

December 9, 2020

To: Laboratories Interested in Testing Hemp for THC Concentration

Subject: California Industrial Hemp Testing Laboratory Requirements

Thank you for your interest in obtaining approval in order to conduct regulatory testing on industrial hemp for tetrahydrocannabinol (THC) concentration.

In accordance with Section 81006 of the California Food and Agricultural Code, a registrant that grows industrial hemp, before the harvest of each crop, must obtain a laboratory test report indicating the THC concentration. The laboratory test report must be issued by a Department approved testing laboratory using an approved testing method.

CDFA has proposed to permanently adopt Sections 4942, 4943, 4944, 4945, and 4946 in Title 3 of the California Code of Regulations pertaining to the approved testing method for THC concentration and the laboratory approval process. The rulemaking package has been submitted to Office of Administirative Law (OAL) on October 20, 2020 for review and approval. CDFA will notify the public via the electronic mailing list when the regulations have been approved by OAL.

In anticipation of OAL's approval of the proposed regulations, CDFA is currently accepting applications from laboratories who are interested in testing industrial hemp for THC concentration to expedite the approval process. CDFA will not be issuing any approvals for testing laboratories until the proposed regulations take effect.

Until the proposed regulations are in effect, all industrial hemp testing requirements must comply with the current emergency regulations. A copy of the California's industrial hemp laws and regulations can be found on our industrial hemp webpage.

For additional information and to sign up to receive updates on the status of industrial hemp from CDFA, please visit us online at <a href="https://www.cdfa.ca.gov/plant/industrialhemp/">https://www.cdfa.ca.gov/plant/industrialhemp/</a>.

Attachments: California Industrial Hemp Proposed Testing Regulations
Industrial Hemp Application for Testing Laboratory Approval





# **Proposed Industrial Hemp Testing Regulations**

The following sections are proposed regulations pertaining to hemp testing method for THC concentration and laboratory approval process. These regulations are currently under review Office of Administrative Law (OAL) and will not become operative until approved by the OAL. This is provided for informational purposes only.

California Code of Regulations
Title 3. Food and Agriculture
Division 4. Plant Industry
Chapter 8. Industrial Hemp Cultivation
Article 2. Regulations for Industrial Hemp Cultivation

## 4942. Approved Testing Method for Testing Industrial Hemp for THC Concentration

- (a) Sample Preparation.
  - (1) The laboratory shall maintain chain of custody upon receiving the samples by documenting the chain of custody information on the sample analysis request form. The laboratory shall provide the information outlined in Sections 4940(b)(3)(M) through 4940(b)(3)(Q) on the sample analysis request form.
  - (2) The laboratory shall check the sample for any signs of tampering. The laboratory shall immediately notify the commissioner and not test the sample if there is evidence of tampering. New samples shall be collected and submitted to the laboratory for testing in accordance with the procedures outlined in Section 4941.
  - (3) Each composite sample shall be maintained and tested separately for THC concentration.
  - (4) All plant material included in the composite sample shall be processed and tested as a single sample.
  - (5) All plant material included in the composite sample shall be dried until the weight of the composite sample remains constant after drying intervals. Drying temperature shall not exceed 90 degrees Celsius.
  - (6) All of the dried plant material included in the composite sample shall be manicured through a wire screen no larger than 1.5 mm x 1.5 mm to remove all mature seeds and larger twigs and stems and milled to a homogenous powder-like consistency and combined before analysis.
- (b) Suitable analytical instrumentation used to determine THC concentration in industrial hemp includes the following:
  - (1) Gas chromatography with flame ionization detector,
  - (2) Gas chromatography coupled with mass spectrometry,
  - (3) Liquid chromatography coupled with mass spectrometry, or
  - (4) Liquid chromatography coupled with diode-array or variable wavelength detector.



#### Proposed Industrial Hemp Testing Regulations (3 CCR § 4942-4945)

- (c) "THC concentration" or "percentage concentration of THC" means the post-decarboxylated value of the percentage of delta-9 THC on a dry weight basis to the nearest thousandth, or three decimal places. The percentage concentration of THC may be measured by using either:
  - (1) a suitable analytical instrumentation described in Section 4942(b) that results in the decarboxylation of THC-acid to delta-9 THC, or
  - (2) a calculated value using a conversion formula of the percentage concentration of delta-9 THC plus eighty-seven and seven tenths (87.7) percent of the percentage concentration of THCacid when a suitable analytical instrumentation described in Section 4942(b) does not result in the decarboxylation of THC-acid to delta-9 THC.
- (d) "Acceptable hemp THC level" means a THC concentration that falls within the distribution or range that includes three-tenths of one percent or less that is produced when the measurement of uncertainty is applied to the reported THC concentration. For example, if the reported THC concentration of a sample is 0.35% and the measurement of uncertainty is ± 0.06%, the measured THC concentration would range from 0.29% to 0.41%. Because 0.3% is within the distribution or range, the sample is within the acceptable hemp THC level.
- (e) Sample Retention and Disposal
  - (1) If the laboratory test report indicates a percentage concentration of THC that is equal to or less than the acceptable hemp THC level, the laboratory shall retain the sample for a minimum of 30 calendar days from the testing date.
  - (2) If the laboratory test report indicates a percentage concentration of THC that is exceeds the acceptable hemp THC level, the laboratory shall retain the sample for a minimum of 60 calendar days from the testing date. The laboratory shall destroy the samples in a manner compliant with Section 297B of the federal Agricultural Marketing Act of 1946 (added by Section 10113 of the federal Agriculture Improvement Act of 2018 (Public Law 115-334), implementing regulations, and guidance

Note: Authority cited: Sections 407 and 81006, Food and Agricultural Code Reference: Section 81006, Food and Agricultural Code

## 4943. Approved Laboratory for Testing Industrial Hemp for THC Concentration

- (a) Testing of industrial hemp for THC concentration shall be conducted by a laboratory with International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) 17025 accreditation using a validated method in accordance with Sections 4942, 4944, and 4945 for THC analysis on plant material. from an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.
  - (1) Laboratories testing industrial hemp for THC concentration shall meet all laboratory registration requirements outlined in Part 990.3 in Title 7 of the Code of Federal Regulations and corresponding guidance.
- (b) A laboratory shall obtain written approval from the Department in order to test industrial hemp for THC concentration. A laboratory shall submit a signed laboratory approval application with the following information to the Department for review and approval:
  - (1) name and contact information of the applicant,
  - (2) name and physical address of the testing laboratory,
  - (3) a copy of the testing laboratory's DEA registration certificate, if applicable,
  - (4) a copy of the testing laboratory's ISO/IEC 17025 certificate of accreditation,

- (5) a copy of the testing laboratory's ISO/IEC 17025 scope of accreditation, and
- (6) a copy of the testing laboratory's standard operating procedures for THC testing.
- (c) If the Department determines that the requirements outlined in this section are met and the laboratory's standard operating procedures for THC testing comply with the requirements outlined in Sections 4942, 4944, and 4945, the Department shall approve the laboratory to conduct THC testing on industrial hemp by issuing a proof of approval, and adding the testing laboratory to the list of approved testing laboratories. When the laboratory is not approved, the Department will notify the laboratory in writing of any deficiencies in the application.
- (d) Laboratory approval shall be valid for one year from date of approval by the Department, after which the laboratory shall renew the approval.
- (e) Laboratories shall request renewal of Department approval in accordance with the procedures outlined in Section 4943(b). Renewed approval shall be valid for one year from date of renewal by the Department.
- (f) Any changes to the approved laboratory's standard operating procedures shall be submitted to the Department for review and approval prior to implementation. Once the Department has determined that the requirements outlined in this section are met and the laboratory's standard operating procedures comply with testing requirements outlined in Sections 4942, 4944, and 4945, the Department shall notify the laboratory that testing may be completed under the revised standard operating procedures.
- (g) The Department shall make a template of a laboratory application and the list of approved testing laboratories available on the Department's website.

Note: Authority cited: Sections 407 and 81006, Food and Agricultural Code Reference: Section 81006, Food and Agricultural Code

## 4944. Notification of Laboratory Test Report

- (a) Laboratories shall issue a separate laboratory test report for each composite sample.
- (b) The laboratory test report shall include the:
  - (1) registration number,
  - (2) unique sample identification number as assigned on the sample analysis request form,
  - (3) name and contact information of the registrant,
  - (4) name of the sampler,
  - (5) dates and times of the sample collection, testing, and test report,
  - (6) name of the cultivar tested,
  - (7) physical address, Global Positioning System coordinates, general description of the planting location, and total acreage or square footage of the planting sampled,
  - (8) name and contact information of the laboratory,
  - (9) name of approved analytical instrumentation used and the limit of detection (LOD),
  - (10) name of the person who received the sample,

- (11) name of the person who tested the sample
- (12) DEA registration number of the laboratory. if applicable,
- (13) identification of a retest, if applicable,
- (14) percentage concentration of THC in accordance with Section 4942,
- (15) measurement of uncertainty as a ± percentage value to the nearest thousandth, or three decimal places, at 95% confidence level,
- (16) the words "OFFICIAL CALIFORNIA REGULATORY SAMPLE",
- (17) and words "PASSED AS CALIFORNIA INDUSTRIAL HEMP" or "FAILED AS CALIFORNIA INDUSTRIAL HEMP" at or near the top of page.
  - (A) If the laboratory test report indicates a percentage concentration of THC that is within the acceptable hemp THC level, the words "PASSED AS CALIFORNIA INDUSTRIAL HEMP" shall appear.
  - (B) If the laboratory test report indicates a percentage concentration of THC that is greater than the acceptable hemp THC level, the words "FAILED AS CALIFORNIA INDUSTRIAL HEMP" shall appear.
- (c) Laboratories shall provide an electronic copy of the laboratory test report to the registrant and commissioner concurrently within five calendar days of the collection of samples.
- (d) Following the electronic notification of the laboratory test report, the laboratory shall:
  - (1) report the test results for all samples tested to USDA.
  - (2) provide the registrant no fewer than ten original paper copies with wet signatures of a passing laboratory test report, signed by an employee authorized to sign by the laboratory.
  - (3) provide the registrant one or more paper copies of a failed laboratory test report, signed by an employee authorized to sign by the laboratory.
- (e) Upon request from the commissioner, the laboratory shall provide a copy of the completed sample analysis request form.
- (f) The laboratory shall retain one or more original copies of each laboratory test report and the completed sample analysis request form for a minimum of three years from the date of sampling.

Note: Authority cited: Sections 407 and 81006, Food and Agricultural Code Reference: Section 81006, Food and Agricultural Code

#### 4945. Approved Testing Method for Retesting of Industrial Hemp for THC Concentration

(a) Additional samples for retesting shall be collected in accordance with the sampling procedures outlined in Section 4941 and tested in accordance with the testing procedures outlined in Sections 4942 through 4944.

Note: Authority cited: Sections 407 and 81006, Food and Agricultural Code Reference: Section 81006, Food and Agricultural Code

State of California DEPARTMENT OF FOOD & AGRICULTURE Pest Exclusion/Nursery, Seed, and Cotton Program Rev. 12/20

cdfa CALIFORNIA DEPART	MENT OF
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Rev. 12/20			□ New	Change Of:	
INDUSTRIAL HEMP	APPLICATION FOR		☐ Renewal	☐ Laboratory Information	
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Copy of ISO/IEC Copy of standard Copy of DEA reg  Ema  By signing this application The testing labor corresponding of the laboratory Code of Regula I understand the CDFA prior to the	Application  I, I hereby certify that: pratory meets all the registration guidance. shall test industrial hemp in accutions. at any changes to the standard esting under the new procedure	ation or testing THC olicable)  dustrialher of Testing or requirements out	np@cdfa.ca.go g Laboratory A tlined in Part 990.3 in sion 24 of the Food an	Fitle 7 of the Code of Federal Regulated Agricultural Code and Title 3 of the last hemp for THC concentration must be	California be approved by
Sign	ature		Print Name and	Title	Date
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Date Received:	Lab #:		Issue Date	Expiration Date	

#### INDUSTRIAL HEMP APPLICATION FOR TESTING LABORATORY APPROVAL INSTRUCTIONS

#### REQUIREMENTS

California Food and Agricultural Code Section 81006 and Section 4943 in Title 3 of the California Code of Regulations, as proposed, require testing laboratories obtain written approval from the Department in order to test industrial hemp for tetrahydrocannabinol (THC) concentration.

### **APPLICATION INSTRUCTIONS**

All information provided must be complete, legible, and accurate. Any incomplete sections or illegible information may delay the processing of the approval.

#### **Laboratory Information**

Applicant must complete all sections for the laboratory information.

- Laboratory Name is the laboratory that will test industrial hemp for THC concentration.
- Provide the **Physical Address** for the laboratory. The address cannot be a P.O. Box.
- Provide the **Phone Number** for the laboratory.

#### **Primary Contact Information**

Applicant must complete all sections for the primary contact information including full name, phone number, and email.

## **Required Attachments**

- Copy of the ISO/IEC 17025 certificate of accreditation provided by an accreditation agency
- Copy of the ISO/IEC 17025 scope of accreditation provided by an accreditation agency
- Copy of laboratory standard operating procedures for testing hemp for THC concentration
- Copy of laboratory certificate issued by the U.S. Department of Justice Drug Enforcement Administration (if applicable)

## **ALTERNATIVE FORMATS**

This application can be made available in alternative formats for visual or hearing-impaired individuals. Please contact the California Department of Food and Agriculture at 916) 654-0435 or <a href="mailto:industrialhemp@cdfa.ca.gov">industrialhemp@cdfa.ca.gov</a> to request the application in an alternative format. Please allow 7-10 working days for production of the alternative format. Requests for an alternative format may be sent to the address and telephone number below.

California Department of Food and Agriculture Industrial Hemp Program 1220 N Street Sacramento, CA 95814 (916) 654-0435