

DEPARTMENT OF FOOD AND AGRICULTURE
PROPOSED AMENDMENT OF THE REGULATIONS

Title 3, California Code of Regulations

Sections 4930, 4935, 4940, 4941, 4942, 4943, 4944, 4945, 4946, 4950, and 4950.1

INITIAL STATEMENT OF REASONS/

PLAIN ENGLISH POLICY STATEMENT OVERVIEW

Description of the Public Problem, Administrative Requirement, or Other Condition or Circumstance the Regulations are Intended to Address

These regulations are intended to address the obligation of the Secretary of Food and Agriculture to establish timeframes, procedures, methods, and confirmation of THC concentration for industrial hemp planting, sampling, laboratory testing, harvest, and destruction.

Specific Purpose and Factual Basis

The specific purpose of California Code of Regulation Sections (CCR) 4930, 4935, 4940, 4941, 4942, 4943, 4944, 4945, 4946, 4950, and 4950.1 is to establish timeframes, procedures, methods, and confirmation of THC concentration for industrial hemp planting, sampling, laboratory testing, harvest, and destruction, as required in Food and Agricultural Code (FAC) Sections 81003, 81004, and 81006.

The factual basis for the determination by the Department that the adoption of these regulations is necessary is as follows:

On June 10, 2019, emergency regulations that established timeframes, procedures, methods, and confirmation for industrial hemp sampling, laboratory testing, harvest, and destruction became effective. However, the federal government published the interim final rule for hemp production (7 Code of Federal Regulations 990) on October 31, 2019. CCR Sections 4940, 4941, 4942, 4943, 4944, 4945, and 4946 are in conflict with some of the federal requirements for hemp production.

The emergency regulations were readopted multiple times so they could be revised and brought into harmony with federal regulations. However, after receiving feedback from the public the Department has decided to make substantive changes to the regulations, and to do so by restarting the rulemaking process.

The purpose of this proposed regulations is to adopt the regulations Sections 4930, 4935, 4940, 4941, 4942, 4943, 4944, 4945, 4946, 4950, and 4950.1. The adoption is based on federal requirements, various recommendations from the Industrial Hemp Advisory Board (IHAB) and county agricultural commissioners, and comments received from the emergency rulemaking comment period.

Existing law, as amended by Senate Bill (SB) 1409, effective January 1, 2019, requires the Department to establish sampling procedures, including the number of samples to be taken and any compositing of samples, the portions of the plants to be sampled, plant parts to be included in a sample, and any additional procedures as necessary to ensure accuracy and the sanitation of the samples and fields (FAC Section 81006(e)(3)). Existing law also requires that the laboratory test report for tetrahydrocannabinol (THC) concentration be issued by a laboratory approved by the Department (FAC Section 81006(e)(5)).

Existing law requires the commissioner to determine that requirements for registration pursuant to FAC Division 24 are met, including requirements for the use of approved cultivars, planting, sampling, laboratory testing, harvesting, and destruction (FAC Section 81003 and 81004).

FAC Section 407 authorizes the Secretary to adopt “such regulations as are reasonably necessary to carry out the provisions of this code which she is directed or authorized to administer or enforce.” Additionally, FAC Section 401.5 requires the Department to “seek to enhance, protect, and perpetuate the ability of the private sector to produce food and fiber in a way that benefits the general welfare and economy of the state.”

Existing law also established an Industrial Hemp Advisory Board (IHAB) composed of 11 members that represent and further the interests of the industrial hemp industry (FAC Section 81001). The IHAB's purpose is to advise the Secretary and make recommendations on matters pertaining to Division 24, including the establishment of timeframes, procedures, methods, and confirmation for industrial hemp planting, sampling, laboratory testing, harvest, and destruction.

On April 25, 2019, CCR Section 4900 pertaining to registration and renewal fees for growers of industrial hemp for commercial purposes and seed breeders was approved and became effective immediately. CCR Section 4900 allowed for industrial hemp growers and seed breeders to register with the county agricultural commissioners and begin to grow industrial hemp.

As of March 4, 2020, there were 706 registered industrial hemp growers and seed breeders with a total of 41,906 acres registered for industrial hemp production. In order for this crop to be harvested, regulations specifying the protocols for industrial hemp sampling, laboratory testing, harvest, and destruction must be promulgated.

Background

Currently, according to the Congressional Research Service, most industrial hemp products processed and manufactured in the United States heavily rely on imported material. Imports of industrial hemp material into the United States have increased over the past decade. Therefore, in order to benefit the agricultural sector and the population of California in general, the Legislature crafted and approved statutes in FAC Division 24, allowing production of industrial hemp in California.

However, industrial hemp, as defined by law, is a crop of *Cannabis sativa* with a THC concentration of no more than three-tenths of one percent (FAC Section 81000(a)(6)). Thus, the Legislature included statutory provisions for obligatory testing to confirm that

the resulting crops would meet the definition of industrial hemp and not qualify as medical or adult-use cannabis under state law (FAC Section 81006(e)(1)).

The Agriculture Improvement Act of 2018 (2018 Farm Bill) authorizes the United States Department of Agriculture (USDA) to develop national regulations pertaining to industrial hemp cultivation and requires states that allow industrial hemp cultivation to submit a state regulatory plan to USDA for approval. USDA established the U.S. Domestic Hemp Production Program through an interim final rule on October 31, 2019. The interim final rule provides the requirements for State and Tribal regulatory plans submitted to USDA for review and approval.

The 2018 Farm Bill outlines several requirements that state regulatory plans must incorporate, including requirements for sampling, post-decarboxylation testing, crop destruction, and records retention. California law currently provides a framework for a state regulatory plan but does not currently reflect all of the requirements for a state regulatory plan outlined in the 2018 Farm Bill and the federal interim rules.

The Department developed the proposed sampling requirements, as authorized in FAC Section 81006(e)(3), by reviewing sampling and testing requirements outlined in the federal interim final rule, various state regulatory plans approved by USDA, and sampling and testing practices in other states, including Colorado, Indiana, Kentucky, Minnesota, and Oregon, with consideration of recommendations from the IHAB. The Department also consulted with county agricultural commissioners, USDA, and the CDFA Center for Analytical Chemistry to determine the necessary adoption of these regulations.

Project Description

These proposed regulations establish timeframes, procedures, methods, and confirmation of THC levels concentration for industrial hemp planting, sampling, laboratory testing, harvest, and destruction. The purpose of the proposed regulations is to promote a well-regulated industry, high-quality industrial hemp production, and allow hemp crops to be harvested.

CCR Section 4930 – Inspections of Industrial Hemp

This section allows for commissioners to conduct annual inspections of registrants to verify registration information and that records are being kept. This will satisfy federal requirements which require annual inspections of industrial hemp producers.

CCR Section 4935 - Planting Notification for Industrial Hemp

This section requires registrants to confirm that a planting, defined as placing seeds or cuttings in the ground for cultivation, of industrial hemp has taken place by submitting a signed planting report within 72 hours following the completion of a planting. This section is necessary because registration of a cultivation site alone does not confirm that a planting has taken place nor indicate that sampling will be required. This provision will provide the commissioner confirmation that a planting has taken place and advance notification of the sampling workload. This will allow the commissioner to plan and manage resources accordingly to complete the required sampling, as required by FAC Section 81006(e)(2).

The signed planting report shall document the planting activities and inform the commissioner of important details needed for compliance enforcement and workload management. Without this report, the commissioner would not know when crops are planted to enforce sampling requirements, making it more difficult for the commissioners to manage their workload. It will also assist with evaluating the performance of various cultivars and cultivation practices in certain areas. Registrants shall submit a signed planting report to the commissioner with the following information to help the commissioner with confirming and scheduling future sampling activities:

- registrant's registration number, as proof of registration,
- name and contact information of the registrant for purposes of scheduling a field inspection,
- planting date(s) so that the commissioner can determine their future workload,
- name of the cultivar(s) and the quantity planted so that the commissioner can confirm the use of registered cultivars,
- physical address, Global Positioning System (GPS) coordinates, general

description of the planting location, and total acreage or square footage of the planting so that the commissioner can confirm that the crop was planted at a registered cultivation site, and

- anticipated growing timeframe before harvest so that the commissioner can determine their future workload.

The Department shall make a template of a planting report available for the registrant's use on the Department's website.

The commissioner may confirm the planting of the crop by conducting field inspections to ensure compliance with FAC Sections 81003(b) and 81004(b).

The registrants must report their hemp crop acreage to the United States Department of Agriculture Farm Service Agency. They will need to report their registration number and physical address, Global Positioning System (GPS) coordinates, general description of the planting location, and total acreage or square footage of the planting.

CCR Section 4940 Sampling Timeframe and Pre-Harvest Notification for Industrial Hemp

This section establishes that sampling for THC concentration shall take place no later than 6 calendar days before the anticipated harvest start date and no more than 15 days before harvest completion (FAC Section 81006(e)(2)).

The THC sampling process begins when the registrant submits a signed pre-harvest report to their commissioner, this report must be submitted at least 20 calendar days prior to harvest. This will allow enough time for the commissioner before the sampling to schedule a staff member to oversee the sampling to ensure the accuracy and sanitation of samples and fields (FAC 81006(e)(3)(D)).

The pre-harvest report shall include:

- registrant's registration number, as proof of registration,

- name and contact information of the registrant,
- anticipated harvest start date,
- name(s) of the cultivar(s) to be harvested,
- physical address, Global Positioning System coordinates, general description of the location, and acreage of the planting to be harvested, and
- name and contact information of the laboratory to conduct the testing for THC concentration.

The sampler as defined in CCR Section 4941(a)(1) is responsible for scheduling the sampling date based on the anticipated harvest start date indicated on the pre-harvest report. If there are any changes to any information given in the preharvest report, the registrant must notify the commissioner no less than two calendar days before the sampling date to ensure the accuracy and sanitation of samples and fields (FAC Section 81006(e)(3)(D)). If the harvest date changes, additional testing for THC may be required to ensure compliance with FAC Section 81006(e)(2).

To ensure the accuracy of the samples, sampling activities must be well documented. It is critical that all samples maintain proper identification to ensure that the laboratory test reports are issued accurately. Thus, the pre-harvest report shall be accompanied by a sample analysis request form to adequately document the chain of custody of the sample and provide the laboratory with important details needed for issuing the laboratory test report. The sample analysis request form shall be used to record the following information for the commissioners and laboratory to document the sampling and testing activities:

- name and contact information of the sample analysis requester and commissioner for the purposes of issuing laboratory test reports as well as the signature of the sample analysis requester to confirm that the registrant was present during the sampling activities,
- registrant's registration number, as proof of registration,
- name and contact information of the commissioner so they can be contacted if needed,
- physical address, general description of the planting location, and total acreage or

square footage of the planting site sampled to identify the cultivation site associated with the sample and laboratory test report,

- lot identification number as provided by U.S. Department of Agriculture Farm Service Agency to comply with USDA's sampling guidelines,
- name of cultivar sampled associated with the sample and laboratory test report,
- description of the planting location sampled including estimated average height, appearance, approximate density, homogeneity, condition of the plants, and degree of maturity of flowering material to comply with USDA's sampling guidelines,
- unique sample identification number for the composite sample that will be associated with the sample and laboratory test report,
- number of the samples taken to confirm compliance with sampling procedures outlined in CCR Section 4941,
- date and time of the sample collection to confirm that sampling was done within the required timeframes,
- name and signature of the sampler for chain of custody,
- name and contact information of the approved laboratory conducting the THC testing for tracking purposes,
- name and signature of the person testing the sample for chain of custody,
- date and time of the sample testing to confirm that testing is done within the required timeframes,
- testing instrumentation used to analyze the sample for THC concentration to confirm to document compliance with CCR Section 4942(b),
- laboratory determination of THC concentration in accordance with CCR Section 4942(c) and limit of detection (LOD), and
- chain of custody information including the name and signature of the person who received and delivered the sample, and the date, time, and location of each possession or transfer of the sample once received at the testing laboratory for tracking purposes and to ensure the integrity of the sample collected and provide an accurate characterization of the plants in a crop, as per FAC Section 81006(e)(3)(D).

The Department shall have a template of a pre-harvest report and sample analysis request form available on the Department's website.

CCR Section 4941 Sampling Procedures for Testing Industrial Hemp for THC Concentration

This section establishes the sampling procedure per FAC Section 81006(e)(3). The sample shall be collected with the registrant present (FAC Section 81006(e)(3) and 7 Code of Federal Regulations (CFR) Section 990.3(a)(2)(iii)). The sampler shall have access to all industrial hemp plants within all registered areas and facilities used for cultivation to ensure compliance with FAC Section 81006(e)(2) and as required by 7 CFR Section 990.3(a)(2)(iv). Prior to the collection of the sample(s), the commissioner, USDA-approved sampling agents, or a federal, state, or tribal law enforcement agent authorized by USDA shall collect samples (7 CFR Section 990.3(a)(2)(i)). The sampler shall verify that the planting to be sampled corresponds to the registered location using the physical address, Global Positioning System coordinates, general description, and total acreage or square footage provided on the pre-harvest report and registration application, prior to the collection of the samples to ensure compliance with FAC Section 81006(e)(2).

To ensure the feasibility of the sampling procedure and to comply with FAC Section 81006(e) and federal requirements, the Department reviewed sampling and testing requirements outlined in the federal interim final rule, various state regulatory plans approved by USDA, and sampling and testing practices in other states, including Colorado, Indiana, Kentucky, Minnesota, and Oregon, to develop regulations as authorized in FAC Section 81006(e)(3). Each sample shall be collected from separate plants and consist of the terminal 8 inches of the top of the plant; unless the plant is less than 8 inches tall in which case the whole plant above ground shall be taken. This is to detect any plant to plant variation. The proposed portion of the plant to be sampled is

based on the federal sampling guidelines and ensure compliance with 7 CFR Section 990.3(a)(2)(i) .

As cultivars vary in average THC concentration and different growing conditions in different fields can lead to different outcomes, a composite sample shall consist of either six samples for planting that are less than or equal to six acres or one sample from each acres for planting greater than six but less than ten acres. For plantings larger than ten acres, the number of samples shall be calculated using the following formula where n is the number of plants to be selected and N is the planting acreage: $n = 299 / (1 + (298 / N))$. This formula is based on the federal sampling guidelines and ensure compliance with 7 CFR Section 990.3(a)(2)(ii). Since multiple cultivars may be planted in one cultivation site, a separate composite sample shall be taken for each cultivar within each registered cultivation site. Indoor and outdoor registered cultivation sites will be treated as separate cultivation sites since different growing conditions affect the chemical profile of the plants.

Each composite sample shall be placed within a permeable bag (e.g. a brown paper bag), kept in a manner not conducive to mold prevent spoilage, and sealed with labels to detect tampering and ensure a chain of custody. Each composite sample shall be stored in separate bags. Tracking the chain of custody is important to ensure the accurate characterization of plants in a particular field (FAC Section 81006(e)(3)(D)). To avoid confusion and ensure accuracy, the sample labels will have a unique sample ID number as assigned on the sample analysis request form and be signed by both the sampler and registrant. The samples will also be accompanied by the following information (per FAC Section 81006(e)(4) and in compliance with FAC Section 81006(e)(3)(D)):

- The registrant's proof of registration,
- The pre-harvest report,
- A sample analysis request form containing information outlined in CCR Sections 4940(b)(2)(B) through 4940(b)(2)(L) provided by the commissioner and CCR Section 4940(b)(2)(A) provided by the registrant.

To ensure freshness and accuracy, the samples shall be delivered to the testing laboratory within 24 hours of collection.

CCR Section 4942 Approved Testing Method for Testing Industrial Hemp for THC Concentration

CCR Section 4943 Approved Laboratory for Testing Industrial Hemp for THC Concentration

These sections establish the approved testing methods and laboratories for testing industrial hemp for THC concentration, as mandated per FAC Section 81006(e).

Upon receiving the samples, the testing laboratory will maintain the chain of custody for each sample by documenting the chain of custody information on the sample analysis request form. The laboratory shall provide the information outlined in CCR Sections 4940(b)(2)(M) through 4940(b)(2)(Q) on the sample analysis request form to ensure accurate record keeping of each composite sample tested (FAC Section 81006(e)(3)(D)). First, the laboratory shall check the sample for tampering. If any tampering is found, the sample will not be tested and the commissioner will be notified. Each composite sample will be maintained and tested separately for THC concentration to be able to identify the THC concentration for each cultivar within each cultivation site. Within each composite sample, all the plant material shall be dried at a temperature that does not exceed 90° F (to avoid excess volatilization of plant compounds) until the weight of the composite sample remains constant after drying intervals. All the dried material in the composite sample will then be milled to combine before analysis and 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 to ensure a standard consistency across samples. The proposed sampling preparation requirements are based on the recommendations of the IHAB and federal testing guidelines.

“THC concentration” or “percentage concentration of THC” means the post-decarboxylated value of the percentage of delta-9 tetrahydrocannabinol (THC) concentration on a dry weight basis to the nearest thousandth, or three decimal places (FAC Section 81006(e)(5)). The percentage concentration of THC may be measured by using one of the following suitable instrumentations:

- Gas chromatography with flame ionization detector,
- Gas chromatography coupled with mass spectrometry,
- Liquid chromatography coupled with mass spectrometry, or
- Liquid chromatography coupled with diode-array or variable wavelength detector.

The definition of “THC concentration” and suitable instrumentations for testing THC concentration mirror federal requirements for a state regulatory plan (7 CFR Section 990.3(a)(3)).

Although accurate, not all of the procedures authorized by the proposed regulation result in complete decarboxylation of THC-A into delta9-THC. Alternatively, 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 THC-acid can be used when a suitable analytical instrumentation described in CCR Section 4942(b) does not result in the decarboxylation of THC-acid to delta-9 THC.

Non-intoxicant THC-A is “decarboxylated” (transformed) into the main intoxicant variant of THC, delta9-THC when heat is applied. Therefore, testing of Cannabis plants grown as industrial hemp is meant to distinguish hemp (defined under federal and state law as Cannabis containing a maximum of 0.3% THC) from adult use Cannabis (defined under federal and state law as Cannabis having more than 0.3% THC). Federal law requires “that a procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration to ensure levels are not more than 0.3% on a dry matter basis in hemp produced in the state or territory of the Indian tribe.” Therefore, any testing protocol not completing decarboxylation must include a conversion factor for THC-A to delta9-THC to comply with federal law. Otherwise, the testing results would not reflect the potential psychoactive THC concentration in a hemp

crop. The conversion factor of 0.877 was provided by the CDFA chemistry laboratory as a credible conversion factor that should be used in “other similarly reliable” THC testing methods that do not result in decarboxylation.

“Acceptable hemp THC level” means a THC concentration that falls within the distribution or range that includes three-tenths of 1 percent or less that is produced when the measurement of uncertainty is applied to the reported THC concentration (7 CFR Section 990.1). For example, if the reported THC concentration of a sample is 0.35% and the measurement of uncertainty is $\pm 0.06\%$, 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.

The length of time that a laboratory is required to retain the sample after testing depends on the percentage concentration of THC found, as that will affect the likely need for retesting at some future date (FAC Section 81006(e)(3)(D)). If the laboratory test report indicates a percentage concentration of THC that is within an acceptable hemp THC level, the laboratory shall retain the sample for a minimum of 30 calendar days from the testing date, in the unlikely case in which retesting must be done for confirmation. If the percentage concentration of THC is greater than the acceptable hemp THC level, the laboratory shall retain the sample for a minimum of 60 calendar days from the testing date, as the sample violated the maximum THC concentration for industrial hemp and may be retested. Retesting would be more likely but may take longer for the requirement to be confirmed.

The laboratory conducting these tests must have International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) 17025 accreditation using a validated method for total THC analysis on plant material to ensure the accuracy in accordance with CCR Sections 4942, 4944, and 4945 and consistency of the results in compliance with FAC 81006(e)(5). The proposed requirement will help satisfy federal standards for THC testing (7 CFR Section 990.3(a)(3)(iii)). The laboratory must have a copy of its ISO/IEC 17025 certificate of

accreditation and make this available for the commissioner upon request to allow confirmation of THC concentration and enforcement of this provision.

Laboratories must also have U.S. Drug Enforcement Administration (DEA) registration to handle controlled substances under the Controlled Substances Act (21 CFR part 1301.13) in order to test industrial hemp.

Laboratories conducting THC concentration testing shall obtain written approval from the Department in order to test industrial hemp. To obtain approval, the laboratory shall submit a signed laboratory approval application with the following information to the Department for review and approval:

- name and contact information of the applicant so they may be contacted,
- name and physical address of the testing laboratory,
- a copy of the testing laboratory's DEA registration certificate as proof of DEA registration, if applicable,
- a copy of the testing laboratory's ISO/IEC 17025 certificate of accreditation, and
- a copy of the testing laboratory's standard operating procedures for THC testing to confirm it is in compliance with testing requirements.

If the requirements outlined in this section have been met and the laboratory's standard operating procedures for THC testing complies with the requirements outlined in CCR Sections 4942, 4944, and 4945, the Department can issue proof of approval to approve the laboratory to conduct THC testing and add it to a list of approved testing laboratories. If the laboratory is not approved, the Department will notify them in writing of the deficiencies. The approval is valid for one year from date of approval. After one year, the laboratory can submit for a renewal using the same processes outlined in CCR Section 4943(b). Any changes to standard operating procedures of an approved laboratory must be submitted to the Department before implementation so it can be reviewed and approved to ensure compliance with state and federal requirements. The Department shall notify the laboratory whether or not testing can be conducted under the revised standard operation procedures in writing for record keeping.

To dispose of samples the laboratory shall destroy samples in a manner that is federally compliant.

A template for laboratory application as well as a list of all approved laboratories will be available on the Department's website.

CCR Section 4944 Notification of Laboratory Test Report

This section establishes the notifications of laboratory testing reports. The testing laboratory will provide a separate test report for each composite sample. In order to ensure an accurate record and traceability (FAC Section 81006 (e)(3)(D)), the laboratory test report for each composite sample will include:

- registration number,
- unique sample identification number as it was assigned on the sample analysis request form,
- name and contact information of the registrant,
- name of the sampler,
- dates and times of the sample collection, testing, and test report,
- name of the cultivar tested,
- physical address, Global Positioning System coordinates, general description of the planting location, and total acreage or square footage of the planting sampled,
- name of approved analytical instrumentation used and the limit of detection (LOD),
- name and contact information of the laboratory
- name of the person who received the sample,
- name of the person who tested the sample,
- DEA registration number of the laboratory
- identification of a retest, if applicable
- percentage concentration of THC in accordance with CCR Section 4942,
- measurement of uncertainty as a \pm percentage value to the nearest thousandth, or three decimal places, at 95% confidence level,
- words "OFFICIAL CALIFORNIA REGULATORY SAMPLE", and

- words “PASSED AS CALIFORNIA INDUSTRIAL HEMP” for percentage concentrations of THC within the acceptable hemp THC level or “FAILED AS CALIFORNIA INDUSTRIAL HEMP” for percentage concentration of THC above the acceptable hemp THC level at or near the top of page depending on the percentage concentration of THC found.

The laboratory shall provide registrant and the commissioner an electronic copy of the laboratory test report concurrently within 5 calendar days from the sample collection date.

Following the electronic notification of the laboratory test report, the laboratory shall report the test results for all samples tested to the USDA. The laboratory will then provide the registrant ten original paper copies with wet signatures of a passing report for their records (FAC Section 81006(e)(6)). If the laboratory test does not pass, one original paper copy will be sent for record keeping. If the commissioner requests, the laboratory shall provide them with a copy of the completed sample analysis request form.

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 for their records.

CCR Section 4945 Approved Testing Method for Retesting of Industrial Hemp for THC Concentration

This section establishes that additional samples for retesting will follow procedures outlined in CCR Section 4941 (statutory language from FAC Section 81006(e)(7) is duplicated for clarity). In order to ensure uniformity, the sampling and testing procedures will be the same as outlined in CCR Sections 4942 through 4944.

CCR Section 4946 Final Disposition for Registered Industrial Hemp Crops

This section establishes that the registrant may harvest a crop for which an electronic passing laboratory test report has been received (FAC 81006(e)(1)). To ensure accurate record keeping and enforcement in compliance with FAC Section 81006(e)(3)(D), the

registrant shall submit a harvest report to the commissioner within 72 hours following completion of the harvest, which they may confirm by conducting field inspections. The harvest report shall include:

- registration number,
- name and contact information of the registrant,
- harvest timeframe including start and end dates,
- name of the cultivar(s),
- unique sample identification number(s) as assigned on the sample analysis request form with the percentage concentration of THC for each cultivar as reported on the laboratory test report,
- physical address, Global Positioning System coordinates, general description of the planting location, and total acreage or square footage of the planting, and
- description and quantity of the material harvested.

A template for harvest report will be available on the Department's website.

Harvest shall be completed within 15 calendar days from the sampling date.

As THC levels can change over time the sampling harvest must be completed within the timeframes given. However, if this is not possible, registrants may request additional sampling and testing to extend the harvest period in accordance with procedures outlined in CCR Section 4940.

The commissioner will use the most recent electronically received laboratory test that is in compliance to confirm the THC levels of the planting (FAC Section 81006(e)(3)(D)). If a new test report is received, any previous laboratory test reports becomes invalid. If the most recent laboratory test report indicates THC levels greater than the acceptable hemp level but does not exceed one percent one additional test can be requested by the registrant. The commissioner may confirm the crops harvest by conducting field inspections.

If a crop's laboratory test report exceeds the acceptable hemp THC level, the registrant shall destroy is within the timeframes to be in compliance.

- If a laboratory test report indicates a percentage concentration of THC that exceeds 1 percent, the destruction shall begin within 48 hours, and be completed within 7 calendar days, after the registrant's receipt of the electric copy of the laboratory test report (FAC Section 81006(e)(8)).
- If a second laboratory test report from retesting indicates a percentage concentration of THC that exceeds the acceptable hemp THC level but is less than one percent, the destruction shall take place as soon as practicable, but no later than 45 calendar days after the registrant's receipt an electronic copy of the second test report (FAC Section 81006(e)(8)).

If the registrant does not obtain a laboratory report, the registrant may not harvest the crop (FAC Section 81006(e)(1)).

CCR Section 4950 Destruction of Non-Compliant Industrial Hemp Crops

CCR Section 4950.1 Voluntary Destruction of Industrial Hemp Crops

These sections establish the procedures and conditions under which a crop of industrial hemp must be destroyed. To ensure compliance, the grower must provide a destruction plan to the commissioner for approval before proceeding with destruction, and the commissioner shall confirm the destruction of the crop by conducting inspections (FAC Section 81006(e)(3)(D)).

An industrial hemp crop which is non-complaint shall be destroyed as soon as practicable, no later than 45 calendar days after the grower receives notification of abatement from the commissioner. If the grower does not complete destruction of the crop within the commissioner's timeframe the county or city within which the crop is located may undertake destruction of the crop.

The city, county, or city and county has police power authority under Section 7 of Article XI of the California Constitution to enforce state or local law on a hemp crop that does not

comply with state or local law.

For purposes of accurate record-keeping and enforcement, growers shall submit a destruction plan to the commissioner at least 24 hours prior to the start of crop destruction, unless a shorter timeframe is requested by the commissioner, which must be approved by the commissioner prior to the start of destruction (FAC Section 81006(e)(3)(D)). The destruction plan shall include:

- registration number, if applicable,
- name and contact information of the grower,
- anticipated destruction date(s) of the crop to be destroyed,
- name of the cultivar(s) to be destroyed,
- unique sample identification number(s) as assigned on the sample analysis request form and percentage concentration of THC for each cultivar as reported on the laboratory test report, if applicable,
- physical address, Global Positioning System coordinates, general description of the planting location, and total acreage or square footage of the crop to be destroyed, and
- proposed destruction method 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

Within 72 hours after the crop is destroyed the grower will submit a destruction report to the commissioner which includes the following for accurate record keeping:

- registration number, if applicable,
- name and contact information of the grower,
- date(s) and time(s) of destruction,
- name of the cultivar(s) destroyed,
- unique sample identification number(s) and percentage concentration of THC for each cultivar as reported on the laboratory test report, if applicable,

- physical address, Global Positioning System coordinates, general description of the planting location, and total square footage or acreage of the destroyed planting, and
- description and quantity of the material destroyed.

In order to ensure uniformity and consistency in enforcement, a grower that wishes to voluntarily destroy an industrial hemp crop shall follow the same procedures, notification, and oversight requirements as for a mandatory destruction in compliance with CCR Sections 4950(b) through 4950(e).

A template for the destruction plan and destruction report is available on the Department's website.

The Department shall notify the USDA promptly by certified mail or electronically of any non-compliant plants or plant material and provide a disposal record for those plants and materials.

Economic Impact Analysis

Existing law provides the regulatory framework for industrial hemp sampling, laboratory testing, harvest, and destruction. The proposed regulation establishes timeframes, procedures, methods, and confirmation for industrial hemp planting, sampling, laboratory testing, harvest, and destruction. Without sampling procedures and approved laboratories registrants cannot meet statutory requirements to harvest their industrial hemp crop. Thus, the establishment of sampling procedures will likely result in the creation of new businesses and the expansion of businesses in California.

Anticipated Benefits from This Regulatory Action

Using the estimated of the benefits to accrue to the state of California due to these regulations, it is estimated that the implementation of these regulations will result in a total economic benefit between \$35,093,877 to \$310,878,294 the first year. This

includes potential gross revenue for growers, eliminating the need to destroy existing crops, and registration fees to be collected by CDFA. Additional benefits include the creation of 147 to 1,657 jobs, the ability for California to submit a state regulatory plan to USDA in accordance to the 2018 Farm Bill, and alleviating risk to growers of falling into non-compliance with federal law.

| Benefits | Estimated Impact |
|--------------------------|-----------------------------------|
| Registration Fees | \$1,019,702 |
| Gross Revenue | \$22,748,520 – 239,143,465 |
| Income Increase | \$6,243,319 – 65,632,791 |
| Crop Destruction Savings | \$5,082,336 |
| Total Benefits | \$35,093,877 – 310,878,294 |

Establishment of sampling and laboratory testing procedures will allow registered industrial hemp plantings to be harvested and allow the growth of the industrial hemp industry in California. Additionally, the planting and preharvest report will document planting activities and inform the commissioner of important details for compliance enforcement and planning, allowing the commissioners to judge their future workloads and plan accordingly.

According to Vote Hemp, the United States has seen significant growth in acreage of industrial hemp cultivation: 9,770 acres of industrial hemp were grown in 2016; 25,713 acres were grown in 2017; and 78,176 acres were grown in 2018.

Currently, most hemp products processed and manufactured in the United States heavily rely on imported material, according to the Congressional Research Service. Imports of industrial hemp material into the United States have increased over the past decade. Without this regulation, California citizens are unable to participate in this emerging industry. With this regulation, the state of California will be able to regulate a new industry, with high quality industrial hemp production.

Assessment

Based upon the Economic Impact Analysis, the Department has made an assessment that the proposed regulation would not eliminate jobs or existing businesses within California. Based on a comparison with states that have implemented hemp laboratory testing, the Department has made an assessment that the proposed regulation would likely lead to the creation of new jobs or businesses, and it would positively affect the expansion of businesses currently doing business within California.

As required by Government Code Section 11346.5(a)(3)(D), the Department has conducted an evaluation of this regulation and has determined that it is not inconsistent or incompatible with existing state regulations.

The Department of Food and Agriculture has determined that the adoption of CCR Sections 4930, 4935, 4940, 4941, 4942, 4943, 4944, 4945, 4946, 4950, and 4950.1 have no savings or increased costs to any state agency, no reimbursable costs or savings under Part 7 (commencing with Section 17500) of Division 4 of the Government Code to local agencies or school districts, no nondiscretionary costs or savings to local agencies or school districts, and no costs or savings in federal funding to the State will result from the proposed action.

The Department has determined that the proposed action will not have a significant adverse economic impact on housing costs or California businesses, including the ability of California businesses to compete with businesses in other states. The Department's determination that this action will not have a significant adverse economic impact on businesses was based on the following effects of the proposed regulation:

- Establishes timeframes, procedures, methods, and confirmation for industrial hemp planting, sampling, laboratory testing, harvest, and destruction for registrants. Without sampling procedures, registrants will not be able to obtain test results and harvest industrial hemp crops. This would limit the amount of domestic

hemp available to product producers and result in higher prices to California consumers if California is not contributing to the domestic hemp supply.

- Authorizes the commissioner to perform regulatory oversight and ensure that industrial hemp plantings meet statutory requirements.
- Helps protect the public and environment from non-compliant cultivation activities. This will improve the health and safety of Californians by creating environmentally safe compliant cultivation.
- Provides a framework for the growth of the industrial hemp industry in California. This will create jobs and lead to the expansion of California businesses.

Estimated Cost or Savings to Public Agencies or Affected Private Individuals or Entities

The proposed regulations will require commissioners to collect samples and oversee hemp planting, sampling, testing, harvest, and destruction activities in their county. Local costs for such activities can be recouped directly from the registered grower by the commissioner. FAC Section 81005(c) authorizes the county to establish a fee in a necessary amount to cover actual costs of the commissioner and county for implementing, administering, and enforcing the requirements for industrial hemp cultivation.

CDFA estimates the direct costs for registered growers for registration, sampling, testing, harvest and/or destruction to be between \$1,995,000 to \$3,595,594 for the first year.

| Cost for Registered Growers | Estimated Direct Costs | RMS II Multiplier | Projected Economic Impact |
|-----------------------------|------------------------|---------------------|---------------------------|
| Registration Fees | \$472,500 | 2.0168 ¹ | \$952,938 |
| Sampling | \$221,156 – 399,000 | 2.0168 ¹ | \$446,027 – 804,703 |

¹ RMS II, Other crop farming 111900, Output

² RMS II, 50-Professional, scientific, and technical services, Output

| | | | |
|---|--------------------------------|---------------------|-------------------------------|
| Testing | \$41,344 – 204,094 | 2.1787 ² | \$90,076– 444,660 |
| Harvest/Destruction | \$1,260,000 – 2,520,000 | 2.0168 ¹ | \$2,541,168 – 5,082,336 |
| Total Costs for Registered Growers | \$1,995,000 – 3,595,594 | | \$4,030,209– 7,284,637 |

Testing laboratories will be required to renew their ISO 17025 accreditation every two years, and DEA registration every year. Although it is unknown how many testing laboratories are interested offering testing services for industrial hemp, there are currently 34 cannabis testing laboratories licensed under the Bureau of Cannabis Control that are ISO/IEC accredited. Assuming that there will be approximately the same number of testing laboratories available for industrial hemp as there are for cannabis testing, CDFA estimates the direct cost for testing laboratories conducting THC analysis for industrial hemp to be between \$178,000 and \$238,000 each year.

| Cost for Testing Laboratories | Estimated Direct Costs | RMS II Multiplier | Projected Economic Impact |
|---|----------------------------|---------------------|---------------------------|
| ISO/IEC 17025 Accreditation | \$170,000 – 229,160 | 2.1787 ² | \$370,379– 499,271 |
| DEA Registration | \$8,296 | 2.1787 ² | \$18,075 |
| Total Costs for Testing Laboratories | \$178,296 – 237,456 | | \$388,454– 517,346 |

CDFA estimates the direct costs to commissioners for training staff to collect samples and confirm the planting, testing, harvest, and destruction of industrial hemp grown by registered growers to be approximately \$68,832 each year. CDFA anticipates filling one vacant Environmental Scientist position as a 24-month limited term to handle the additional workload. The incurred cost for the additional staff member, estimated to be approximately \$67,290 a year.

CDFA anticipates the number of registered growers to gradually increase in the next five years under the proposed regulations due to the profitability of CBD production and federal legalization of industrial hemp. However, there is no available data at this time to estimate the increase in registration activities. California had a total of 664 registered

growers in the first year of registration. Grower registration has since decreased as a result of more stringent statutory requirements for cultivation and the surplus of existing harvested industrial hemp material. Thus, the estimated direct and benefits costs are projected to remain the same for the next five years.

Assuming the total hemp sales revenue to range between \$10,773,630 – 113,257,620, the projected sales tax revenue estimates at 7.25 % from sales of hemp in California in the first year of implementation of the proposed regulations range from \$781,088 to \$8,211,177. This would result in an economic impact between \$1,575,300 to 16,560,300 using the RMS II, Other crop farming 111900, Output multiplier. In addition, CDFA anticipates collecting approximately \$472,500 in registration fees each year as a result of this regulation, assuming that registration activities will remain constant year to year.

Alternatives Considered

Below are two alternatives CDFA considered for the proposed regulations:

Alternative 1 – Allow Registered Growers to Collect Samples for THC Testing

CDFA considered allowing the registered grower to collect their own samples to minimize the sampling costs to registered growers. Growers would be responsible to collect samples in accordance with the proposed sampling requirement and deliver the samples to the testing laboratory for THC analysis.

The alternative would provide registered growers more flexibility than the proposed regulations because they would be able to use other resources like farmworkers and testing laboratories to collect samples. The USDA Economic Research Service estimated the hourly wage for all farm occupations in 2019 to be approximately \$14.91. CDFA estimates that it would take approximately four hours to collect the required 23 samples for a crop size of 24 acres. It would cost a registered grower approximately \$60 to hire farmworkers to collect samples.

Alternatively, some testing laboratories offer sampling services in addition as well. Due to the limited data available on the sampling fees, sampling costs to use a testing laboratory is estimated to be approximately \$210 based on an estimate CDFA obtained from a testing laboratory. The estimated costs include an estimated mileage cost of \$110, assuming the average trip would be approximately 200 miles to account for plantings in rural areas.

This alternative would result in a total annual cost for growers between \$1,805,344 and \$3,301,594. The total economic impact would range between \$3,641,018 and \$6,658,655.

| Cost for Registered Growers | Estimated Direct Costs | RMS II Multiplier | Projected Economic Impact |
|---|--------------------------------|--------------------------|----------------------------------|
| Registration Fees | \$472,500 | 2.0168 ² | \$952,938 |
| Sampling | \$31,500 – 110,250 | 2.0168 ¹ | \$63,530 – 222,352 |
| Testing | \$41,344 – 204,094 | 2.1787 ⁵ | \$90,076– 444,660 |
| Harvest/Destruction | \$1,260,000 – 2,520,000 | 2.0168 ¹ | \$2,541,168 – 5,082,336 |
| Total Costs for Registered Growers | \$1,805,344 – 3,306,844 | | \$3,647,712– 6,702.286 |

Compared to the sampling costs associated with the proposed regulations, the registered growers would potentially save between \$189,656 and \$294,000 per year in direct costs using alternative samplers instead of the county staff. The total benefits compared to the proposed regulation would remain unchanged.

Although this alternative would, if feasible, prove more cost effective for registered growers, it was abandoned because of concerns regarding regulatory action, specifically crop destruction, based on samples not taken by a regulatory official. This alternative would necessitate additional sampling and testing conducted by the commissioner to confirm THC results before abatement of the crop. Additional sampling and testing would cause delays in destruction enforcement that would

² RMS II, Other crop farming 111900, Output

⁵ RMS II, 50-Professional, scientific, and technical services, Output

increase the likeness for the illegal harvest of the crop. In additional, it later transpired that this alternative likely would conflict with amended federal requirements. USDA’s current sampling guidelines prohibit growers from collecting testing samples themselves.

Alternative 2 – Require Bureau of Cannabis Control License for Testing Laboratories

CDFA considered requiring the use of testing laboratories licensed by the Bureau of Cannabis Control (BCC). A Testing Laboratory license issued by BCC allows a laboratory in the state California to offer or perform testing of cannabis goods. Testing laboratories under the BCC license must obtain and maintain ISO/IEC 17025 accreditation. BCC-licensed laboratories were considered because the laboratories had already gone through a vetting process to conduct THC analysis on cannabis material.

The cost of a BCC testing laboratory license varied between \$3,000 to \$112,000, depending on the estimated annual gross revenue of the testing laboratory. Based on the number of testing laboratories currently licensed by the BCC and using the previously stated estimated cost for ISO/IEC accreditation, the total annual costs for testing laboratories under this alternative would range between \$280,296 to \$4,045,456. This alternative would result in an additional \$610.681– 8,813.836 in costs for the testing laboratories and the economy. The total benefits compared to the proposed regulation would remain unchanged.

| Cost for Testing Laboratories | Estimated Direct Costs | RMS II Multiplier | Projected Economic Impact |
|---|-------------------------------|--------------------------|----------------------------------|
| ISO/IEC 17025 Accreditation | \$170,000 – 229,160 | 2.1787 ² | \$370,379 – 499,271 |
| DEA Registration | \$8,296 | 2.1787 ² | \$18,075 |
| BCC License | \$102,000 – 3,808,000 | 2.1787 ² | \$222,227 – 8,296,490 |
| Total Costs for Testing Laboratories | \$280,296 – 4,045,456 | | \$610.681– 8,813,836 |

However, this alternative was abandoned because the alternative cause an unnecessary financial burden on the testing laboratories. Although BCC regulates

licensed laboratories for cannabis testing, the BCC would be unable to provide any regulatory oversight for industrial hemp testing activities.

CDFA determined that simply requiring ISO/IEC 17025 accreditation would provide both the confidence in the testing laboratories that are performing THC testing and quality assurance in the test results. The ISO/IEC 17025 standard is also an internationally recognized and widely accepted confirmation of testing competency. Generally, ISO-accreditation would ensure that testing methods used by testing laboratories meet the following federal standards:

- Laboratory quality assurance must ensure the validity and reliability of test results,
- Analytical method selection, validation, and verification must ensure that the testing method used is appropriate and that the laboratory can successfully perform the testing,
- Demonstration of the testing validity must ensure consistent, accurate analytical performance, and
- Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of detectability requirements.

Information Relied Upon

The Department is relying upon the following studies, reports, and documents in proposing the adoption of CCR Sections 4930, 4935, 4940, 4941, 4942, 4943, 4944, 4945, 4946, 4950, and 4950.1:

302 KAR 50:020. Policies and procedures for growers. February 12, 2018, Kentucky Department of Agriculture

“Economic Impact Analysis: Registration of Industrial Hemp Growers – Registration Fees”, dated October 9, 2018, CDFA Hemp Program

“Economic Impact Analysis: Sampling and Testing of Industrial Hemp for THC Content,” dated May 15, 2019, CDFA Hemp Program

“Economic Impact of the Proposed Regulations to Establish Timeframes, Procedures, Methods, and Confirmation for Industrial Hemp Planting, Sampling, Laboratory Testing, Harvest, and Destruction,” dated July 29, 2020, CDFA Hemp Program
Email from Michelle Phillips, dated May 14, 2019
Hemp as an Agricultural Commodity, Congressional Research Service, June 22, 2018.
Minutes, dated February 22, 2018, Industrial Hemp Advisory Board.
Minutes, dated April 24, 2018, Industrial Hemp Advisory Board.
Minutes, dated May 30, 2018, Industrial Hemp Advisory Board.
Minutes, dated September 26, 2018, Industrial Hemp Advisory Board.
Excerpt of Board Motion, dated October 30, 2018, Industrial Hemp Advisory Board.
Excerpt of Board Motion, dated December 12, 2018, Industrial Hemp Advisory Board.
Section 10113, Hemp Production, Agriculture Improvement Act Of 2018, 115th Congress, 2d Session
Vote Hemp, 2018, U.S. Hemp Crop Report