of the results for a series of replicates used to determine a justifiable limit of detection. Limits of quantitation are matrix, method, and analyte specific.
- 1.3.25 "Matrix" means the components of a Sample other than the Analyte(s) of interest (i.e., Sample type).
- 1.3.26 "Measurement Uncertainty" is defined as a parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand. The following equation is recommended:



Equation:  $U = k \times u_r$ 

Where, 
$$u_c = \sqrt{u_r^2 + u_R^2 + u_{bias}^2}$$

And:

u =standard uncertainty (standard deviation)

 $u_r$  = uncertainty due to repeatability

 $u_r$  = uncertainty due reproducibility

 $u_{bias}$  = uncertainty due to accuracy (bias)

 $u_c$  = combined standard uncertainty

 $U = \text{Expanded uncertainty} = \frac{u}{Mean} * k_{95\% \ confidence \ level}$ , k = 2

k = coverage factor, use 2 for 95% confidence level

- 1.3.27 "Moisture Content" means the percentage of water in a Sample, by weight.
- 1.3.28 "Nonconformance" means a non-fulfillment of a requirement or departure from written procedures, work instructions, or quality system, as defined by the laboratory's written Corrective Action and Preventive Action procedures.
- 1.3.29 "Person" means a natural person, an estate, a trust, an Entity, or a state or other jurisdiction.
- 1.3.30 "Preventive Action" means a proactive action implemented to eliminate the cause of a potential Nonconformance or other quality problem before it occurs.
- 1.3.31 "Proficiency Testing" means an assessment of the performance of a Hemp Testing Laboratory's methodology and processes. Proficiency Testing is also known as inter-laboratory comparison. The goal of Proficiency Testing is to ensure results are accurate, reproducible, and consistent.
- 1.3.32 "Quality Control" means the set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control for which errors have been reduced to acceptable levels.
- 1.3.33 "Reference Material" means material containing a known concentration of an Analyte of interest that is in solution or in a homogeneous Matrix.
- 1.3.34 "Reference Method" means the method by which the performance of an alternate method is measured or evaluated.
- 1.3.35 "Sample" means the Industrial Hemp, Industrial Hemp Product or Unfinished Industrial Hemp Product submitted to a Hemp Testing Laboratory for compliance testing required by the Department or the Colorado Department of Agriculture.
- 1.3.36 "Scope of Accreditation" means the tests or types of tests performed, materials or products



- tested, and the methods used for testing cannabis or cannabis products for which the accreditation has been granted.
- 1.3.37 "Standard Operating Procedure" (SOP) means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.
- 1.3.38 "Target Organism" means an organism that is being tested for in an analytical procedure or test method.
- 1.3.39 "THC" means tetrahydrocannabinol.
- 1.3.40 "THCA" means tetrahydrocannabinolic acid.
- 1.3.41 "Total CBD" means the sum of the percentage by weight of CBDA multiplied by 0.877 plus the percentage by weight of CBD i.e., Total CBD= (%CBDA x 0.877) + %CBD.
- 1.3.42 "Total THC" means the sum of the percentage by weight of THCA multiplied by 0.877 plus the percentage by weight of THC i.e., Total THC = (%THCA x 0.877) + %THC.
- 1.3.43 "Unfinished Industrial Hemp Product" means an oil, concentrate or other substance that has a total THC concentration above 0.3% and less than or equal to 5.0%, is not for consumer use or distribution, must be sold or transferred between registered industrial hemp manufacturers, and will undergo further refinement or processing into an industrial hemp product.

# Rule 2: Hemp Testing Laboratory Certification Authorizations

- 2.1 <u>Testing of Industrial Hemp Authorized</u>. A Hemp Testing Laboratory may accept Samples of Industrial Hemp, Industrial Hemp Products, and Unfinished Industrial Hemp Products from Persons registered with the Commissioner of the Colorado Department of Agriculture, pursuant to section 35-61-104, C.R.S. or registered with the Colorado Department of Public Health and Environment pursuant to section 25-5-426, C.R.S. for testing purposes only.
  - 2.1.1 Before a Hemp Testing Laboratory accepts a Sample of Industrial Hemp, Industrial Hemp Product or Unfinished Industrial Hemp Product, the laboratory shall verify that the Person submitting the Sample is registered with the Colorado Department of Agriculture or registered with the Colorado Department of Public Health and Environment.
- 2.2 A Hemp Testing Laboratory shall be permitted to test Samples of Industrial Hemp, Industrial Hemp Product, and Unfinished Industrial Hemp Product for required tests pursuant to 6 CCR 1010-21 and 35-61-105.5(d), C.R.S. only in the category(ies) that the Hemp Testing Laboratory is certified to perform testing in pursuant to Rule 4.1 Hemp Testing Laboratory: Certification Requirements.
- 2.3 <u>Transferring Samples to another Certified Hemp Testing Laboratory.</u> A Hemp Testing Laboratory may transfer Samples to another certified Hemp Testing Laboratory for testing. All laboratory reports provided to an Industrial Hemp Cultivator or Industrial Hemp Manufacturer must identify the Hemp Testing Laboratory that actually conducted the test.
- 2.4 A Hemp Testing Laboratory shall provide the results of any required compliance testing performed



on a Sample of Industrial Hemp, Industrial Hemp Product, and Unfinished Industrial Hemp Product to the Person submitting the Sample. Quality control data associated with the Sample shall be provided when requested by the Person submitting the Sample.

- 2.4.1 Results for Total THC compliance testing of Industrial Hemp must also be provided to the Colorado Department of Agriculture.
- 2.4.2 Results for Total THC compliance testing of Industrial Hemp must also be provided to the United States Department of Agriculture (USDA) in accordance with federal guidelines.
- 2.5 To the extent any activities authorized under these rules are also subject to the Colorado Marijuana Rules, 1 CCR 212-3, the provisions imposing the greater restriction shall be applicable.

# Rule 3: Hemp Testing Laboratories: General Limitations or Prohibited Acts

- 3.1 Conflicts of Interest. The Hemp Testing Laboratory, including those that are internal departments of Industrial Hemp Cultivators or Industrial Hemp Manufacturers, shall establish policies to prevent the existence of or appearance of undue commercial, financial, or other influences that may diminish the competency, impartiality, and integrity of the Hemp Testing Laboratory's testing processes or results, or that may diminish public confidence in the competency, impartiality and integrity of the Hemp Testing Laboratory's testing processes or results. At a minimum, employees, owners or agents of a Hemp Testing Laboratory who participate in any aspect of the analysis, resulting, and/or reporting of a Sample are prohibited from improperly influencing the testing process, improperly manipulating data, or improperly benefiting from any on-going financial, employment, personal or business relationship with the Industrial Hemp Cultivator or Industrial Hemp Manufacturer that provided the Sample. The Hemp Testing Laboratory shall provide documentation showing a clear delineation between production and lab testing activities reflected in their quality management system documentation. Any conflicts of interest must be documented and disclosed.
- 3.2 <u>Transfer of Industrial Hemp and Industrial Hemp Product Prohibited.</u> A Hemp Testing Laboratory shall not transfer Industrial Hemp or Industrial Hemp Product to an Industrial Hemp Cultivator or Industrial Hemp Manufacturer or a consumer, except that a Hemp Testing Laboratory may transfer a Sample to another Hemp Testing Laboratory.
- 3.3 <u>Destruction of Received Samples</u>. A Hemp Testing Laboratory shall properly dispose of all Samples it receives, that are not transferred to another Hemp Testing Laboratory, after all necessary tests have been conducted and any required period of storage. *See* Rule 14 Waste Disposal.
- 3.4 Sample Rejection. A Hemp Testing Laboratory shall reject any Sample where:
  - 3.4.1 The condition of the Sample at receipt indicates that the Sample may have been tampered with or could have become contaminated as a result of damaged or improper packaging; OR
  - 3.4.2 The Sample of Industrial Hemp has not been collected in accordance with 8 CCR 1203-23.

#### **Rule 4: Hemp Testing Laboratories: Certification Requirements**

4.1 <u>Certification Category</u>. For required tests, the Hemp Testing Laboratory must be certified by the Department in the category in order to perform that type of testing.



- 4.1.1 Residual solvents:
- 4.1.2 Microbials;
- 4.1.3 Mycotoxins;
- 4.1.4 Pesticides;
- 4.1.5 THC and other Cannabinoid potency;
- 4.1.6 Metals; and
- 4.1.7 Moisture content.
- 4.2 <u>Certification Procedures and Principles.</u> The Hemp Testing Laboratory certification program is contingent upon successful on-site inspection, successful participation in proficiency testing, and ongoing compliance with the requirements in this Rule.
  - 4.2.1 <u>Certification Inspection</u>. A Hemp Testing Laboratory must be inspected prior to initial certification and annually thereafter by the Department.
  - 4.2.2 <u>Standards for Certification.</u> A Hemp Testing Laboratory must meet standards of performance,
    - as established by these rules, in order to obtain and maintain certification. Standards of performance include but are not limited to: Personnel Qualifications, Standard Operating Procedures, analytical processes, Proficiency Testing, Quality Control, quality assurance, security, Chain of Custody, Sample retention, Sample disposal, space, records, and results reporting.
      - 4.2.2.1 A Hemp Testing Laboratory must be accredited under the International Organization for Standardization/International Electrotechnical Commission 17025:2017 Standard (ISO/IEC 17025), or any subsequent superseding ISO/IEC 17025 standard, by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). In order to obtain and maintain certification in a testing category from the

Department, the Hemp Testing Laboratory's Scope of Accreditation must specify that particular testing category, including the applicable methods and Analytes.

- addition, Hemp Testing Laboratories must be registered with the United States Drug Enforcement Administration.
- 4.2.2.2 Certification will be granted when laboratories have met all certification requirements, including ISO/IEC 17025 accreditation and DEA registration.
- 4.2.2.3 The Department may grant provisional certification for a testing category if the laboratory has not yet obtained ISO/IEC 17025 accreditation and DEA registration,

but meets all other certification requirements. Such provisional certification shall



be for a period not to exceed twelve months.

4.2.2.4 The Department may grant conditional certification to laboratories who have obtained ISO/IEC 17025 accreditation and, and have met all other certification requirements, but are not registered with the DEA. Such conditional certification shall expire on December 31, 2022.

# 4.2.3 Personnel Qualifications.

competency.

- 4.2.3.1 <u>Laboratory Director.</u> A Hemp Testing Laboratory must employ, at a minimum, a laboratory director with sufficient education and experience in a regulated laboratory environment in order to obtain and maintain certification. *See* Rule 5 Hemp Testing Laboratories: Personnel.
- 4.2.3.2 Employee Competency. A Hemp Testing Laboratory must have a written and documented system to evaluate and document the competency in performing authorized tests for employees. Prior to independently analyzing Samples, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge Samples (proficiency

  Samples or internally generated quality controls). Analysts must, at a minimum, annually (or upon method modification) demonstrate continued acceptable
- 4.2.4 <u>Standard Operating Procedures.</u> A Hemp Testing Laboratory must have written Standard Operating Procedures meeting the minimum standards set forth in these rules detailing the performance of all methods employed by the facility used to test the Analytes it reports

and made available for testing analysts to follow at all times.

- 4.2.4.1 The current laboratory director must approve, sign and date each procedure. If any
  - modifications are made to those procedures, the laboratory director must approve,
  - sign, and date the revised version prior to use.
- 4.2.4.2 A Hemp Testing Laboratory must maintain a copy of all Standard Operating Procedures to include any revised copies for a minimum of three years. *See* Rule 12 Hemp Testing Laboratories: Records Retention and Rule 13 Hemp Testing Laboratories: Business Records Required.
- 4.2.4.3 A Hemp Testing Laboratory must inform the Department of any major changes to Standard Operating Procedures pertaining to analytical methods subsequent to initial certification. Major method changes include, but are not limited to: modifications to Sample preparation, changes in column type, changes in enrichment media, changes in solvent(s) used, etc.
- 4.2.5 Analytical Processes. A Hemp Testing Laboratory must maintain a listing of all analytical



- methods used and all Analytes tested and reported. The Hemp Testing Laboratory must provide this listing to the Department upon request.
- 4.2.6 <u>Proficiency Testing</u>. A Hemp Testing Laboratory must successfully participate in a Department approved Proficiency Testing program in order to obtain and maintain certification.
- 4.2.7 Quality Assurance and Quality Control. A Hemp Testing Laboratory must establish and follow a quality assurance and Quality Control program to ensure sufficient monitoring of laboratory processes and quality of results reported.
- 4.2.8 <u>Security</u>. A Hemp Testing Laboratory must be located in a secure setting as to prevent unauthorized persons from gaining access to the testing and storage areas of the laboratory.
- 4.2.9 <u>Chain of Custody.</u> A Hemp Testing Laboratory must establish a system to document the complete Chain of Custody for Samples from receipt through disposal.
- 4.2.10 <u>Space</u>. A Hemp Testing Laboratory must be located in a fixed structure that provides adequate infrastructure to perform analysis in a safe and compliant manner consistent with federal, state, and local requirements.
- 4.2.11 <u>Records</u>. A Hemp Testing Laboratory must establish a system to retain and maintain records for a period not less than three years. *See* Rules 12 Hemp Testing Laboratory: Records Retention and Rule 13 Hemp Testing Laboratories: Business Records Required.
- 4.2.12 <u>Results Reporting</u>. A Hemp Testing Laboratory must establish processes to ensure results are
  - reported in a timely and accurate manner. A Hemp Testing Laboratory's process may require
  - that the Industrial Hemp Cultivator or Industrial Hemp Product Manufacturer remit payment
  - for any test conducted by the laboratory prior to reporting results. A Hemp Testing Laboratory's process established under this subparagraph (12) must be maintained on the premises of the Hemp Testing Laboratory.
- 4.2.13 <u>Conduct While Seeking Certification</u>. A Hemp Testing Laboratory, and its agents and employees shall provide all documents and information required or requested by the Department and its employees in a full, faithful, truthful, and fair manner.

# **Rule 5: Hemp Testing Laboratories: Personnel**

- 5.1 <u>Laboratory Director.</u> The laboratory director is ultimately responsible for the overall analytical operation and quality of the results reported by the Hemp Testing Laboratory, including the employment and supervision of personnel who are competent to perform test procedures and record and report test results promptly, accurately, and proficiently, and for assuring compliance with the standards set forth in this Rule.
  - 5.1.1 The laboratory director may also serve as a supervisory analyst or testing analyst, or both,



for a Hemp Testing Laboratory.

- 5.1.2 The laboratory director for a Hemp Testing Laboratory must meet one of the following qualification requirements:
  - 5.1.2.1 Be a Medical Doctor (M.D.) licensed to practice medicine in Colorado and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; OR
  - 5.1.2.2 Hold a doctoral degree in one of the natural sciences and have at least three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; OR
  - 5.1.2.3 Hold a master's degree in one of the natural sciences and have at least five years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body; OR
  - 5.1.2.4 Hold a bachelor's degree in one of the natural sciences and have at least seven years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body.
- 5.2 <u>What the Laboratory Director May Delegate.</u> The laboratory director may delegate the responsibilities assigned under this Rule to a qualified supervisory analyst, provided that such delegation is made in writing and a record of the delegation is maintained. *See* Rule 13 Business Records Required. Despite the designation of a responsibility, the laboratory director remains responsible for ensuring that all duties are properly performed.
- 5.3 Responsibilities of the Laboratory Director. The laboratory director must:
  - 5.3.1 Ensure that the Hemp Testing Laboratory has adequate space, equipment, materials, and controls available to perform the tests reported;
  - 5.3.2 Establish and ensure adherence to written Standard Operating Procedures used to perform the tests reported;
  - 5.3.3 Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;
  - 5.3.4 Ensure that the physical location and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees



- are protected from physical, chemical, and biological hazards;
- 5.3.5 Ensure that the test methodologies selected are fit-for-purpose and appropriate to ensure the quality of results required for the level of testing the laboratory is certified to perform;
- 5.3.6 Ensure that validation and verification test methods used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;
- 5.3.7 Ensure that testing analysts perform the test methods as required for accurate and reliable results;
- 5.3.8 Ensure that the laboratory is enrolled in and successfully participates in a Department approved Proficiency Testing program;
- 5.3.9 Ensure that the Quality Control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;
- 5.3.10 Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;
- 5.3.11 Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that test results are reported only when the system is functioning properly;
- 5.3.12 Ensure that reports of test results include pertinent information required for interpretation;
- 5.3.13 Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation of said results;
- 5.3.14 Employ a sufficient number of laboratory personnel who meet the qualification requirements and provide appropriate consultation, properly supervise, and ensure accurate performance of tests and reporting of test results;
- 5.3.15 Ensure that prior to testing any Samples, all testing analysts receive the appropriate training for the type and complexity of tests performed, and have demonstrated and documented that they can perform all testing operations reliably to provide and report accurate results;
- 5.3.16 Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process Samples, perform test procedures and report test results promptly and proficiently, avoid actual and apparent conflicts of interests, and whenever necessary, identify needs for remedial training or continuing education to improve skills;
- 5.3.17 Ensure that an approved Standard Operating Procedure manual is available to all personnel responsible for any aspect of the testing process; and
- 5.3.18 Specify, in writing, the responsibilities and duties of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies



which examinations and procedures each individual is authorized to perform, whether supervision is required for Sample processing, test performance or results reporting, and whether consultant or laboratory director review is required prior to reporting test results.

- 5.4 <u>Change in Laboratory Director.</u> In the event that the laboratory director leaves employment at the Hemp Testing Laboratory, the Hemp Testing Laboratory shall:
  - 5.4.1 Provide written notice to the Department within seven days of the laboratory director's departure; and
  - 5.4.2 Designate an interim laboratory director within seven days of the laboratory director's departure. At a minimum, the interim laboratory director must meet the qualifications of a supervisory analyst.
  - 5.4.3 The Hemp Testing Laboratory must hire a permanent laboratory director within 60 days from the date of the previous laboratory director's departure.
  - 5.4.4 Notwithstanding the requirement of subparagraph 5.4.3, the Hemp Testing Laboratory may submit a waiver request to the Department to receive an additional 60 days to hire a permanent laboratory director provided that the Hemp Testing Laboratory submits a detailed oversight plan along with the waiver request.
- 5.5. Supervisory Analyst. Supervisory analysts must meet one of the qualifications for a laboratory director or have at least a bachelor's degree in one of the natural sciences and two years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing in which the testing methods were recognized by an accrediting body. A combination of education and experience may substitute for the two years of full-time laboratory experience.
- 5.6. <u>Laboratory Testing Analyst.</u>
  - 5.6.1 <u>Educational Requirements</u>. An individual designated as a testing analyst must meet one of the qualifications for a laboratory director or supervisory analyst; OR
    - 5.6.1.1 Have at least a bachelor's degree in one of the natural sciences; OR
    - 5.6.1.2 Have earned an associate degree in a laboratory science from an accredited institution; OR
    - 5.6.1.3 Have education and training equivalent to that specified in 5.6.1.2 of this section that includes at least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include:
      - a. 24 semester hours of science courses that include:
        - 1. Six semester hours of chemistry;
        - 2. Six semester hours of biology; AND
        - 3. Twelve semester hours of chemistry, biology, or cannabis laboratory sciences in any combination; AND



- b. Have laboratory training that includes at least 3 months documented laboratory training in each testing category in which the individual performs testing; OR
- 5.6.1.4 Have at least 5 years of full time experience in laboratory testing and have laboratory training that includes at least 3 months documented laboratory training in each testing category in which the individual performs testing.
- 5.6.2 <u>Responsibilities</u>. In order to independently perform any test for a Hemp Testing Laboratory, an individual must at least meet the educational requirements for a testing analyst.

#### Rule 6: Hemp Testing Laboratories: Standard Operating Procedures

- 6.1 Standard Operating Procedures must include, but need not be limited to, procedures for:
  - 6.1.1 Sample receiving;
  - 6.1.2 Sample accessioning;
  - 6.1.3 Sample storage;
  - 6.1.4 Identifying and rejecting unacceptable Samples;
  - 6.1.5 Recording and reporting discrepancies;
  - 6.1.6 Security and stability of Samples, aliquots and extracts and records;
  - 6.1.7 Sample retention to assure stability of retain Samples for 90 days.
  - 6.1.8 Validating a new or revised method prior to testing Samples to include the performance criteria as stated in Rule 7.1.5;
  - 6.1.9 Aliquoting Samples to avoid contamination and carry-over;
  - 6.1.10 Preparation of Samples;
  - 6.1.11 Disposal of Samples;
  - 6.1.12 The theory and principles behind each assay;
  - 6.1.13 Preparation and identification of reagents, standards, calibrators and controls and ensure all standards are traceable to a certified vendor that meets the accreditation requirements of the laboratory, such as National Institute of Standards of Technology (NIST), ISO 17034, or other similar entities;
  - 6.1.14 Special requirements and safety precautions involved in performing assays;
  - 6.1.15 Frequency and number of control and calibration materials;
  - 6.1.16 Recording and reporting assay results;
  - 6.1.17 Protocol and criteria for accepting or rejecting analytical procedure to verify the accuracy of the final report;
  - 6.1.18 Pertinent literature references for each method;



- 6.1.19 Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by a testing analyst;
- 6.1.20 Acceptability Criteria for the results of calibration standards and controls as well as between two aliquots, Sample duplicates, new standard lots, or columns;
- 6.1.21 A documented system for reviewing the results of testing calibrators, controls, standards, and Sample test results, as well as reviewing for clerical errors, analytical errors and any unusual analytical results; and
- 6.1.22 A documented system for issuing, implementing, and monitoring Corrective Actions, including instructions for the laboratory to contact the requesting entity, when required;
- 6.1.23 Policies and procedures to follow when Samples are requested for referral and testing by another certified Hemp Testing Laboratory or an approved local or state agency's laboratory;
- 6.1.24 Protocol and criteria for calculating and applying Measurement Uncertainty;
- 6.1.25 Policies and procedures including the titles and required training of individuals responsible for the transport of biohazardous materials; and
- 6.1.26 Procedures and/or protocols for general laboratory upkeep and cleaning, including specific procedures to eliminate or avoid cross-contamination.

#### **Rule 7: Hemp Testing Laboratories: Analytical Processes**

- 7.1 <u>Method Validation and Verification</u>. Analytical method selection, validation, and verification must ensure that the test method used is fit-for-purpose and that the laboratory can successfully perform the testing.
  - 7.1.1 The demonstration of testing validity must ensure consistent, accurate and reproducible analytical performance in the matrices tested by the laboratory.
  - 7.1.2 Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of Rules Pertaining to the Administration and Enforcement of the Industrial Hemp Regulatory Program Act, 8 CCR 1203-23 Part 4 and Colorado Wholesale Food, Industrial Hemp and Shellfish Regulations, 6 CCR 1010-21.
  - 7.1.3 To the extent practicable, laboratory test methods must meet AOAC International standard method performance requirements.
  - 7.1.4 The laboratory must implement a performance based measurement system for the selected methodology and validate the method following good laboratory practices in accordance with AOAC, United States Pharmacopeia (USP), United States Food and Drug Administration (FDA) United States Department of Agriculture (USDA), and other reputable validation guidelines and methodology prior to reporting results. Validation, verification, or Matrix extension of methodology must include when applicable, but is not limited to:
    - 7.1.4.1 Verification of Accuracy



- 7.1.4.2 Verification of Precision
- 7.1.4.3 Verification of Analytical Sensitivity
- 7.1.4.4 Verification of Analytical Specificity
- 7.1.4.5 Verification of the LOD
- 7.1.4.6 Verification of the LOQ
- 7.1.4.7 Verification of the Reportable Range
- 7.1.4.8 Identification of Interfering Substances
- 7.1.4.9 Verification of Recovery
- 7.1.4.10 Inclusivity
- 7.1.4.11 Exclusivity
- 7.1.4.12 Measurement Uncertainty
  - 7.1.4.12.1 Subsequent to initial validation, Measurement Uncertainty must be re-evaluated at least annually or whenever method modifications are made.
  - 7.1.4.12.2 For GC cannabinoid methods, experimental determination of actual conversion rate of THCA to THC.
- 7.1.5 Validation or verification of methodology must be documented in a validation report. The validation report shall include, but is not limited to, the following:
  - 7.1.5.11 Validation plan;
  - 7.1.5.12 Introduction and summary;
  - 7.1.5.13 Materials, to include identification of certified Reference Materials, and preparation methods;
  - 7.1.5.14 Method parameters;
  - 7.1.5.15 Raw data, including instrument raw data such as chromatograms, for each test method and each instrument, if any;
  - 7.1.5.16 Instrument calibration data, if any;
  - 7.1.5.17 Data, calculations, and results;
  - 7.1.5.18 Method Acceptability Criteria performance data;



#### 7.1.5.19 Conclusion and discussion; and

#### 7.1.5.20 References.

- 7.1.6 Software must be validated prior to testing Samples, including but not limited to: analytical software, application programming interface(s) (APIs), laboratory information management systems (LIMS), etc.
- 7.1.7 Prior to use, methodology must have a Standard Operating Procedure approved and signed by the laboratory director.
- 7.1.8 Testing analysts must have documentation of competency assessment prior to testing Samples.
- 7.1.9 Any changes to the approved methodology must be revalidated and documented prior to testing Samples. The documentation of changes and revalidation must be provided to the Department prior to implementation.
- 7.2 <u>Gas Chromatography (GC).</u> A Hemp Testing Laboratory using GC must:
  - 7.2.1 Document the conditions of the gas chromatograph, including the detector response;
  - 7.2.2 Perform and document preventive maintenance as required by the manufacturer and SOPs;
  - 7.2.3 Ensure that records are maintained and readily available to the staff operating the equipment;
  - 7.2.4 Document the performance of new columns before use;
  - 7.2.5 Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified;
  - 7.2.6 Establish Acceptability Criteria for variances between different aliquots and different columns;
  - 7.2.7 Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency over time of the analytical system;
  - 7.2.8 Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing subject Samples; and
  - 7.2.9 Monitor and document the performance of the instrument each day of testing.
- 7.3 <u>Gas Chromatography Mass Spectrometry (GC/MS).</u> A Hemp Testing Laboratory using GC/MS must:
  - 7.3.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;
  - 7.3.2 Document and maintain records when cleaning or changes in source, source conditions, column, or other routine maintenance are made to the instrument;
  - 7.3.3 Ensure that records are maintained and readily available to the staff operating the equipment;



- 7.3.4 Maintain records of mass spectrometric tuning;
- 7.3.5 Establish written criteria for an acceptable mass-spectrometric tune;
- 7.3.6 Document corrective actions if a mass-spectrometric tune is unacceptable;
- 7.3.7 Monitor analytic analyses to check for contamination and carry-over;
- 7.3.8 Use selected ion monitoring within each run to assure that the laboratory compares ion ratios and retention times between calibrators, controls and Samples for identification of an Analyte;
- 7.3.9 Use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
- 7.3.10 Document the monitoring of the response (area or peak height) for the internal standard to ensure consistency over time of the analytical system;
- 7.3.11 Define the criteria for designating qualitative results as positive;
- 7.3.12 When a library is used to qualitatively identify an Analyte, the identity of the Analyte must be confirmed before reporting results by comparing the relative retention time and mass spectrum to that of a known standard or control run on the same system;
- 7.3.13 Evaluate the performance of the instrument after routine and preventive maintenance (*e.g.* clipping or replacing the column or cleaning the source) prior to analyzing subject Samples; and
- 7.3.14 Monitor and document the performance of the instrument each day of testing.
- 7.4 <u>Immunoassays</u>. A Hemp Testing Laboratory using Immunoassays must:
  - 7.4.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;
  - 7.4.2 Ensure that records are maintained and readily available to the staff operating the equipment;
  - 7.4.3 Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Sample is not included within the types of Samples approved by the manufacturer; and
  - 7.4.4 Define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay, which must be consistent with manufacturer's instructions.
- 7.5 <u>High Performance Liquid Chromatography (HPLC)</u>. A Hemp Testing Laboratory using HPLC must:
  - 7.5.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;
  - 7.5.2 Ensure that records are maintained and readily available to the staff operating the equipment;
  - 7.5.3 Monitor and document the performance of the HPLC instrument each day of testing;



- 7.5.4 Evaluate the performance of new columns before use;
- 7.5.5 Create written standards for acceptability when eluting solvents are recycled;
- 7.5.6 Use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified when available or appropriate for the assay;
- 7.5.7 Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency over time of the analytical system;
- 7.5.8 Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing subject Samples; and
- 7.5.9 Monitor and document the performance of the instrument each day of testing.
- 7.6 <u>Liquid Chromatography Mass Spectrometry (LC/MS).</u> A Hemp Testing Laboratory using LC/MS must:
  - 7.6.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;
  - 7.6.2 Ensure that records are maintained and readily available to the staff operating the equipment;
  - 7.6.3 Establish written criteria for an acceptable mass-spectrometric tune;
  - 7.6.4 Maintain records of mass spectrometric tuning;
  - 7.6.5 Document Corrective Actions if a mass-spectrometric tune is unacceptable;
  - 7.6.6 Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
  - 7.6.7 Document the monitoring of the response (area or peak height) of the internal standard to ensure consistency over time of the analytical system;
  - 7.6.8 Compare two transitions and retention times between calibrators, controls and Samples within each run;
  - 7.6.9 Document and maintain records when changes or cleaning in source, source conditions, eluent, or column are made to the instrument;
  - 7.6.10 Evaluate and document the performance of the instrument after routine and preventative maintenance and when changes in: source, source conditions, eluent, or column are made prior to reporting test results; and
  - 7.6.11 Monitor and document the performance of the instrument each day of testing.
- 7.7 <u>Inductively Coupled Plasma Mass Spectrometry (ICP/MS)</u>. A Hemp Testing Laboratory using ICP must:
  - 7.7.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;



- 7.7.2 Ensure that records are maintained and readily available to the staff operating the equipment;
- 7.7.3 Establish written criteria for an acceptable mass-spectrometric tune;
- 7.7.4 Maintain records of mass spectrometric tuning;
- 7.7.5 Document Corrective Actions if a mass-spectrometric tune is unacceptable;
- 7.7.6 Use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay;
- 7.7.7 Document the monitoring of the response (counts per second) of the internal standard to ensure consistency over time of the analytical system;
- 7.7.8 Compare mass-to-charge ratios between calibrators, controls and Samples within each run;
- 7.7.9 Monitor analyses to check for contamination and carry-over;
- 7.7.10 Evaluate and document the performance of the instrument after routine and preventative maintenance and when changes in: source, conditions, or detector are made prior to reporting test results; and
- 7.7.11 Monitor and document the performance of the instrument each day of testing.
- 7.8 <u>Microbial Assays</u>. A Hemp Testing Facility using microbial assays must:
  - 7.8.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;
  - 7.8.2 Ensure that records are maintained and readily available to the staff operating the equipment;
  - 7.8.3 Validate any changes or modifications to a manufacturer's approved assays or testing methods when a Sample is not included within the types of Samples approved by the manufacturer:
  - 7.8.4 Verify the method at the Action Levels for each Analyte. Verification at the qualitative presence/absence limit shall include a fractional recovery study;
  - 7.8.5 The laboratory shall include controls for each set of Samples. Quantitative microbial methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;
  - 7.8.6 For molecular methods, the laboratory shall include controls for each individual analytical run. Quantitative molecular methods shall use controls of a specific known value or set of values that lies within the quantifiable range of the method;
  - 7.8.7 PCR-based and qPCR-based methods must include validated internal amplification controls; and



- 7.8.8 Microbial methods must include steps to confirm presumptive positive results; confirmation methods may be molecular or cultural or both. Where applicable, confirmation of viability must be performed.
- 7.9 Moisture Content Analysis. A Hemp Testing Laboratory analyzing percent moisture must:
  - 7.9.1 Perform and document preventive maintenance as required by the manufacturer and SOPs;
  - 7.9.2 Ensure that records are maintained and readily available to the staff operating the equipment;
  - 7.9.3 Validate any changes or modifications to an approved method when a Sample is not included within the types of Samples for which the method was originally validated;
  - 7.9.4 Ensure SOPs specify all unique method parameters, such as temperature, sample surface area, etc., that prevent loss of volatile compounds, the oxidation of oils and/or the re-absorbance of water;
  - 7.9.5 Ensure that appropriate quality assurance and Quality Control measures are performed and documented as necessary for the assay;
  - 7.9.6 Evaluate the performance of the method after routine and preventive maintenance prior to analyzing subject Samples.
  - 7.9.7 Establish criteria for acceptable moisture analyzer performance. It may be necessary to obtain a reference material that is tested prior to analyzing samples each day in order to ensure the acceptability of the analyzer.
- 7.10 Other Analytical Methodology. A Hemp Testing Laboratory using any other analytical methodology must:
  - 7.10.1 Perform and document preventive maintenance as required by the manufacturer or SOP;
  - 7.10.2 Ensure that records are maintained and readily available to the staff operating the equipment;
  - 7.10.3 Ensure that appropriate quality assurance and Quality Control measures are performed and documented as necessary for the specific methodology;
  - 7.10.4 Evaluate the performance of the instrument after routine and preventive maintenance prior to analyzing subject Samples.
- 7.11 <u>Cannabinoid Methodology</u>. At a minimum, analytical testing of Samples for delta-9 tetrahydrocannabinol (THC) must use post-decarboxylation or other similarly reliable methods. The testing methodology must consider the potential conversion of delta-9 tetrahydrocannabinolic acid (THCA) into THC. The results reported must reflect the Total THC content.



- 7.11.1 The Total THC concentrations of Industrial Hemp shall be determined and reported on a Dry Weight Basis.
  - 7.11.1.2 A Hemp Testing Laboratory must ensure reporting of Total THC includes a calculation for moisture correction based on a theoretical concentration of zero percent moisture. The following conversion formula is recommended:

$$P2 = \left(\frac{100 - M2}{100 - M1}\right) P1$$

Where:

P2 = adjusted constituent percentages at moisture M2 (percent)

M2 = moisture basis (percent, i.e., 0%)

P1 = original (as-is) constituent percentage

M1 = original moisture (percent)

7.11.2 The Cannabinoid concentrations of Industrial Hemp Products shall be determined and reported on an "as-is" basis (i.e., in the form submitted to the laboratory).

#### **Rule 8: Hemp Testing Laboratories: Proficiency Testing**

- 8.1 <u>Proficiency Testing Required</u>. A Hemp Testing Laboratory must participate in a Proficiency Testing program for each approved category in which it seeks certification under Rule 4 Hemp Testing Laboratories: Certification Requirements.
- 8.2. <u>Participation in Designated Proficiency Testing Event</u>. If required by the Department as part of certification, the Hemp Testing Laboratory must have successfully participated in Proficiency Testing in the category for which it seeks certification, within the preceding 12 months.
  - 8.2.1 The laboratory shall request the proficiency testing provider to send results concurrently to the Department, if available, or the laboratory shall provide the proficiency testing results to the Department within 3 business days after the laboratory receives notification of their results.
- 8.3 <u>Continued Certification</u>. To maintain continued certification, a Hemp Testing Laboratory must participate twice per calendar year in a designated Proficiency Testing program with continued satisfactory performance as determined by the Department as part of certification. The Department may designate a local agency, state agency, or independent third-party to provide Proficiency Testing.
- 8.4 <u>Analyzing Proficiency Testing Samples</u>. A Hemp Testing Laboratory must analyze Proficiency Test Samples using the same procedures with the same number of replicate analyses, standards, testing analysts, equipment, and data review processes as used in its Standard Operating Procedures.
- 8.5 <u>Proficiency Testing Attestation</u>. The laboratory director and all testing analysts who participated in Proficiency Testing must sign corresponding attestation statements.



- 8.6 <u>Laboratory Director Must Review Results.</u> The laboratory director must review and evaluate all Proficiency Testing results after receiving them from the proficiency testing provider.
- 8.7 Remedial Action. A Hemp Testing Laboratory must take and document remedial action when a score of less than 100% is achieved on any test during Proficiency Testing. Remedial action documentation must include a review of Samples tested and results reported since the last successful Proficiency Testing event. A requirement to take remedial action does not necessarily indicate unsatisfactory participation in a Proficiency Testing event.
- 8.8 <u>Unsatisfactory Participation in a Proficiency Testing Event</u>. Unless the Hemp Testing Laboratory positively identifies at least 80% of the target Analytes tested, participation in the Proficiency Testing event will be considered unsatisfactory. A positive identification must include accurate quantitative and qualitative results as applicable. Any false positive result reported will be considered unsatisfactory participation in the Proficiency Testing event.
- 8.9 <u>Consequence of Unsatisfactory Participation in Proficiency Testing Event</u>. Unsatisfactory participation in a Proficiency Testing event may result in limitation, suspension or revocation of certification. A Hemp Testing Laboratory's certification will be suspended for the relevant testing category if two consecutive unsatisfactory Proficiency Testing events occur, or if two out of three consecutive unsatisfactory Proficiency Testing events occur. Certification may be reinstated after successful participation in the next Proficiency Testing event. Failure to achieve a satisfactory score in the next test event will result in the revocation of the certification and will require two successful consecutive Proficiency Testing events before the laboratory may be eligible to reapply for certification. Any limitation, suspension or revocation of certification must be disclosed to clients.

#### Rule 9: Hemp Testing Laboratories: Quality Assurance and Quality Control

- 9.1 <u>Quality Assurance Program Required</u>. A Hemp Testing Laboratory must establish, monitor, and document the ongoing review of a quality assurance program that is sufficient to identify problems in the laboratory preanalytic, analytic and postanalytic systems when they occur and must include, but is not limited to:
  - 9.1.1 Review of instrument preventive maintenance, repair, and troubleshooting;
  - 9.1.2 Documentation of Nonconformances and implementation of Corrective Actions and Preventative Actions when necessary;
  - 9.1.3 Review of quality assurance documentation must be performed by the laboratory director or designated supervisory analyst on an ongoing basis to ensure the effectiveness of actions taken over time;
  - 9.1.4 Review by the laboratory director or designated supervisory analyst of all ongoing quality assurance; and
  - 9.1.5 Review of the performance of validated methods used by the Hemp Testing Laboratory to include calibration standards, controls and the Standard Operating Procedures used for analysis on an ongoing basis to ensure quality improvements are made when problems are identified or as needed.



- 9.2 Quality Control Measures Required. A Hemp Testing Laboratory must establish, monitor and document on an ongoing basis the Quality Control measures taken by the laboratory to ensure the proper functioning of equipment, validity of Standard Operating Procedures and accuracy of results reported. The laboratory must ensure that appropriate quality assurance and Quality Control measures are performed and documented as necessary for the specific methodology. Such Quality Control measures must include, but shall not be limited to:
  - 9.2.1 Documentation of instrument preventive maintenance, repair, troubleshooting and Corrective Actions taken when performance does not meet established levels of quality;
  - 9.2.2 Review and documentation of the accuracy of automatic and adjustable pipettes and other measuring devices when placed into service and annually thereafter;
  - 9.2.3 Cleaning, maintaining, verifying, and calibrating as needed the analytical balances and in addition, verifying the performance of the balance annually using certified weights to include three or more weights bracketing the ranges of measurement used by the laboratory;
  - 9.2.4 Annually verifying working thermometers against a certified reference thermometer.

    Certified reference thermometers shall be calibrated traceable to the SI (International System of Units) through NIST, or equivalent by an ISO/IEC 17025 accredited calibration laboratory with a listed certification date;
  - 9.2.5 Recording temperatures on all equipment when in use where temperature control is specified in the Standard Operating Procedures, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers;
  - 9.2.6 Properly labeling reagents as to the identity, the concentration, date of preparation, storage conditions, lot number tracking, expiration date and the identity of the preparer;
  - 9.2.7 Avoiding mixing different lots of reagents in the same analytical run;
  - 9.2.8 Performing and documenting a calibration curve with each analysis using at minimum five calibrators throughout the reporting range;
  - 9.2.9 For qualitative analyses, analyzing, at minimum, a negative and a positive control with each batch of Samples analyzed;
  - 9.2.10 For quantitative analyses, analyzing, at minimum, a negative and two levels of controls that challenge the linearity of the entire curve;
  - 9.2.11 Using a control material or materials that differ in either source or, lot number, or concentration from the calibration material used with each analytical run;
  - 9.2.12 For multi-Analyte assays, performing and documenting calibration curves and controls specific to each Analyte, or at minimum, one with similar chemical properties as reported in the analytical run;
  - 9.2.13 Analyzing an appropriate Matrix blank and control with each analytical run, when available;
  - 9.2.14 Analyzing calibrators and controls in the same manner as unknowns;



- 9.2.15 Documenting the performance of calibration standards and controls for each analytical run to ensure the Acceptability Criteria as defined in the Standard Operating Procedure is met;
- 9.2.16 Documenting all Corrective Actions taken when unacceptable calibration, control, and standard or instrument performance does not meet Acceptability Criteria as defined in the Standard Operating Procedure;
- 9.2.17 Maintaining records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), LOD, LOQ, and verification of the linear range; and
- 9.2.18 Performing testing that follows the current Standard Operating Procedures for the test or tests to be performed.

# Rule 10: Hemp Testing Laboratories: Certificate of Analysis (COA)

- 10.1 The laboratory shall generate a Certificate of Analysis (COA) for each Sample that the laboratory.
- 10.2 The laboratory shall ensure that the COA contains the results of all requested analyses performed

the Sample.

or

- 10.3 The laboratory shall, within 1 business day of completing Total THC analysis of a Sample, provide a copy of the COA to the submitting Industrial Hemp Cultivator and the Colorado Department of Agriculture Hemp Regulatory Program.
  - 10.3.1 The laboratory shall indicate that a Total THC test result is for "official compliance" purposes on the COA for Samples of Industrial Hemp when applicable.
- 10.4 The COA shall contain, at minimum, the following information:
  - 10.4.1 Laboratory's name, address, and contact information;
  - 10.4.2 Industrial Hemp Cultivator's or Industrial Hemp Manufacturer's name, address, and USDA licensee number if applicable;
  - 10.4.3 Sampler identification;
  - 10.4.4 Sample identifying information, including Matrix type and unique Sample identifiers, including lot identification number when applicable;
  - 10.4.5 Sample received date, and the date(s) of Sample analyses and corresponding testing results;
  - 10.4.6 Units of measure:
  - 10.4.7 The analytical methods, analytical instrumentation used, and corresponding Limits of Detection (LOD) and Limits of Quantitation (LOQ);
  - 10.4.8 For Samples of Industrial Hemp, identification of a pre-harvest or post-harvest retest (i.e., remediated) when applicable.
  - 10.4.9 For Samples of Industrial Hemp, reported cannabinoid results must include the range of



estimated uncertainty which shall be reported as a ± value in the same units of measure as the test result, following best practices for significant figures and rounding; and

- 10.4.9.1 For Samples of Industrial Hemp, reported cannabinoid results must provide a calculated Total THC value + uncertainty on a dry weight basis.
- 10.4.10 A dedicated area to include any qualifiers or comments needed for interpretation, (when applicable to the test method and results being reported) to include any identified and documented discrepancies.
- 10.4.11 The COA may contain additional information at the discretion of the laboratory and submitting client.
- 10.5 The laboratory shall report test results for each representative Sample on the COA as follows:
  - 10.5.1 When reporting qualitative results for each Analyte, the laboratory shall indicate presence or absence;
  - 10.5.2 When reporting quantitative results for each Analyte, the laboratory shall only report results that are above the lowest concentration of calibrator or standard used in the analytical run;
  - 10.5.3 When reporting results for any Analytes that were detected below the analytical method LOQ and above the LOD, indicate "<LOQ";
  - 10.5.4 When reporting results for any Analytes that were not detected or detected below the LOD, indicate "ND" or "<LOD"; and
- 10.6 The laboratory director or supervisory analyst shall validate the accuracy of the information contained on the COA.

#### Rule 11: Hemp Testing Laboratories: Chain of Custody

- 11.1 <u>General Requirements</u>. A Hemp Testing Laboratory must establish an adequate Chain of Custody and Sample requirement instructions that must include, but not limited to:
  - 11.1.1 Issue instructions for the minimum Sample requirements and storage requirements;
    - 11.1.1.1 Separate Sample into a test and a retain Sample;
      - 11.1.1.1 The Sample shall be fully homogenized prior to dividing into test and retain Samples. The test and retain Samples shall each be sufficient to conduct the required analyses on the Sample.
      - 11.1.1.1.2 The test Sample shall be carried through analysis.
      - 11.1.1.1.3 Retain Sample shall be packaged and stored in accordance with rule 6.1.7.
  - 11.1.2 Document identifying information of the submitting Industrial Hemp Cultivator or Industrial Hemp Manufacturer, including harvest or production batch identification;



- 11.1.3 Assign and document a unique Sample identifier;
- 11.1.4 Document the condition of the external package and integrity seals utilized to prevent contamination of, or tampering with, the Sample;
- 11.1.5 Document the condition, temperature, Matrix, and amount of Sample provided at the time of receipt;
- 11.1.6 Document all persons handling the original Samples, aliquots, and extracts;
- 11.1.7 Document all Transfers of Samples, aliquots, and extracts referred to another certified Hemp Testing Laboratory for additional testing or whenever requested by a client;
- 11.1.8 Maintain a current list of authorized personnel and restrict entry to the laboratory to only those authorized;
- 11.1.9 Secure the Laboratory during non-working hours;
- 11.1.10 Secure short and long-term storage areas when not in use;
- 11.1.11 Ensure Samples are stored appropriately as defined in the written SOP; and
- 11.1.12 Document the disposal of Samples, aliquots, and extracts.

#### **Rule 12: Hemp Testing Laboratories: Records Retention**

- 12.1 <u>General Requirements.</u> A Hemp Testing Laboratory must maintain all required business records. *See* Rule 13 Business Records Required.
- 12.2 <u>Specific Business Records Required Record Retention.</u> A Hemp Testing Laboratory must establish processes to preserve records in accordance with Rule 13 that includes, but is not limited to;
  - 12.2.1 Test Results, including final and amended reports, and identification of analyst and date of analysis;
  - 12.2.2 Quality Control and quality assurance Records, including accession numbers, Sample type, and acceptable reference range parameters;
  - 12.2.3 Standard Operating Procedures;
  - 12.2.4 Personnel Records:
  - 12.2.5 Chain of Custody Records;
  - 12.2.6 Proficiency Testing Records; and
  - 12.2.7 Analytical Data to include data generated by the instrumentation, raw data of calibration standards and curves.

#### Rule 13: Hemp Testing Laboratories: Business Records Required

- 13.1 General Requirements.
  - 13.1.1 A Hemp Testing Laboratory shall retain all records required by this rule for the current



year and three preceding calendar years.

- 13.1.1.1 On premises records: The Hemp Testing Laboratory records for the preceding six months (or complete copies of such records) must be maintained onsite at all times.
- 13.1.1.2 On- or off-premises records: Records associated with older periods may be archived onsite or offsite.
- 13.1.2 The records must include, but shall not be limited to:
  - 13.1.2.1 Current Employee List This list must provide the full name and job title of each employee who works at the laboratory;
  - 13.1.2.3 Visitor Log List of all visitors entering any limited or restricted access areas as defined by the laboratory;
  - 13.1.2.4 Waste Log Comprehensive records regarding all waste that accounts for, reconciles, and evidences all waste activity related to the disposal of any Sample that tests above 0.3% THC with at least 95% confidence and the disposal of any chemically hazardous or biohazardous waste;
  - 13.1.2.5 Testing Records The laboratory must maintain all testing records, to include calibration records, analytical data, calculations, test reports, and worksheets
  - 13.1.2.6 Standard Operating Procedures All Standard Operating Procedures as required by these Rules;
  - 13.1.2.7 Corrective Action and Preventive Action records;
  - 13.1.2.8 Chain of Custody records; and
  - 13.1.2.9 All other records required by these Rules.
- 13.1.3 Loss of Records and Data. Any loss of electronically-maintained records shall not be considered a mitigating factor for violations of this Rule. Laboratories are required to exercise due diligence in preserving and maintaining all required records.
- 13.1.4 Provision of Any Requested Record to the Department. A Hemp Testing Laboratory must provide on-demand access to on-premises records following a request from the Department during normal business hours or hours of apparent operation, and must provide access to off-premises records within three business days following a request from the Department.

#### **Rule 14: Waste Disposal**

14.1 <u>All Applicable Laws Apply</u>. All waste must be stored, secured, and managed in accordance with all



applicable federal, state, and local statutes, regulations, ordinances, or other requirements, including but not limited to the "Regulations Pertaining to Solid Waste Sites and Facilities" (6 CCR 1007-2, Part 1) and "Regulation No. 100 – Water and Wastewater Facility Operations Certification Requirements" (5 CCR 1003-2).

- 14.1.1 Samples exceeding the acceptable hemp THC level must be disposed of in accordance with the Controlled Substances Act and DEA regulations as such product is marijuana and not hemp.
- 14.2 <u>Liquid Waste</u>. Liquid waste from Hemp Testing Laboratories shall be disposed of in compliance with all applicable federal, state and local laws, regulations, rules, and other requirements.
- 14.3 <u>Chemical, Dangerous and Hazardous Waste.</u> Disposal of chemical, dangerous, and hazardous waste must be conducted in a manner consistent with federal, state and local laws, statutes, regulations, rules, and other requirements.



Appendix H: CDA Hemp Sample Preparation Standard Operating Procedure/Analysis of Moisture Content in Hemp Using the Mettler Toledo HE73 Moisture Analyzer



# **CDA Uncontrolled Document**

Biochemistry Laboratory SOP No.: PT-LBOP-014		Page 1 of 5
Title: Hemp Sample Preparation		
Revision: 05	Replaces: Rv04 10/31/2019	Effective: 06/25/2021

## 1. Purpose:

To provide a standard operating procedure (SOP) for the *drying and* homogenization of industrial hemp samples. This SOP describes the drying, sorting, and grinding of hemp samples.

# 2. Scope, Responsibilities, and Authorities:

This SOP applies to staff members performing hemp sample *preparation* analysis in the Chemical Sciences and Pesticides Unit at the CDA-BCL. This SOP shall be used in conjunction with the SOPs listed in the reference section. Staff members shall adhere to the requirements specified in this SOP and report non-compliance to the Quality Assurance Officer (QAO) and/or the Laboratory Manager. The Laboratory Manager and QAO are authorized to request and review records.

#### 3. Outline of Procedure:

- 6.1 Safety Precautions and General Requirements
- 6.2 Resources: Equipment, Chemicals, Supplies
- 6.3 Hemp Sample Drying
- 6.4 Hemp Sample Grinding/Homogenization
- 6.5 Sample Storage, Disposal and Clean-up
- 6.6 Records

#### 4. References, Related Procedures, and Forms:

#### SOPs (current revisions)

SL-LBOP-004 Laboratory, Equipment, and Glassware Cleaning

SL-LBOP-013 Sample Receipt, Handling, Storage, Protection and Disposal

SL-INST-007 Operation and Maintenance of Ovens

#### Forms

PTM031A THC in Hemp Bench sheet, current version

PTL013A Pesticide Sample Preparation log, current version

SLI007A Oven Log (or electronic equivalent)

#### 5. Definitions:

5.1 Homogeneous – having a uniform composition or structure.

## 6. Specific Procedures:

- 6.1 Safety Precautions and General Requirements.
  - 6.1.1 Oven sides and shelving units may be hot. Use caution when loading samples into and out of the oven.
  - 6.1.2 Blender blades are sharp. Use caution when handling.
  - 6.1.3 Dry hemp samples can cause respiratory irritation during grinding. Always grind hemp samples in a well-ventilated area, preferably a fume hood, and wear appropriate personal protective equipment (PPE), including a lab coat, safety glasses, gloves, and face mask or respirator.



# **CDA Uncontrolled Document**

Biochemistry Laboratory SOP No.: PT-LBOP-014		Page 2 of 5
Title: Hemp Sample Preparation		
Revision: 05	Replaces: Rv04 10/31/2019	Effective: 06/25/2021

- 6.2 Resources: Equipment, Chemicals, Supplies
  - 6.2.1 Aluminum Foil and/or Aluminum Cupcake Liners, food service grade or equivalent 6.2.2 Polypropylene specimen containers with caps
  - 6.2.3 Analytical Mill, Blender, Magic Bullet®, or equivalent
  - 6.2.4 Pulverisette 11 knife mill, Fritsch, or equivalent
  - 6.2.5 Drying Oven
  - 6.2.6 Scissors
- 6.3 Hemp Sample Drying
  - 6.3.1 Hemp samples are received, stored, protected and disposed per SL-LBOP-013. Hemp samples may be air-dried, oven dried, or a combination of both. Hemp samples are considered dry *enough to homogenize* when the plant material easily crumbles
    - between the fingers and the stem is brittle and cracks easily.
  - 6.3.2 The entire sample shall be dried.
  - 6.3.3 Hemp samples that are dried in the oven shall be recorded on form SLI007A, or electronic equivalent
  - 6.3.4 If a sample contains significant mold *it shall be placed on hold per SL-LBOP-013*, *and* the program manager shall be contacted for written directions on how to proceed. An issue shall be entered into SharePoint and sample issues shall be documented in the Sample Comments section of Labworks.
  - 6.3.5 Hemp samples *shall* may be dried using the following procedure:
    - 6.3.5.1 Fold up the edges of a piece of aluminum foil to form a tray large enough to hold the entire sample. Label the tray with at least two identifiers (e.g., the Labworks sample number and registrant number).
    - 6.3.5.2 For large samples that require more than one tray, ensure that each tray is labeled with at least two identifiers and given a unique number (e.g., the Labworks sample number and registrant number followed by 1/3, 2/3, 3/3, etc.).
    - 6.3.5.3 Spread the entire hemp sample on the aluminum tray or onto multiple trays if necessary. Use clean scissors to cut if the stems are too long to fit in the foil tray.
      - 6.3.5.4 If air-drying, allow the sample to dry until the plant material easily crumbles between the fingers and the stem *is brittle and cracks easily*.
    - 6.3.5.5 To avoid the growth of mold, store hemp samples in a dry, well-ventilated area.

      Space hemp samples and/or fold the sides of the aluminum tray high enough to avoid cross contamination. While air-drying, it may be helpful to gently mix larger samples at least once to achieve a more even drying.



6.3.5.6 If additional drying is necessary or samples need to be dried within a shorter amount of time, they may be dried in an oven until the plant

# **CDA Uncontrolled Document**

Biochemistry Laboratory SOP No.: PT-LBOP-014		Page 3 of 5
Title: Hemp Sample Preparation		
Revision: 05	Replaces: Rv04 10/31/2019	Effective: 06/25/2021

material easily crumbles between the fingers and the stem *is brittle and cracks easily*.

- 6.3.5.7 The oven temperature shall not exceed 65° C 95° C. At temperatures exceeding 80° C, significant loss of volatile compounds within the plant material begins, which can have a measurable effect on the loss of mass in the plant material.
- 6.3.5.8 To dry samples within a 24-hour period, immediately after laying the sample on the aluminum tray, place the sample into the oven at approximately 60 °C and allow to dry overnight.
- 6.4 Hemp Sample Grinding/Homogenization
  - 6.4.1 The entire hemp sample, including seeds and stems, shall be ground and homogenized. Follow manufacturer's instructions for use and cleaning of the mill.
  - 6.4.2 If necessary, cut the large stems and plant material with scissors in order to fit inside the grinder.
  - 6.4.3 *To avoid exposure to potentially irritating dust,* samples should be ground in a hood. If it is *not possible* to grind samples outside of a hood, samples shall be ground in an sealed area that is well ventilated. Any personnel who enters a room where hemp samples are being ground outside of the hood shall wear an *N-95 mask or* respirator at all times.
  - 6.4.4 The laboratory currently uses Magie Bullet® Blenders to grind hemp, however, most analytical mills or simple blenders will sufficiently grind the hemp sample. The grinder should be equipped with a flat blade for the finest and most efficient grind. Crossblades may be used, but will take more care and time to ensure that the sample is ground to a fine, even consistency.
  - 6.4.5 Place the sample into the analytical mill or blender; do not overfill. Grind the sample until a fine, even texture is achieved.
  - 6.4.6 Grind the <u>entire</u> sample. It may be necessary to grind large samples in multiple separate portions. If the sample has been ground in separate portions, combine all ground portions and mix well.
  - 6.4.7 Place the ground sample into a specimen cup labeled with the two identifiers, (e.g. the Labworks sample number and registrant number). *Only one sample cup needs to be retained. Excess ground sample may be disposed.*
  - 6.4.8 The Wash the blender or mill vessel, lid eup and blender blade shall be washed according to SL-LBOP-004 between each sample. before using it to grinding another sample. Blender cups and blades may be hand washed or washed in the dishwasher per SL-LBOP-004. If washed in the dishwasher, rinse the blender cup and blade with methanol or acetone after the dishwasher cycle



has completed. Rinse Magic Bullet® blender cups and blender blades with methanol only. DO NOT rinse Magic Bullet® blender accessories with acetone, as it breaks down and damages the plastic.

# **CDA Uncontrolled Document**

Biochemistry Laboratory SOP No.: PT-LBOP-014		Page 4 of 5
Title: Hemp Sample Preparation		
Revision: 05	Replaces: Rv04 10/31/2019	Effective: 06/25/2021

- 6.4.9 If sample is spilled on the blender base, wipe it clean with a moist, soapy paper towel or cloth, followed by a paper towel or cloth wetted with water only, followed by a dry paper towel or cloth.
- 6.4.10 Analyze the moisture content of the dried ground sample.
- 6.5 Sample Storage, Disposal and Clean-up
  - 6.5.1 Samples (original and prepared) shall be stored in a secure location. <del>Unprepared</del>
  - 6.5.2 Samples that have been removed from their original packaging and laid out on an aluminum tray can be stored at room temperature on drying racks.
  - 6.5.3 Samples that have not been removed from their original packaging shall be stored in a secured, designated laboratory freezer.
  - 6.5.4 Dried and ground samples shall be stored in a designated freezer.
  - 6.5.5 All sample materials and extracts are stored and shall be disposed of per SL-LBOP 013.

#### 6.6 Records

- 6.6.1 All samples that are dried in the oven shall be recorded on form SLI007A. The drying method (air, oven, air/oven) may be noted in the comment section of PTM031A.
  - 6.6.2 Temperatures and oven logs shall be completed and maintained per SL-INST-007.
- 6.6.3 Records shall be made available for internal and external audits, assessments, reviews, and inspections.

# **CDA Uncontrolled Document**

Biochemistry Laboratory SOP No.: PT-LBOP-014		Page 5 of 5
Title: Hemp Sample Preparation		
Revision: 05	Replaces: Rv04 10/31/2019	Effective: 06/25/2021



# 7. Revisions:

**Revision:** 05

**Date of Revision**: 6/11/2021

**Revision made by:** Staff Collaboration

**Description of Revision:** 

- New text additions are in italics and red type.
- Deletions are crossed out with a single.
- The section providing instructions for sample sieving has been removed.

# 8. Approvals:

Original Author: Daya Mitchell

<u>06/25/2021</u> Approved By: Kristina McCallum Date Laboratory Manager, CDA-BCL

<u>06/25/2021</u> Approved By: Ellen LaRiviere Date Quality Assurance Officer, CDA-BCL

Biochemistry Laboratory SOP No.: PT-METH-044		
Title: Analysis of Moisture Content in Hemp Using the Mettler Toledo HE73 Moisture Analyzer		
Revision: Original	Replaces: NA	Effective: DRAFT



### 1. Purpose:

This standard operating procedure (SOP) describes the procedure for the analysis of moisture content in hemp using the Mettler Toledo HE73 Moisture Analyzers. This SOP also details the operation and maintenance of the Moisture Analyzers.

#### 2. Scope, Responsibilities, and Authorities:

This SOP applies to staff members who perform moisture content analysis at the CDA-BCL. This SOP shall be used in conjunction with the SOPs listed in the reference section. The Pesticide Unit Work Leader(s) have the responsibility for ensuring that personnel have completed training in the proper use of the instrumentation. Trained staff members shall adhere to the requirements specified in this SOP and report non-compliance to the Quality Assurance Officer (QAO) and the Laboratory Manager. The Laboratory Manager and QAO are authorized to request and review records.

#### 3. Outline of Procedure:

- 6.1 System Overview
- 6.2 Operator Requirements
- 6.3 Safety Precautions and General Requirements
- 6.4 Resources: Equipment, Reference Materials, Chemicals, Supplies
- 6.5 Instrument Set-up
- 6.6 Method Set-up
- 6.7 Instrument Conditions
- 6.8 Operation of Instrument
- 6.9 Sample Analysis
- 6.10 Quality Control
- 6.11 Accuracy, Precision, and Measurement Uncertainty
- 6.12 Data Review and Reporting
- 6.13 Maintenance and Cleaning
- 6.14 Troubleshooting and Diagnostics
- 6.15 Records

#### 4. References, Related Procedures, and Forms:

#### CDA-BCL SOPs (current revisions)

SL-DATA-002 Data Collection, Review, Approval, Reporting, Storage, Protection and Confidentiality

PT-LBOP-014 Hemp Sample Preparation

#### **CDA-BCL Forms (current versions)**

PTM044A Moisture Analyzer Log

#### Instrument Manuals and Software

IM1166.1 and IM1369.1 Moisture Analyzer HE73 User Manual, 04/2016.

IM1166.2 and IM1369.2 Guide to Moisture Analysis: Fundamentals and Applications, 10/2016.

SW1166.1 Mettler Toledo Moisture Analyzer HE53, HE73 Installation Videos, Operating Instructions, User Manual, Moisture Guide, SOPs Routine Testing, 03/2017.

#### **External Documents**

ED781 Domestic Hemp Production Program Final Rules, USDA, 7 CFR 990, January 19, 2021.

# 5. <u>Definitions</u>:

5.1 Dry weight basis – the weight of a cannabis sample after excluding moisture from the sample. This definition is based on ED718 Domestic Hemp Production Final Rules.



- 5.2 Hygrometer an instrument that measures the amount of water in the air.
- 5.3 Moisture the water present in a sample.
- 5.4 Moisture content the ratio of the amount of moisture in a sample to the amount of dry solid in a sample.
- 5.5 Performance Evaluation Sample a hemp sample of known moisture content evaluated daily to verify the moisture analyzer's performance integrity.
- 5.6 Relative Atmospheric Humidity (%RH) A measure of the amount of water in the air compared to the total amount of water the air can hold at a given temperature.

# 6. **Specific Procedures**:

- 6.1 System Overview
  - 6.1.1 The HE73 Moisture Analyzer consists of a heating module connected to a balance. Figure 1 displays the Analyzer, its main components, and other small parts.

Figure 1. HE73 Moisture Analyzer. Mettler Toledo Operating Instructions, SW1166.1, p10.

- 6.1.2 The HE73 Moisture Analyzer employs the use of a halogen radiator that contains a glass pipe filled with halogen gas and a gold-plated reflector. The halogen radiator's low mass allows the Moisture Analyzer to quickly reach the maximum programmed temperature. The gold-plated reflector evenly distributes the generated heat over the entire surface of the sample.
- 6.1.3 The HE73 Moisture Analyzer calculates moisture content by recording a sample's starting weight, then drying the sample with the halogen radiator while the balance continuously records the sample's weight until it reaches a constant mass. The moisture content is then calculated based on the total loss in sample weight.

#### 6.2 Operator Requirements:

- 6.2.1 Only trained, competent, and authorized CDA-BCL personnel are allowed to operate the HE73 Moisture Analyzers. Authorized operators shall have signed training documents demonstrating competence in the operation of the HE73 Moisture Analyzers prior to independent operation.
- 6.2.2 Appropriate laboratory PPE, including a lab coat, safety glasses, and gloves, shall be worn by personnel operating the Moisture Analyzers.
- 6.3 Safety Precautions and General Requirements
  - 6.3.1 The Moisture Analyzer functions by using heat. Components inside of the heating module have the potential to reach 400 °C. Never open the heating module during operation.
  - 6.3.2 Use caution when removing the sample, as the sample and/or components of the Moisture Analyzer may still be very hot.
  - 6.3.3 Do not place the following materials on or near the Moisture Analyzers: flammable or explosive substances, substances containing solvents, volatile substances that create flammable or explosive gases or vapors when heated, substances that contain caustic or toxic components, substances that create corrosive vapors when heated (e.g. acids).
  - 6.3.4 The room temperature should be maintained between 10 °C and 30 °C.
  - 6.3.5 The analyzer should be operated within a range of 10 to 80% RH.



6.4 Resources: Equipment, Reference Materials, Supplies

#### **Equipment**

- 6.4.1 Moisture Analyzer, Mettler Toledo HE73 or equivalent
- 6.4.2 Printer, Mettler Toledo LC-P45 or equivalent
- 6.4.3 Printer, Mettler Toledo, P-58RUE or equivalent
- 6.4.4 Hygrometer, VWR Traceable Memory-Loc Hygrometer Cat# 76047-586, or equivalent

#### Reference Materials

6.4.6 SmartCal Moisture Analyzer Test Substance, Mettler Toledo PN: 30005793 or equivalent

## **Supplies**

- 6.4.7 Aluminum Sample Pans, Mettler Toledo PN: 13865, VWR Cat. #11278-144 or equivalent
- 6.4.8 Printer Paper, Mettler Toledo PN: 72456, VWR Cat. #11277-683
- 6.4.9 Sterile Tongue Depressors

#### 6.5 Instrument Set-up

- 6.5.1 Ensure that the instrument is configured as shown in Figure 2.
- 6.5.2 The analyzers should be placed on a stable workbench, out of direct sunlight, in an area that is free from vibrations and drafts. The corner of the room is an ideal location.
- 6.5.3 Do not obstruct the vent over the sample in any way and ensure that there is approximately one meter of free space above the heating module to avoid heat accumulation and overheating.
- 6.5.4 It is imperative that the instrument is level in order to ensure accurate and repeatable results. The Analyzers have a level indicator (Fig. 1-12) in the upper left corner of the display area and a leveling foot (Fig. 1-15) on each side. Check the level and adjust if necessary, prior to analyzing samples each day.
- 6.5.5 The balance must be adjusted before the instrument is used for the first time and/or after a change of location, in order to match the gravitational acceleration of its location and obtain accurate results. Perform the balance weight adjustment using the steps below.
  - 6.5.5.1 Obtain a 50 gram test weight from one of the reference weight sets throughout the lab.
  - 6.5.5.2 Ensure that the Analyzer is level. If it is not level, adjust the leveling feet on either side of the Analyzer until it is level.
  - 6.5.5.3 Press the Power button on the bottom left corner of the display screen to turn on the Analyzer.
  - 6.5.5.4 Open the heating module.
  - 6.5.5.5 Ensure that there is no weight on the sample pan holder (Fig. 2-2).
  - 6.5.5.6 Press [Menu] three times. CAL will display on the screen.
  - 6.5.5.7 Press the Stop/Enter button. S.CAL will display on the screen.
  - 6.5.5.8 Press the Start/Down button. WEIGH will flash on the screen.
  - 6.5.5.9 Press the Stop/Enter button. The instrument will tare and 50.000 g will flash on the screen.
  - 6.5.5.10 Place the 50 g weight on the sample pan holder. [-----] will display on the



screen, which will be followed by 0.000 g flashing on the screen.

Remove the test weight

- 6.5.5.11 [-----] will display on the screen, followed by DONE.
- 6.5.5.12 The weight adjustment is complete and the printer will generate a printout for record-keeping. Record the completion of the weight adjustment in the instrument log book and tape the printout next to the record.
- 6.5.5.13 If the weight is left on the sample pan holder for too long after 0.000 g begins flashing on the screen, the Analyzer will error and the weight adjustment will need to be restarted. If this occurs, remove the weight, press the Print/Cancel/Exit button and restart the process at step

# 6.6 Method Set-up

The Moisture Analyzer can be programmed for two separate methods. One method each can be programmed to either the [] button or the [] button. Create a method by using the following procedures.

\*Navigate back to the main display screen by pressing the Print/Cancel/Exit button at any time during the process. It may be necessary to press the button multiple times.

## Setting the Drying Program

The drying program sets the speed and temperature ramp used to dry samples.

- 6.6.1 Press [Menu]. METH.A will display on the screen. Press the Start/Down button to display METH.B. Press the Tare/Zero/Up button to return to METH.A. Whichever label is displayed on the screen is the label the method will save under.
- 6.6.2 Press the Stop/Enter button . PROG will show on the screen.
- 6.6.3 Press the Stop Button or the Tare/Zero/Up button to display flashing RAPID.
- 6.6.4 Press the Start/Down
- 6.6.5 Press the Stop/Enter button to select either STD or RAPID. /Enter the button again and STD will flash on the screen.
- STD Denotes the standard drying program, and is suitable for most samples. The sample is heated to the drying temperature. The selected drying temperature is maintained until drying is complete.
  - RAPID Denotes the rapid drying program, and is primarily used for high moisture content samples (>30%). The sample is heated to a temperature that is 40% higher than the selected temperature for a total of three minutes in order to compensate for cooling due to vaporization and to speed up the drying process. The temperature is then lowered to and maintained at the set value.

# Setting the Drying Temperature

The drying temperature is the set temperature at which the samples will dry.

6.6.6 From the main display screen, press [] for METH.A or [] for METH.B.



- 6.6.7 Press the temperature button to display the set drying temperature.
- 6.6.8 Press the or button to toggle to the desired drying temperature.
- 6.6.9 Set the drying temperature by pressing when the desired number has been reached.

# Setting the Switch-off Criterion

The switch-off criterion programs when the instrument will end the drying process.

- 6.6.10 While viewing the main display screen, press [Menu] for METH.A or [Menu] > for METH.B.
- 6.6.11 After the method has been selected, press then press two times. SOC will display on the screen.
- 6.6.12 Press. The switch-off options will flash.
- 6.6.13 Press or to toggle through AUTO, TIMED, or FREE.
  - AUTO This is the default factory setting and is suitable for most kinds of samples. On this setting, switch-off occurs at a sample weight loss rate of 0.001 g/50 s.
  - TIMED Switch-off time is manually set. A preset time of 1 to 120 minutes may be selected in increments of 10 seconds.
  - FREE Switch-off time is set based on 1 mg weight loss per unit of time. Available options include: 1 mg/10 s, 1 mg/20 s, 1 mg/50 s, 1 mg/90 s, and 1 mg/140 s.
- 6.6.14 Set the switch-off criterion by pressing when the desired setting is flashing.

#### Setting the Start Mode

The start mode programs whether the drying will start automatically or manually.

- 6.6.15 From the main display screen, press [Menu] once to display METH.A or twice to display METH.B.
- 6.6.16 Press the Stop/Enter button . PROG will show on the screen.
- 6.6.17 Press the Start/Down button three times to display ST. MOD.
- 6.6.18 Press the Stop/Enter button and AUTO will flash on the screen.
- 6.6.19 Press or to toggle between AUTO or MAN.
  - AUTO When using this setting, the Analyzer will record the initial weight of the sample and begin the drying process automatically upon closing the lid.
  - MAN When using this setting, it is necessary to press the button to begin the drying process.
- 6.6.20 Set the start program by pressing when the desired setting is flashing.

#### Setting the Display Mode

This mode selects the measurement value that will display and print. The following options are available:



- %MC Moisture Content (calculated value): displays and prints out moisture content as a percentage of the sample's wet weight.
- %DC Dry Content (calculated value): displays and prints out the dry content of the sample □ as a percentage of the sample's wet weight.
- %AM ATRO Moisture Content (calculated value): displays and prints out the moisture content of the sample as a percentage of the sample's dry weight.
- %AD ATRO Dry Content (calculated value): displays and prints out the wet weight of the sample as a percentage of the dry weight.
- **g** Weight in grams.
- *Note An asterisk next to a number on the display denotes a calculated value.*
- 6.6.21 From the main display screen, press [Menu] once to display METH.A or twice to display METH.B.
- 6.6.22 Press the Stop/Enter button . PROG will show on the screen.
- 6.6.23 Press the Start/Down button four times to display DISP. U.
- 6.6.24 Press the Stop/Enter button . UNIT will display and one of the five defined measurement value options will be flashing.
- 6.6.25 Press or to toggle between the different measurement value options.
- 6.6.26 Press the Stop/Enter button when the desired measurement value is flashing.

#### 6.7 Instrument Conditions

- 6.7.1 Instrument Conditions for Hemp Moisture Content Analysis shall be set as follows:
  - 6.7.1.2 Temperature: 80 °C
  - 6.7.1.3 Switch-off Criterion: AUTO
  - 6.7.1.4 Start Mode: AUTO 6.7.1.5 Display Mode: %MC
- 6.8 Operation of Instrument
  - 6.8.1 Ensure that the Moisture Analyzer is level each day, prior to analyzing samples. Note that the level has been verified/adjusted on form PTM044A.
- 6.9 Sample Analysis
  - 6.9.1 Prepare samples per PT-LBOP-014 Hemp Sample Preparation prior to analysis of the Moisture Analyzers.
- 6.10 Quality Control
  - 6.10.1 It is recommended by the manufacturer that SmartCal Substance should be analyzed on a weekly basis to ensure the performance of the Moisture Analyzers.
    - 6.10.1.1 Open the Analyzer Lid and place the sample pan on the holder.
    - 6.10.1.2 Press [Menu] three times to display CAL on the screen.
    - 6.10.1.3 Press to display S.CAL on the screen.



- 6.10.1.4 Press again to display a number that denotes the current temperature setting.
- 6.10.1.5 Press or to toggle to 70.
- 6.10.1.6 Press to set the temperature at 70 °C.
- 6.10.1.7 Close the lid to tare the Analyzer.
- 6.10.1.8 Open the lid, place one full pack of SmartCal beads on the sample pan. Ensure that they are as evenly spaced as possible.
- 6.10.1.9 Close the lid. The analysis will begin. Record the temperature and the %RH.
- 6.10.1.10 After 10 minutes have passed, the analysis should be complete and a receipt should have printed.
- 6.10.1.11 Record the date, SmartCal lot No., %RH, °C, %MC, analyst initials, and any important remarks in the SmartCal Normalization Chart.
- 6.10.1.12 If the %MCN is not within the chart limits, an adjustment is needed for the analyzer.
- 6.10.2 The Moisture Analyzers' performance shall be verified prior to analysis each day of use by evaluating a performance evaluation sample with a known moisture content. The sample shall be either a University of Kentucky PT sample or a certified reference material from a material producer accredited to the ISO/IEC 17034 standard.
- 6.10.3 Daily Performance Evaluation Sample results shall be within 3 standard deviations of the sample's known moisture content value. If the moisture analysis fails, the analyst shall:
  - 6.10.3.1 Obtain and evaluate a different Performance Evaluation Sample to verify that it is not the degradation of the original Performance Evaluation Sample.
  - 6.10.3.2 If results are still unacceptable, perform a weight adjustment and reanalyze the sample.
  - 6.10.3.3 If results are still unacceptable, perform a SmartCal verification. If the SmartCal verification passes, re-analyze the Performance Evaluation Sample.
  - 6.10.3.4 If results are still unacceptable, remove the moisture analyzer from service.
  - 6.10.5 The instrument shall be calibrated annually by an ISO/IEC 17025 accredited calibration company in order to ensure optimal instrument performance. Hemp season generally begins around mid-to-late summer. Ideally, the scheduling of calibration for the Moisture Analyzers should occur in mid-to-late spring, where possible.
- 6.11 Accuracy, Precision, and Measurement Uncertainty
- 6.12 Data Review and Reporting
- 6.13 Maintenance and Cleaning
  - 6.13.1 Ensure that the moisture analyzer is clean before use each day. If there is any debris on or around the draft shield, brush it off with a small paintbrush.
  - 6.13.2 Ensure that the moisture analyzer is clean between the analysis of each sample. If there is any debris on or around the draft shield, brush it off with a small paint brush.
  - 6.13.3 The shall be calibrated each year by a service company accredited to ISO 17025 or by a Mettler Toledo service technician. balance and heating element
  - 6.13.4 Clean off the outside of the analyzers using a cloth dampened with water as needed when it becomes dusty.



# 6.14 Troubleshooting and Diagnostics

#### 6.15 Records

- 6.15.1 The Moisture Analyzer logbooks and form PTM044A shall be maintained near the Moisture Analyzers per SL-DATA-002.
- 6.15.2 Records shall be made available for internal and external audits, inspections, assessments, and reviews.

# 7. Revisions:

**Dates of Revision:** NA – Original Version

# 8. Approvals:

Approved By: Kristina McCallum Date Laboratory Manager, CDA-BCL Approved By: Ellen LaRiviere Date Quality Assurance Officer, CDA-BCL



# **Appendix I: CDA Hemp THC Testing Standard Operating Procedure**



#### CDA - Uncontrolled Document

SOP No.: PT-METH-031		Page 1 of 8
Title: Determination of Delta-9-THC in Hemp by Gas Chromatography with Flame Ionization Detection (GC/FID)		
Revision: 03	Replaces: 02 10/29/2019	Effective: 08/19/2020

# 1. Purpose:

This standard operating procedure (SOP) describes the extraction of  $\Delta^9$ -tetrahydrocannabinol (THC) from hemp vegetation, followed by analysis using an Agilent 6890N *or* 8890 Gas Chromatograph with a Flame Ionization Detector (GC/FID).

# 2. Scope, Responsibilities, and Authorities:

This SOP applies to staff members working in the Chemical Sciences and Pesticides Unit at the CDA-BCL. This SOP shall be used in conjunction with the SOPs listed in the reference section. Chemical Sciences and Pesticides Unit staff members shall adhere to the requirements specified in this SOP and report non-compliance to the Quality Assurance Officer (QAO) and/or the Laboratory Manager. The Laboratory Manager and QAO are authorized to request and review records.

# 3. Outline of Procedure:

- 6.1 Safety Precautions and General Requirements
- 6.2 Resources: Reference Materials, Chemicals, Reagents, and Equipment
- 6.3 Reagent Preparation
- 6.4 Reference Material Preparation
- 6.5 Sample Preparation
- 6.6 Sample Analysis
- 6.7 Instrument Conditions
- 6.8 Quality Control
- 6.9 Detection Limits, Accuracy, Precision, and Measurement Uncertainty
- 6.10 Data Review and Reporting
- 6.11 Records
- 6.12 Sample Disposal and Clean-up

# 4. References, Related Procedures, and Forms:

#### **External Documents**

ED628 – Gas Chromatographic Determination of Tetrahydrocannabinol in Cannabis, Chemistry Section, Bureau of Drug Research Health Protection Branch, Health Canada, October 1992 ED629 – Marijuana Potency Testing – Quick and Easy by GC or LC, Restek application note, 2012 ED640 – Medical Marijuana Solvent Extraction Efficiency – Potency Determinations with GC-FID, 2011

# CDA-BCL SOPs and Manuals (current revision)

PT-INST-024 Operation and Maintenance of the Agilent 6890N GC/FID Gas

Chromatograph/Flame Ionization Detectors (GC/FIDs)

PT-LBOP-014 Hemp Sample Preparation SL-LBOP-001 Chemical, Reagent, and Reference



Material Ordering, Receipt, Preparation, Storage, and Disposal

- SL-DATA-002 Data Collection, Review, Approval, Reporting, Storage, Protection, and Confidentiality
- SL-QAQC-003 Nonconformances, Corrective and Preventive Actions and Continuous Improvement Process

SOP No.: PT-METH-031		Page 2 of 8
Title: Determination of Delta-9-THC in Hemp by Gas Chromatography with Flame Ionization Detection (GC/FID)		
Revision: 03	Replaces: 02 10/29/2019	Effective: 08/19/2020

SL-QAQC-022 Method Validation and Verification

Minor update to PTM031A. Updated form version # to 4.1 eml – 08/23/2020

<u>CDA-BCL Forms</u> PTM031A THC in Hemp Bench Sheet

# v0**4.1 5. Definitions:**

- 5.1 Cannabidiol (CBD) one of at least 85 active cannabinoids identified in cannabis. It is a major phytocannabinoid, accounting for up to 40% of the plant's extract. CBD is considered to have a wider scope of medical applications than tetrahydrocannabinol.
- 5.2 Cannabinol (CBN) a weak psychoactive cannabinoid found only in trace amounts in *Cannabis sativa* and *Cannabis indica*. It is mostly a metabolite of tetrahydrocannabinol.
- 5.3 Decarboxylation with respect to cannabis, decarboxylation is the process of converting THCA to THC.
- $5.4 \, \Delta^9$ -tetrahydrocannibinol (THC) cannabinoid that is the primary psychoactive constituent of marijuana and hemp products.
- 5.5 Method Blank (MB) Matrix matched material that contains no analyte of interest. The MB is extracted alongside customer samples to ensure that there is no contamination. The final extract from the method blank is used in the preparation of calibration standards.
- 5.6 Laboratory Control Sample (LCS) Matrix matched material fortified with *that contains* a known concentration of THC. The LCS is extracted alongside customer samples to monitor THC recovery. *Blank material can be spiked with a known concentration of THC if a suitable reference material is not available.*
- 5.7 Reagent Blank (RB) a matrix-free sample extracted alongside customer samples to ensure there is no contamination in any solution or solvent used.



# 6. Specific Procedures:

- 6.1 Safety Precautions and General Requirements.
  - 6.1.1 Individuals using this procedure shall be familiar with the toxicity of all chemicals involved prior to use by reading the specific MSDS sheets. Appropriate personal protective equipment (PPE) shall be worn while performing work under this procedure.
- 6.2 Resources: Reference Materials, Chemicals, Reagents, and Equipment

#### Reference Materials

- 6.2.1 Cannabinoids standards 1000-μg/ml each CBD, CBN and/or THC, Restek or equivalent
- 6.2.2 Method Blank Hemp samples that have previously been tested and found to contain no detectable THC.
- 6.2.3 LCS *Current hemp reference material is provided by the University of Kentucky, Division of Regulatory Services. If no suitable reference material is available, it is acceptable to spike* hemp samples that have previously been tested and found to contain no detectable THC. This blank hemp sample material is *shall be* spiked with 0.200 ml of the 1000-µg/ml stock standard solution.

SOP No.: PT-METH-031		Page 3 of 8
Title: Determination of Delta-9-THC in Hemp by Gas Chromatography with Flame Ionization Detection (GC/FID)		
Revision: 03	Replaces: 02 10/29/2019	Effective: 08/19/2020

## <u>Reagents</u>

6.2.4 Methanol –ACS grade or higher, or equivalent

#### <u>Equipment</u>

- 6.2.5 Gas chromatograph/flame ionization detector (GC/FID) Agilent 6890N, 8890 or equivalent
- 6.2.6 Analytical Column HP-5ms UI 15m x 0.25 mm x 0.25 $\mu$ m Agilent 19091S-431UI or equivalent
- 6.2.7 Graduated Cylinder, 50-ml, Class A
- 6.2.8 Pipettes, 20-µl to 1000-µl
- 6.2.9 Bottle-top Dispenser, capable of dispensing 40 ml
- 6.2.10 50-ml plastic centrifuge tubes, VWR PN: 21008-242 or equivalent
- 6.2.11 Geno Grinder or Wrist Action Shaker
- 6.2.12 Top-loading Balance, 0.01g minimum tolerance
- 6.2.13 Amber Autosampler Vials and caps, VWR PN: 82030-974 or equivalent



# 6.3 Reagent Preparation

6.3.1 No reagent preparation is necessary.

# 6.4 Reference Material Preparation

- 6.4.1 Record standard preparation per SL-LBOP-001.
- 6.4.2 Stock Standard Solution
  - $6.4.2.1\ 1000$ -µg/ml Cannabinoids standards in methanol, from Restek or equivalent

### 6.4.3 Matrix Matched Calibration Standards

6.4.3.1 Calibration standards are prepared using the extract of the MB. Previously or separately prepared MB extract may also be used. 6.4.3.2 Levels are prepared to match expected responses at corresponding percentages of THC in the 0.20 g sample. Example: 0.30% of a 0.20g hemp sample is 0.60 mg or 600  $\mu g$ . Extraction in 40 ml of methanol would result in a concentration of THC at 600  $\mu g/40$  ml which equals 15  $\mu g/ml$ .

6.4.3.3 Calibration Levels: Prepare a minimum of 6 calibration levels in control hemp matrix. The following chart-Table 1 may be used as a guide for calibration standard preparation:

SOP No.: PT-METH-031	Page 4 of 8		
Title: Determination of Delta-9-THC in Hemp by Gas Chromatography with Flame Ionization Detection (GC/FID)			
Revision: 03	Effective: 08/19/2020		

*Table 1: Calibration curve preparation auide.* 

Level	Standar d (µg/ml)	Amount (ml)	Dilution (ml)	Conc. (µg/ml)	% THC
1	1000	0.100	1.0	100	2
2	1000	0.050	1.0	50	1
3	1000	0.025	1.0	25	0.5
4	100 (1)	0.150	1.0	15	0.3



5	50 (2)	0.100	1.0	5	0.1
6	25 (3)	0.100	1.0	2.5	0.05

6.4.3.4 Continuing Calibration Verification Standard (CCV): The CCV shall be prepared using the extract of the MB, at 0.3% THC. The CCV shall be prepared using a second source, different lot, or different analyst than used to prepare the calibration standards.

# 6.5 Sample Preparation

- 6.5.1 Prepare the hemp samples per PT-LBOP-014.
- 6.5.2 Weigh 0.20 g prepared hemp sample into a 50-ml centrifuge tube and recording the weight on form PTM031A.
- 6.5.3 Add 40 ml methanol to the centrifuge tube. Cap and shake to ensure that the entire sample is wet.
- 6.5.4 Place on the Geno Grinder for approximately 5 minutes at 500 rpm. It is also acceptable to use either a wrist action shaker or to shake manually for approximately 5 minutes.
- 6.5.5 Allow the samples to settle for at least one hour.
- 6.5.6 Dispense a 1-ml aliquot of the sample solution into  $a^n$  2-ml amber autosampler vial.
- 6.5.7 Samples—extracts may be stored in a refrigerator if analysis is not completed immediately.

### 6.6 Sample Analysis

6.6.1 Samples shall be analyzed *for Total THC* by GC/FID. Samples are analyzed for Total THC. Any THCA in the sample is converted to THC through the heat of the GC inlet injector port. Refer to PT-INST-024 for specific operational procedures.

SOP No.: PT-METH-031 Page 5 of 8				
Title: Determination of Delta-9-THC in Hemp by Gas Chromatography with Flame Ionization Detection (GC/FID)				
Revision: 03 Replaces: 02 10/29/2019 Effective: 08/19/2020				

### 6.7 Instrument Conditions



# 6.7.1 GC-FID instrument parameters:

<u>Oven</u>

Initial Temp: 200° C at 0 min

Ramp: 15° C/min to 300° C, hold 0 min

Front Inlet Mode: Split

Initial temp: 250° C Pressure: 9.52 psi Split ratio: 20:1

Split flow: 15.6 ml/min Total flow: 19.1 ml/min

Gas Saver: On

Saver flow: 20.0 ml/min Saver time: 2.00 min Gas type: Helium

# 6.8 Quality Control

6.8.1 Sample sets shall contain one each of an RB, MB, LCS, and randomly chosen duplicate sample. Sets may contain any number of samples.

6.8.2 Sample concentrations shall not exceed 10% of the highest calibrator. Samples with a higher concentration of THC shall be diluted to fall within the calibration curve.

6.8.3 Duplicate sample results shall be within ± 25 relative percent difference (RPD). If the RPD is greater than 25%, an investigation shall be conducted to determine the cause.

6.8.4 The Reagent Blank or Method Blank shall not contain THC at a level greater than the LOQ.

6.8.4.1 If the RB or MB contain THC at a level greater than the LOQ, the data set shall be evaluated and sample results shall be reported at the discretion of the OAU.

# 6.8.5 LCS Criteria

6.8.5.1 LCS reference material shall be approved by the QAU and the expected concentration of the LCS shall be updated in LabWorks prior to use during sample analysis.

6.8.5.2 If suitable hemp reference material is not available, blank hemp matrix shall be used for the LCS. The LCS blank hemp matrix shall be spiked at

0.1% THC. This is equivalent to 0.20 g of blank matrix spiked with  $200~\mu l$  of  $1000~\mu g/ml$  stock standard.



SOP No.: PT-METH-031 Page 6 of 8				
Title: Determination of Delta-9-THC in Hemp by Gas Chromatography with Flame Ionization Detection (GC/FID)				
Revision: 03 Replaces: 02 10/29/2019 Effective: 08/19/2020				

6.8.5.3 The LCS recovery shall fall within the current limits—established by control charted data trends control chart limits.

6.8.5.4 LCS recoveries falling outside of the accepted established range shall be evaluated and possibly re-injected. Continued failure of LCS recoveries shall be investigated according to SL-QAQC-003.

### 6.8.6 Instrument Calibration

6.8.6.1 The calibration curve shall use a linear regression with a 1/x weighting.

6.8.6.2 The calibration correlation coefficient ( $r^2$ ) shall be  $\geq$  0.995.

6.8.6.3 It is acceptable for the initial instrument calibration to be used for analysis of samples if a continuing calibration standard is analyzed and within±15% accuracy.

6.8.6.4 Calibration integrity shall be calculated for each sample set by analyzing a continuing calibration verification (CCV) standard. Results of calibration integrity shall be documented in the sample set report.

6.8.6.5 The CCV shall be within ±15% accuracy. If a CCV is outside of this range, the samples shall be reanalyzed back to the last acceptable CCV.

6.8.6.6 Continuing calibration standards shall be injected at the following intervals in the sample sequence; after calibration before the sample set, after every 15 samples, and at the end of the sample run.

6.9 Detection, Accuracy, Precision, and Measurement Uncertainty

6.9.1 The LOD and LOQ are listed in the table below. Accuracy (%A), Precision (%CV), and Measurement of Uncertainty (MU) were determined



according to SL-QAQC 022, using 20 hemp matrix spiked samples containing 0.3% THC. Table 2 lists the results of the verification study. Accuracy and precision shall be monitored through control charting per SL-QAQC-015.

*Table 2: Method performance parameters.* 

		Instrument Detector Cannabinoid	%A	%CV	MU	LOQ (%)	LOD (%)
GC12	Front	THC	89	8.35	0.0447	0.05	0.025
GC41	Front	THC	99.0	13.2	0.0782	0.05	0.025
GC41	Back	THC	102.6	8.72	0.0537	0.05	0.025

6.9.2 Potential sources of measurement uncertainty for this procedure include, but are not limited to:

- · Quality of reference standards
- · Preparation of stock, process and spike solutions
- · Equipment variances

SOP No.: PT-METH-031	Page 7 of 8		
Title: Determination of Delta-9-THC in Hemp by Gas Chromatography with Flame Ionization Detection (GC/FID)			
Revision: 03	Replaces: 02 10/29/2019	Effective: 08/19/2020	

- · Quality of chemicals and reagents
- · Sample matrix
- · Condition of samples upon receipt
- · Extraction process
- · Staff member performing analysis

# 6.10 Data Review and Reporting

6.10.1 Sample results may be reported directly from the printouts generated by the instrument for this method. Include a copy of the instrument calibration table and curve with the data. shall be uploaded or manually entered into LabWorks.

- 6.10.2 Results shall be reported to two decimal places.
- 6.10.3 Data shall be evaluated for acceptability based on the Quality Control



section of this SOP and SL-QAQC-015.

6.10.4 The data shall be approved per SL-DATA-002 prior to release to customer(s).

### 6.11 Records

# 6.11.1 Sample preparation shall be recorded on form PTM031A.

- 6.11.2 Completed data packages are-shall be stored and archived according to the requirements listed in SL-DATA-002.
- 6.11.3 Data shall be made available for internal and external audits, inspections, assessments, and reviews.

# 6.12 Sample Disposal and Clean-up

6.12.1 After the sample results and associated quality control have been electronically transmitted to the client, the sample extracts, analytical extracts and the raw samples shall be disposed of as follows:

- 6.12.1.1 Sample extracts: Non-chlorinated hazardous liquid waste.
- 6.12.1.2 Analytical extracts: Non-chlorinated hazardous liquid waste.

6.12.1.3 Raw Samples: Raw samples shall be retained for one additional sampling season after the season in which they were received. After the holding time for raw samples has passed, place them in a trash receptacle, if THC content is passing. If THC content fails, samples shall be rendered unrecognizable by mixing them with random vegetation clippings prior to disposal in a trash receptacle. Retain sample in secure storage if THC content fails, and discard upon authorization from the hemp-program coordinator.





SOP No.: PT-METH-	300/5	Page 8 of 8
Determination	of Delta-9-THC in Hemp by Gas Chromato	graphy with Flame Ionization
Detection (GC/FID)		

# 7. Revisions:

Revision: 03

Date of Revision: 07/15/2020 Revision made by: Daya Mitchell

Description of Revision:

New additions are in italics and red type. Deletions are crossed out with a single line.

# 8. Approvals:

Original Authors: Staff Collaboration

08/19/2020 Approved By: Kristina McCallum Date Laboratory Manager, CDA-BCL

Approved By: Ellen LaRiviere Quality Assurance Officer, CDA-BCL 08/19/2020

Date



COLORADO  Department of Agriculture  Division of Laboratory Services	
Title: THC in Hemp Bench	Procedure No.:
Sheet Number: PTM031A	PT-METH-031 Revision: 02
Version: 03	
Equipment/Instrument No.: CDA496, GC-FID #12	Page 1 of 2

Materials: Date:

Components		Initials	Comments
A 1 1 1 C 1		-	Town of a stinus
Analytical Column			<u>Investigations:</u>
Pipettes:			
Balance:	CDA		
Geno Grinder or Wrist Action Shaker:	CDA		
Oven	CDA		
Balance	CDA		Sample Numbers:
Methanol:	Exp:		
Calibration Stds:	Exp:		
CCV Std:	Exp:		
LCS Spike Std:	Exp:		
Matrix Blank:	Exp:		

# **Hemp Sample Preparation:**

Procedure	Initials	Comments
Prepare samples per PT-LBOP-014. Record		
sample weights in grams on page 2		

# <u>Laboratory Control Sample Preparation (LCS):</u>

Procedure	Initials	Comments
Weigh 0.20 g of blank matrix into a 50-ml		
centrifuge tube and record the weight in the		
Sample Weight Table.		
Add 200 µl of the 1000-µg/ml LCS Spike Std.		

Method Blank I	Prepa:	ration (	MB	):

Date:

Date:

Date:



Procedure	Initials	Comments
Weigh 0.20 g of blank matrix material into a 50-ml centrifuge tube and record the weight in the Sample Weight Table.		

# Reagent Blank Preparation (RB):

Date:

Procedure	Initials	Comments
Label a blank 50-ml centrifuge tube.		

COLORADO  Department of Agriculture  Division of Laboratory Services	
Title: THC in Hemp Bench	Procedure No.:
Sheet Number: PTM031A	PT-METH-031 Revision: 02
Version: 03	
Equipment/Instrument No.: CDA496, GC-FID #12	Page 2 of 2

# **Sample Extraction:**

# Date:

Procedure	Initials	Comments
Weigh 0.20 g of each sample into separate 50-ml		
centrifuge tubes and record the weights in the		
Sample Weight Table.		
Add 40 ml of Methanol to each sample, the LCS,		
MB, and RB. Cap and shake.		
Place on the Geno Grinder @ 500 rpm, a wrist		
action shaker, or shake manually for		
approximately 5 minutes.		
Remove and allow to settle for at least 1 hour.		
Dispense 1-ml of the extraction solution into a		
2-ml amber autosampler vial, cap, and analyze.		

# **Sample Weight Table:** Analyst Initials:

# Date:

					ı		<u> </u>
	Sample	Tra	Initial	Final	Analytica	Oven	Comments
	#	<b>y</b>	Weigh	Weigh	l Weight	Used	
		Tar	t	t			
		е					
1							
2							
3							
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20				
Dup				
MB				
LCS				
RB				



# Appendix J: Notification of Hemp Lot Exceeding Acceptable Total THC and Remediation/Disposal Form



Date

BUSINESS NAME c/o Name, Registered Agent Address City, State Zip

RE: 2022 Hemp Sample Results for Registration No.[insert number]; Notification of Hemp Lot Exceeding Acceptable Total THC Level

Dear [insert name]:

This is written notification to BUSINESS NAME that the hemp sample that the Authorized Sampler on behalf of the Colorado Department of Agriculture ("Department") collected on DATE from the following Registered Land Area ("RLA") returned with detection of \_\_\_\_\_ percent THC: PHYSICAL ADDRESS, CITY, COLORADO, ZIP. Please see the attached sample result(s) for your records.

Because the test result is between 0.3 percent and 1.0 percent THC, 990.3(a)(6)(iii) of the USDA Final Rule states BUSINESS NAME may elect to perform remediation activities on its non-compliant lot, and additional sampling and testing of the post remediated lot must occur to determine THC concentration levels. Or, BUSINESS NAME may elect to dispose of its non-compliant lot. BUSINESS NAME must return the following form to the Department within 10 days of this notification with its decision to remediate or dispose of the non-compliant lot. Do not commingle the non-compliant lot with other lots.

If BUSINESS NAME elects to remediate its non-compliant lot, BUSINESS NAME must choose one of the following:

- separate and remove all flowers from stalks, leaves and seeds of the lot (flowers must be
  destroyed with one of the approved disposal methods on the following Remediation or
  Disposal Form ("Form")), or
- shred to create a homogenous, uniform biomass.

The Department must collect a post-harvest sample(s) from the remediated lot(s) within 10 days of BUSINESS NAME's date of remediation. Additional fees will apply.

If BUSINESS NAME chooses not to remediate, the lot(s) must be disposed of using one of the approved disposal methods in a manner approved of and verified by the Commissioner of the Department on the following Form. The Department must approve the disposal method prior to disposal.

BUSINESS NAME must submit the attached Form to Margaret Foderaro at margaret.foderaro@state.co.us. To be considered, the Form must be completed in its entirety and returned to the Department within 10 days of the date of this notification.

In the meantime, please be advised that the lot(s) that is the subject of this letter is prohibited from:

- Leaving the RLA;
- Entering the stream of commerce; or
- Being used for human or animal consumption.

Please do not hesitate to contact me at any time if you have questions.

Sincerely,

Margaret Foderaro Hemp Inspection and Outreach Coordinator Margaret.Foderaro@state.co.us

Attachments

Cc: Business Name; Registration Year, Reg. No. [insert number]

Emailed to Key Participants and others additional contacts listed on the application



### REMEDIATION OR DISPOSAL FORM

Hemp registrants whose hemp tests higher than 0.3 percent total THC but less than 1.0 percent total THC may elect to remediate the lot or to dispose of the lot on-site in a manner approved of and verified by the Commissioner of the Colorado Department of Agriculture ("Department").

The industrial hemp that the Authorized Sampler on behalf of the Department collected on Date from BUSINESS NAME's Registered Land Area ("RLA") returned with a concentration of \_\_\_\_\_ percent total THC. Therefore, BUSINESS NAME hereby submits the following information.

# <u>PAI</u>

PART 1 - REGISTRANT AND L	OT INFORMATION					
Registrant Name:						
Registration Number:						
Registered Land Area:						
Strain/Variety to be Destroy	ed:					
	riety to be Destroyed (or GPS):					
,	re feet or acres):					
Estimate of Biomass (lbs): _						
Remediation Date or Dispos	al Date:					
PART 2 - ELECTION TO REME	<u>DIATE</u>					
Please select one of the followi	ng:					
☐ Removal of Flowers:	The flowers, including buds, trichomes, "trim," and "kief," must be removed from the lot and destroyed. Methods may include, but are not limited to, the removal, by hand, of non-compliant flowers and floral materials and the mechanical removal of non-compliant flowers and floral materials.  Until such time as the non-compliant flowers and floral material are disposed of, the stalks, leaves, and seeds should be separated from the non-compliant floral material and clearly labeled and demarcated as "hemp for remediation purposes."  The biomass that remains shall be resampled and retested to ensure compliance before entering the stream of commerce in accordance with 7 CFR §990.3(a)(6) and §990.27(c).  Seeds removed from non-compliant hemp during remediation should not be used for propagative purposes. Remediation and Disposal Guidelines for					

January 15, 2021.

Hemp Growing Facilities U.S. Domestic Hemp Production Program Issued

Flowers must be destroyed with an approved disposal method (see below)

☐ Blending of Lot: The entire lot be shredded to create a homogenous, uniform

biomass. Methods may include, but are not limited to, the shredding of

hemp plants through shredders, chipper, or specialty mechanical

equipment that renders the plant material as unrecognizable. The biomass created through this process shall be resampled and retested to ensure compliance before entering the stream of commerce in accordance with 7 CFR §990.3(a)(6) and §990.27(c). Biomass that fails the retesting is non-compliant hemp and shall be destroyed. Remediated biomass should be separated from any compliant hemp stored in the area and clearly labeled and demarcated as "hemp for remediation purposes." All lots subject to remediation should be stored, labeled and demarcated apart from each other and from other compliant hemp lots stored or held nearby. Remediated biomass should not leave the labeled and demarcated area until a test result showing compliance with the acceptable hemp THC level is received or until the biomass will be destroyed. Remediation and

Disposal Guidelines for Hemp Growing Facilities U.S. Domestic Hemp Production Program Issued January 15, 2021.

### <u>OR</u>

### PART 2 - DISPOSAL METHOD

<u>Please select one of the following approved methods of destruction:</u>

	_	
	Plowing under:	Curved plow blades rotate subsoil to the surface and bury crops below. <i>Plant material is used on-site and amends soil directly from crops.</i>
_	Mulching/composting:	Field crops cut and blended with manure and other biomass material. <i>Plant material is used on-site by mulching with manure and other biomass.</i>
⊐	<u>Disking:</u>	Leveling of field using tow-behind disk implement.  Plant material is used on-site and amends soil directly while leveling the field.
_	Bush Mower/Chopper:	Commercial lawn mower used to shred and mix thick vegetation. <i>Plant material is used on-site and shredded biomass decomposes into soil.</i>
⊐	<u>Deep Burial:</u>	Fields are trenched and surface soil is buried at a depth of at least twelve inches.  Field biomass is buried in trenches and covered with soil.
	Burning:	Setting fire to specific production fields or biomatter piled on the field.  Must comply with any local burning restrictions and receive the required burn permits from local and state agencies.
_	Other:	If the crop cannot be destroyed within a registered land area, it must be taken to an off-site disposal area to be rendered unusable and unrecognizable. Please describe the proposed destruction and disposal plan, including dates of destruction and disposal, in the space provided:

# PART 3 - CONFIRMATION AND VERIFICATION

Method of remediation and or disposal verified by CDA on this date:

Please describe how remed	ation and or disposal will be confirmed (e.g., photographs, videos, inspection):				
The Department must approve the remediation and or disposal plan described herein before remediation and or disposal takes place. The Department must verify remediation and or disposal consistent with the plan described herein.					
PART 4 - SIGNATURE					
that I have personally examidocument and any attachme	make this submission on behalf of the registrant and certify under penalty of law ined, and am familiar with, the statements and information submitted in this ents. Based on my inquiry of those individuals with primary responsibility for certify that the statements and information are to the best of my knowledge and mplete.				
Signature	Date				
Remediation or Disposal Form Plan for remediation and or c	FOR OFFICE USE ONLY  I received by CDA within 10 days of letter: Yes NoDate form received:  isposal approved by CDA: Yes No On this date:  lisposal provided with plan: Yes No				

Remediation and or disposal verified by: photo/video documentation\_\_ physical inspection\_\_ other-explain\_\_\_\_\_



# **Appendix K: Letter of Certification**

134



June 1, 2021

The Honorable Tom Vilsack Secretary of Agriculture U.S. Department of Agriculture 1400 Independence Avenue SW Washington, DC 20250

# **RE: Colorado State Hemp Management Plan - Certification of Resources**

Dear Secretary Vilsack:

My signature below certifies that the State of Colorado has the resources and the personnel to carry out the practices and procedures described in this State Hemp Management Plan submitted on June 1, 2021, to the United States Department of Agriculture.

This certification is pursuant to the Agriculture Improvement Act of 2018 (Section 297B(a)2(A) (i-vii)), and more formally outlined in the Final Rule (7 CFR § 990), and the regulations authorized by the Colorado General Assembly in Colorado Revised Statutes (§ 35-61-109) and Colorado Code of Regulations (§ 1203-23).

Sincerely,

Kate Greenberg, Commissioner

Colorado Department of Agriculture