DEPARTMENT OF FOOD AND AGRICULTURE

PROPOSED AMENDMENT OF THE REGULATIONS

Title 3, California Code of Regulations

Sections 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 for industrial hemp planting, sampling, laboratory testing, harvest, and destruction.

Specific Purpose and Factual Basis

The specific purpose of Sections 4935, 4940, 4941, 4942, 4943, 4944, 4945, 4946, 4950, and 4950.1 is to establish timeframes, procedures, methods, and confirmation 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 amendment of this regulation 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. The purpose of this proposed adoption is to make the regulations permanent, amend Sections 4940, 4941, 4942, 4943, 4944, 4945, 4946, 4950, and 4950.1, and add Section 4935. The adoption, amendments, and additions are based on various recommendations from the IHAB, county agricultural commissioners, and the 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(d)(3)). Existing law also requires that the laboratory test report for tetrahydrocannabinol (THC) content be issued by a laboratory approved by the Department (FAC Section 81006(d)(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).

In addition, FAC Section 407 authorizes the Secratary to adopt "such regulations as are reasonably necessary to carry out the provisions of this code which he 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 sampling, laboratory testing, 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. 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 August 26, 2019, there were 292 registered industrial hemp growers and seed breeders with a total of 17,572 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, most industrial 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. 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 content of no more than three-tenths of one percent (FAC Section 81000(d); HSC Section 11018.5). 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).

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. States that do not have an approved state regulatory plan will be required to follow the national regulations.

The 2018 Farm Bill outlines several components that state regulatory plans must incorporate, including records retention, post-decarboxylation testing procedure, crop destruction, and sampling procedures. California law currently provides a framework for

a state regulatory plan but does not currently address all of the components for a state regulatory plan outlined in the 2018 Farm Bill.

The Department reviewed sampling practices in other states, including Colorado, Indiana, Kentucky, Minnesota, and Oregon, and developed the proposed sampling requirements, as per FAC Section 81006(d)(3), with consideration of recommendations from the IHAB. The Department also consulted with county agricultural commissioners and the CDFA Center for Analytical Chemistry to determine the necessary amendments to existing regulations.

Project Description

These proposed regulations establish timeframes, procedures, methods, and confirmation 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.

**Section 4935 - Planting Notification for Industrial Hemp**

This section requires registrants to confirm that a planting 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 confirmation that a planting has taken place and provide advance notification of sampling workload to the commissioner, which will allow the commissioner to plan and manage resources accordingly to complete the required sampling within 30 calendar days prior to the harvest date, as required by FAC Section 81006(d)(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 have a template of a planting report for the registrant's use available 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).

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

This section establishes the timeline and notification of anticipated harvest activities, and a procedure for requesting sampling prior to harvest. The purpose of this section is to provide adequate notification and timeframes for sampling in order to accurately measure the THC concentration of a planting at the time of harvest. The proposed amendments change the notification timeframe of anticipated harvest activities, specify pre-harvest

reporting requirements, clarify information is to be recorded on the sample request form, and establish a minimum timeframe for sample collection.

This section requires that sampling for THC concentration shall take place no more than 30 calendar days before harvest, as per FAC Section 81006(d)(2). Any changes to harvest date may require additional sampling to ensure an accurate measurement of THC concentration prior to harvest and compliance with FAC Section 81006(d)(2).

As growing times vary between cultivar and crop, it is not possible to predict when harvest will occur based on the planting date alone. The signed pre-harvest report confirms the registrant's intention to harvest a crop and identifies the planting in need of sampling. A separate pre-harvest report is required for each planting to be harvested in order to track each crop to be harvested separately to ensure compliance with FAC Section 81006.

The registrant initiates the sampling process for THC testing by submitting a signed pre-harvest report to the commissioner at least 45 calendar days prior to the anticipated harvest date. The timeframe for the submission of the pre-harvest report was amended from 30 days to 45 days to allow sufficient time for sample collection, laboratory analysis, and reporting. Because the laboratory is allotted up to 10 days to complete the THC analysis, the commissioner may have only 19 days to schedule and conduct sampling activities based on the current 30-day notification window. 45 calendar days will provide the commissioner or a third-party sampler designated by the commissioner adequate time to schedule and perform the sampling activities in accordance with FAC Section 81006(d)(3)(D) while still accommodating the laboratory's allotted timeframe for THC testing and reporting.

The signed pre-harvest report shall document the proposed harvest activities and inform the commissioner of important details for compliance enforcement and workload management. Without this report, the commissioner would not know when a crop requires sampling for THC testing, making regulatory enforcement difficult. Registrants

shall submit a signed pre-harvest report 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 and confirming sampling,
- anticipated harvest date to ensure that sampling and testing for THC concentration is completed prior to harvest,
- name of the cultivar(s) to be harvested so that the commissioner can confirm the use of registered cultivars and help identify the sample to be collected,
- physical address, GPS coordinates, general description of the planting location, and total acreage or square footage of the planting to be harvested so that the commissioner can confirm that the crop was planted at a registered cultivation site and help identify the sample to be collected, and
- name and contact information of the laboratory to conduct the testing for THC concentration so that the commissioner can confirm the use of an approved laboratory and to assist with sample delivery.

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:

- registrant's registration number, as proof of registration,
- name and contact information of the sample analysis requester and commissioner for the purposes of issuing laboratory test reports,
- signature of the sample analysis requester to confirm that the registrant was present during the sampling activities,
- 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,

- name of the cultivar sampled to identify the cultivar associated with the sample and laboratory test report,
- unique sample identification number for the composite sample for tracking purposes,
- number of the primary samples taken to confirm compliance with sampling procedures outlined in 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 Section 4942(b),
- laboratory determination of THC concentration in accordance with 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(d)(3)(D).

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

The commissioner, or third-party sampler designated by the commissioner, will then schedule a sampling date within 30 calendar days of the harvest date, as per FAC Section

81006(d)(2). The commissioner or the third-party sampler must schedule the sampling date no later than 11 calendar days prior to the anticipated harvest date to provide at least 10 days for sample delivery, laboratory testing and test report issuance. If there are any changes to any information provided in the pre-harvest report, the registrant must notify the commissioner no less than five calendar days before the sampling date to provide the commissioner with sufficient time to adjust plans and manage resources as needed.

**Section 4941 - Sampling Procedures for Testing Industrial Hemp for THC Concentration**

This section establishes sampling procedures, as per FAC Section 81006(d)(3). The purpose of this section is to ensure accuracy, consistency, and feasibility in sampling activities. The proposed amendments provide further clarification on sample volume and composition. The section has also been amended to remove existing language regarding maintaining chain of custody at the laboratory since it is addressed in subsequent sections.

Samples shall be collected by the commissioner or a third-party sampler designated by the commissioner. Allowing a third-party sampler designated by the commissioner to collect samples provides commissioners the flexibility to delegate the sampling activities to ensure that sampling is completed in a timely manner as required by the FAC Section 81006(d)(2). Collection of samples by the commissioner or a third-party sampler designated by the commissioner will provide the official sample to support any regulatory enforcement.

Prior to the collection of the sample(s), the sampler shall verify that the planting to be sampled corresponds to the registered cultivation site to ensure compliance with FAC Section 81006(d)(2) using the physical address, GPS coordinates, and general description provided on the pre-harvest report and registration application.

Samples shall be collected with the registrant present, and 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(d)(2).

Primary samples will include all parts of the plant present, including stems, stalks, flowers, leaves, seeds, and buds, to achieve an overall measurement of the THC concentration in the planting and comply with FAC Sections 81006(d)(1), 81006(d)(3(B), and 81006(d)(3)(C).

The primary sample shall consist of the terminal 18 inches of the top lateral branch and terminal 18 inches of one lateral branch from the lower one-third of the plant if two or more lateral branches are present on the industrial hemp plant. If any branch is less than 18 inches, the whole branch shall be taken. If two lateral branches are not present, then the primary sample shall consist of the terminal 18 inches from the terminal bud at the top of the plant. The whole plant above ground shall be taken if the plant itself is less than 18 inches tall. Sampling of disparate parts of the plant ensures the sample collected would provide an accurate representation of the average THC concentration of the planting as a whole. These standards are easily understood and capable of consistent application across different field conditions for samplers. Whole plant sampling was considered but was not a feasible option due to the large amount of plant material needed to be collected, transported, delivered, and prepared, tested, and retained.

Each composite sample will be made up of at least five primary samples from different plants to account for the THC variation from plant to plant. Because the THC concentration can vary for cultivars and different growing conditions and practices can produce crops with different averages of THC concentration, a separate composite sample will be taken for each cultivar within each registered cultivation site in order to comply with FAC Section 81006(d)(3)(D). Indoor and outdoor growing areas will be treated as separate cultivation sites due to different growing conditions, which may affect the chemical profile of the plants.

Section 4941 has been amended to remove language restricting sampling within 10 feet of field edges to allow the sampler to collect a representative sample of the crop. Restricting sampling of field edges by a specified distance could allow for clandestine plantings of medical or adult-use cannabis to occur.

The sample shall be placed within a permeable bag (e.g., a brown paper bag), kept in a manner not conducive to mold, and sealed with labels to detect tampering and ensure a chain of custody. In addition, the sample shall be labeled with a unique sample identification number as assigned on the sample analysis request form and signed by both the sampler and registrant to ensure the accuracy of the sample and avoid potential confusion. On the sample analysis request form, the registrant shall document the information outlined in Section 4940(b)(2)(A) and the commissioner shall document the information outlined in Sections 4940(b)(2)(B) through 4940(b)(2)(J). The sampler shall include the sample analysis request form and the following documentation with the sample, as per FAC Section 81006(d)(4) and in compliance with FAC Section 81006(d)(3)(D):

- registrant's proof of registration, as proof of registration,
- pre-harvest report to confirm the registrant's request for sampling,
- seed certification documentation for the certified cultivar used, and
- THC testing report for each certified cultivar used.

The samples shall be delivered to the testing laboratory within 24 hours of collection to ensure freshness and accuracy of the testing. Longer delivery timeframes would increase the likelihood for problems with the sample, including mold, pests, and lapses in the chain of custody, resulting in inaccurate testing.

**Section 4942 - Approved Testing Method for Testing Industrial Hemp for THC Concentration**

This section establishes approved testing methods for testing industrial hemp for THC concentration, as mandated per FAC Section 81006(d). The purpose of this section is to

ensure accuracy and consistency in testing activities. The proposed amendments specify chain of custody and other documentation for the sample analysis request form, expand instrumentation from the emergency regulation to allow various types of UV detectors, and remove the limit of quantitation (LOQ) requirement. The section has also been amended to include a revised definition of "THC concentration," which was previously defined in Section 4944.

Upon receiving the samples, the testing laboratory will maintain the chain of custody and accuracy by documenting the movement and testing of the sample on the sample analysis request form to ensure a sound testing process. This section has been amended to clarify that the chain of custody and testing process must be documented on the sample analysis request form for accuracy and uniformity.

Each composite sample will be maintained and tested separately for THC concentration in order to identify the cultivars and plantings that may be harvested. No plant parts collected as part of the composite sample will be removed during the sample preparation to ensure an accurate and representative reading of the THC concentration of the crop. Within each composite sample, all parts of the plant will be heat-dried at a temperature that does not exceed 90° F, to avoid burning the sample, until the weight of the sample remains constant after drying intervals. This provision is necessary to ensure the THC concentration is determined and reported on a dry weight basis, as required by FAC Section 81006(d)(5). Each dried sample will then be milled into a homogenous, powder-like consistency before analysis to ensure a standard consistency across all samples.

To ensure accuracy and consistency, based on the boards and the state laboratory recommendations the following analytical instrumentation must be used to determine THC concentration in industrial hemp:

- 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.

This amendment specifies diode-array or variable wavelength detectors as the types of ultraviolet detectors deemed suitable to be used with liquid chromatography for accuracy and uniformity.

A revised definition of “THC concentration” has been added to this section from Section 4944, where it was removed. “THC concentration” or “percentage concentration of THC” means the post-decarboxylated value of the percentage of delta-9 THC on a dry weight basis. The THC concentration may be measured by using a suitable analytical instrumentation that results in the decarboxylation of THC-acid (THC-A) to delta-9 THC, or 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 when a suitable analytical instrumentation described in Section 4942(b) does not result in the decarboxylation of THC-acid to delta-9 THC.

Although accurate, not all of the testing instrumentation authorized by the proposed regulations result in the decarboxylation of THC-A into delta-9 THC. Some analytical instrumentations heat the sample in the process of measuring the THC concentration, which “decarboxylates” (transforms) the cannabinoid THC-A into the restricted cannabinoid delta-9 THC. Therefore, a conversion formula shall be used for any analysis that was completed using an analytical instrumentation that does not include decarboxylation to ensure consistency between in the analyses.

Testing of *Cannabis* plants grown as industrial hemp is meant to distinguish hemp as defined under both federal and state law as *Cannabis* containing a maximum THC concentration of three-tenths of one percent from medical or adult-use cannabis defined as *Cannabis* having a THC concentration greater than three-tenths of one percent. Federal law requires state regulatory plans to include “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.” Therefore, the testing method of industrial hemp for THC concentration must measure

the post-decarboxylated value of the percentage of delta-9 THC in order to comply with federal law. The conversion factor of 87.7% is based on the molecular weight difference between THC-A and delta-9 THC and was confirmed by the CDFA Center for Analytical Chemistry as a reliable conversion factor that should be used as for “similarly reliable” THC testing methods that do not include decarboxylation.

The length of time that the laboratory must retain the sample after tests depends on the percentage concentration of THC found, as that will increase the potential need for the sample for investigative or regulatory enforcement purposes. If the THC is above three-tenths of one percent then the sample must be retained for further investigatory purposes. If the laboratory test report indicates a percentage concentration of THC that is equal to or less than three-tenths of one percent, the laboratory shall retain the sample for a minimum of 30 calendar days from the testing date. If the percentage concentration of THC is greater than three-tenths of one percent and does not exceed one percent, the laboratory shall retain the sample for a minimum of 60 calendar days from the testing date. If the THC concentration is greater the one percent, the laboratory shall retain the sample for a minimum of 90 calendar days from the testing date.

**Section 4943 - Approved Laboratory for Testing Industrial Hemp for THC Concentration**

This section establishes approved laboratories for testing industrial hemp for THC concentration, as mandated per FAC Section 81006(d). The proposed amendments require laboratories to obtain approval from the Department prior to testing THC concentration on industrial hemp.

Laboratories analyzing industrial hemp for THC concentration must have 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. This requirement is necessary to ensure the accuracy and consistency of the results in compliance with laboratory test results required in FAC Section 81006(d)(5). The ISO/IEC 17025 accreditation ensures that the

laboratory meets general requirements for the competence, impartiality, and consistent operation of testing laboratories. The laboratory must provide a copy of its ISO/IEC 17025 certificate of accreditation and standard operating procedures for THC testing on industrial hemp plant material to the commissioner upon request to allow confirmation and enforcement of the provision. This provision is necessary as it distinguishes laboratories that have been validated and requires the laboratories to provide that they are in compliance with code.

Beginning March 1, 2020, a laboratory shall obtain approval from the Department before testing industrial hemp for THC concentration by submitting a signed application with the following information to the Department. This necessary requirement is needed to confirm their eligibility to test industrial hemp for THC concentration:

- name and contact information of the applicant,
- name and physical address of the testing laboratory,
- a copy of the laboratory's ISO/IEC 17025 certificate of accreditation, and
- a copy of the laboratory's standard operating procedures for THC testing.

The March 2020 is necessary to give enough time to laboratories to create standard operating procedures and obtain ISO/IEC 17025 certificate of accreditation. For approval to conduct THC testing on industrial hemp, the requirements outlined in this section must be met and the laboratory's standard operating procedures for THC testing must comply with the requirements outlined in Sections 4942, 4944 and 4945. The Department provides approval to the laboratory to conduct THC testing on industrial hemp in writing by issuing a proof of approval and adding the laboratory to the list of approved testing laboratories for their record keeping. The Department will also notify the laboratory in writing of any deficiencies when the laboratory is not approved. This requirement provides the Department a necessary structure to approve or not approve laboratories and the laboratories can make changes to become approved.

Laboratory approval shall be valid for one year from date of approval by the Department, after which the laboratory shall renew the approval by submitting the laboratory application. Renewed approval shall be valid for one year from date of renewal by the

Department. Approval shall be renewed each year to confirm standard practices and accreditation are current. This will allow the Department an annual opportunity to confirm that the laboratories are continuing accreditation and have the compliant testing procedures.

Any changes to the approved laboratory's standard operating procedures shall be submitted to the Department for review and approval prior to implementation to confirm they are within the compliant standards. 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.

The Department shall make a template of a laboratory application and the list of approved testing laboratories available online on the Department's website. This provision is necessary to provide a state procedure for reviewing and approving applications.

**Section 4944 - Notification of Laboratory Test Report**

This section establishes the notification requirements of laboratory testing reports. The proposed amendments define a passing and failing laboratory test, change the required information on a laboratory test report, allow commissioners to request copies of the sample analysis request form, and increase the record retention requirement to three years.

Laboratories will issue a separate laboratory test report for each composite sample. This in necessary to communicate to the growers or commissioners the THC levels of each tested cultivation site so the correct crops can be harvested or destroyed. The laboratory test report for each composite sample will include the following information in order to ensure an accurate record and traceability in compliance with FAC Section 81006(d)(3)(D):

- registration number,

- unique sample identification number, as 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 and testing,
- name of the cultivar tested,
- physical address, GPS 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 of the person who received the sample,
- name of the person who tested the sample,
- percentage concentration of THC in accordance with Section 4942, and at or near the top of the page, as per FAC Section 81006(d)(5):
    - the words “PASSED AS CALIFORNIA INDUSTRIAL HEMP” if the laboratory test report indicates a percentage concentration of THC that is equal to or less than three-tenths of one percent, or
    - “FAILED AS CALIFORNIA INDUSTRIAL HEMP” shall appear if the laboratory test report indicates a percentage concentration of THC that is greater than three-tenths of one percent.

“Limit of detection” (LOD) means the lowest concentration of an analyte that can be distinguished from the absence of that analyte within a stated confidence limit. LOD is the minimum concentration of an analyte that gives a measurable response. It is necessary to require the laboratory test report to contain the LOD to verify that the laboratory is competent to perform and can confidently report an accurate value for the detection of THC concentration within the target specifications (greater than or less than three-tenths of one percent on a dry-weight basis). Reporting the LOD is a necessary component of a laboratory’s method validation as well as quality control procedures when conducting sample analysis.

The testing laboratory must provide an electronic copy of the laboratory test report to the registrant and commissioner concurrently within ten calendar days of the sample collection to ensure notification of the THC analysis is received in a timely manner prior to the anticipated harvest date. Following the electronic notification of the laboratory test report, the laboratory shall provide the registrant at least ten original paper copies with wet signatures of any passing laboratory test reports and at least one paper copy of any failed laboratory test reports, as per FAC Section 81006(d)(6). This is necessary so they can provide copies to buyers, transporters, and anyone otherwise obtaining industrial hemp from the registrant. Upon request of the commissioner, the laboratory will provide a copy of the completed sample analysis request form for their records. The laboratory shall retain one or more original copies of each laboratory test report for a minimum of three years from its date of sampling in order to comply with the 2018 Farm Bill requirements.

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

This section specifies the method for retesting. It requires that, if the first laboratory test report indicates the sample failed but does not exceed one percent, the registrant shall submit additional samples for retesting, as per FAC Section 81006(d)(7). In order to ensure uniformity, retesting will follow the same sampling and testing procedures as outlined in Sections 4942 through 4944. This ensures that cultivation sites that fail the THC test by a small margin are retested in the event of testing errors.

**Section 4946 Final Disposition for Registered Industrial Hemp Crops**

This section specifies the timeframes for harvest and destruction and requires documentation of any harvest activities to ensure compliance with FAC Sections 81006(d)(1), 81006(d)(2), and 81006(d)(8). The proposed amendments provide clarity on the harvest window, provide clarify on the required information on the harvest report, and address the handling of multiple test reports for the same planting.

Registrants may harvest a sampled crop upon receipt of an electronic copy of a passing

test report as it is then meets the definition for industrial hemp. To ensure accurate record keeping and enforcement in compliance with FAC Section 81006(d)(3)(D), the registrant shall submit a signed harvest report to the commissioner within 72 hours following completion of the harvest, which the commissioner may confirm by conducting field inspections. To comply with FAC Section 81006(d)(3)(D), the harvest report shall include the:

- registration number, as proof of registration,
- name and contact information of the registrant to schedule a field inspection,
- harvest date(s) to insure notification of harvest was done in a timely manner,
- name(s) of the cultivar(s), to confirm that registered cultivars were harvested,
- unique sample identification number(s) and percentage concentration of THC for each cultivar as reported on the laboratory test report to confirm laboratory test reports,
- The physical address, GPS coordinates, general description of the harvested planting location, and total acreage or square footage of the harvested planting to confirm registration of the cultivation site, and
- description and quantity of the material harvested for the commissioner's records.

The Department shall have a template of a harvest report for the registrant's use available on the Department's website. This provision in necessary to provide a procedure for reviewing and approving applications.

Harvest must be completed within 30 days from sampling, as per FAC Section 810069(d)(2), as further development of the plants can result in changing THC levels. Registrants may request additional sampling and testing to extend the harvest timeframe in the event that they are not able to harvest within 30 days. If additional sampling and testing occur, the most recent laboratory test report received electronically by the commissioner will be considered the effective THC concentration of the planting and used for determining compliance with FAC Division 24. All previous laboratory test reports for the same planting shall be invalid upon the commissioner's electronic receipt of the most recent laboratory test report.

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

This section also specifies that a registrant must destroy a crop that received a failed laboratory test report for THC concentration, as per FAC Section 81006(d)(8) unless the failed test is under but does not exceed one percent, in which case retesting is allowed. If a laboratory test report indicates a percentage concentration of THC that exceeds one percent, the destruction shall begin within 48 hours and be completed within 7 calendar days after the registrant's receipt of an electronic copy of the laboratory test report, as per FAC Section 81006(d)(8) since the product grown is non-compliant industrial hemp crop. If a second laboratory test report from retesting indicates a percentage concentration of THC that exceeds three-tenths of one percent 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 of the second laboratory test report, as per FAC Section 81006(d)(8) since the product grown is non-compliant industrial hemp crop.

**Section 4950 - Destruction of Non-Compliant Industrial Hemp Crops**

This section establishes the procedures and conditions under which a non-compliant crop of industrial hemp must be destroyed. The proposed amendments allow the commissioner to specify a shorter timeframe for submission of a destruction plan, provide clarify on the required information on the harvest report and requires a destruction report from the registrant following destruction activities.

Unless otherwise specified in the proposed Section 4946(b), any non-compliant industrial hemp crop shall be destroyed as soon as practical but must be completed no later than 45 calendar days after the grower's receipt of notification of abatement from the commissioner. The 45 calendar days is necessary as it allows time for the growers destruction report to be created and submitted to the commissioner.

For purposes of accurate record-keeping as required in the Section 10113 of the 2018

Farm Bill and enforcement in compliance with FAC Section 81006(d)(3)(D), growers shall submit a signed destruction plan to the commissioner at least 24 hours prior to the start of crop destruction for approval, unless a short timeframe is specified by the commissioner. A shorter notification timeframe will potentially allow registrants to begin destruction sooner, providing them more time to complete destruction within the timeframes required in FAC Section 81006(d)(8). The destruction plan shall include the:

- registration number, if applicable, as proof of registration,
- name and contact information of the registrant to schedule a field inspection,
- anticipated destruction date(s) so that the commissioner can determine their workload,
- name(s) 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 seed cultivar as reported on the laboratory test report, if applicable, for the commissioner's records,
- physical address, GPS coordinates, general description of the planting location to be destroyed, and total acreage or square footage of the planting to be destroyed to identify the cultivation site, and
- proposed destruction method for the commissioner's review and approval.

The commissioner shall review and approve the proposed destruction plan in writing for accurate recordkeeping.

For purposes of accurate record-keeping as required in Section 11013 of the 2018 Farm Bill and enforcement in compliance with FAC Section 81006(d)(3)(D), growers shall submit a signed destruction report to the commissioner within 72 hours following the completion of the destruction to confirm destruction for accurate recordkeeping. The destruction report shall include the:

- registration number, if applicable, as proof of registration,
- name and contact information of the grower to schedule a field inspection,
- date(s) and time(s) of destruction, in order to schedule a field inspection,
- name(s) of the cultivar(s) destroyed,

- unique sample identification number(s), as assigned on the sample analysis request form and percentage concentration of THC for each seed cultivar as reported on the laboratory test report, if applicable, for the commissioner's records,
- physical address, GPS coordinates, general description of the planting location, and total acreage or square footage of the destroyed planting to identify the cultivation site, and
- Description and quantity of the material destroyed for the commissioner's records.

The commissioner shall confirm the destruction of the crop by conducting field inspections to ensure compliance with FAC Section 81006(d)(8).

**Section 4950.1 Voluntary Destruction of Industrial Hemp Crops**

This section establishes the procedures and conditions under which a crop of industrial hemp can be voluntarily destroyed. The proposed amendments remove the description of destruction plan and instead reference Sections 4950(b) through 4950(e).

Growers may choose to voluntarily destroy their crop for a variety of reasons including damage from weather, pests, or market forces that affect the potential profitably of the harvest. 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 outlined in proposed Sections 4950(b) through 4950(e). This section is necessary as it provides recourses that allows growers to take action outside of a failed THC test to destroy their crops.

<u>Economic Impact Analysis</u>

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 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.

The proposed rulemaking would require the samples to be tested by a laboratory with ISO/IEC 17025 accreditation. Based on quotes from three different accredited laboratories in California, estimated testing costs for THC concentration are approximately $63 per sample. The proposed rulemaking would require commissioners to conduct the sampling activities and confirm harvest and destruction activities. Estimated sampling costs would vary because counties generally determine costs based on a standard hourly rate and charge accordingly. The statewide average hourly rate from all counties that participated in an earlier survey to determine industrial hemp application fees was $84.36.

These costs will more than likely be offset by the revenue collected by the registrant over one year. It is anticipated that this regulation will allow the growth of the industrial hemp industry in California, with an increase in the number of businesses dedicated to producing hemp and the concomitant increase in jobs. There are no anticipated eliminations of jobs and businesses within California.

Anticipated Benefits from This Regulatory Action

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 planned 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 Sections 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 sampling, laboratory testing, harvest, and destruction for registered growers and seed breeders. 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 regulation will require the payment for sampling and testing for THC concentration by registrants. The cost for sampling and testing activities for THC analysis should be exceeded by revenue collected by the grower or seed breeder over the registration period of one year. The agency is not aware of any additional cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Alternatives Considered

The Department of Food and Agriculture must determine that no alternative considered would be more effective in carrying out the purpose for which the action is proposed or

would be as effective as and less burdensome to affected private persons than the proposed action.

The Department considered taking no action. If no action is taken the current emergency action would expire and the testing of industrial hemp would not be available; this would continue to encourage illegal cultivation of this in-demand crop or result in hemp being imported from other markets. Without testing procedures and methods, the Department will not have the framework and rules necessary to conduct regulatory enforcement efforts regarding cultivation of Industrial hemp. The alternative was rejected because it would prevent the implementation of the Program and creation of a new industry in California.

Information Relied Upon

The Department is relying upon the following studies, reports, and documents in proposing the adoption of Sections 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

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