Department of Cannabis Control
California Code of Regulations Title 4, Division 19

Notice of Proposed Rulemaking

Notice Date: June 17, 2022

Subject Matter of Proposed Regulations: Standard cannabinoids test method and standardized operating procedures for all licensed commercial cannabis testing laboratories.

Sections Affected: Title 4, California Code of Regulations (CCR), sections 15712.1 and 15712.2.

Notice is hereby given that the Department of Cannabis Control (Department) proposes to adopt the proposed amended regulations, described below, after considering all comments, objections, and recommendations regarding the proposed action. The Department, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below, or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for inspection and copying 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

All the proposed text sections are proposed to be added to the California Code of Regulations (CCR), under Division 19 of Title 4.

Public Hearing

The Department will hold a virtual public hearing at the following date and time listed below:

Tuesday, August 1, 2022 – 9:00 AM to 12:00 PM

Attendees may participate via WebEx online meeting platform or telephone conferencing. To participate via WebEx online meeting platform please email Charisse Diaz at Charisse.Diaz@cannabis.ca.gov or (916) 465-9025 by 4:30 p.m. July 29, 2022 to request a link to the meeting. A link to the meeting will also be posted on the Department's website no later than 9:00 a.m. the day of the hearing.

As a reasonable accommodation, limited in-person seating may be available at the hearing in the Department Hearing Room, 2920 Kilgore Road, Rancho Cordova, CA 95670. Attendees must comply with all COVID-19 safety protocols. Please contact

Charisse Diaz at Charisse.Diaz@cannabis.ca.gov or (916) 465-9025 by 4:30 p.m. on July 29, 2022**,** if an accommodation is necessary.

Participants will be given instructions on how to provide oral comment once they have accessed the hearing. The hearings will proceed on the dates noted above until all testimony is submitted or **12:00 PM**, whichever is later. At the hearing, any person may present oral or written statements or arguments relevant to the proposed action described in the Informative Digest. The Department requests, but does not require, that persons who make oral comments at the hearing also submit a written copy of their testimony via email.

Written Comment Period

Any interested person, or the interested person's authorized representative, may submit written comments relevant to the proposed regulatory action to the Department. Written comments, including those sent by mail or e-mail, can be submitted to the addresses listed below. **Comments submitted must be received by the Department at its office by 5:00 p.m. on August 2, 2022.**

Submit comments to:

Department of Cannabis Control
Legal Affairs Division
2920 Kilgore Road
Rancho Cordova, CA 95670
E-mail: publiccomment@cannabis.ca.gov

Authority and Reference

Business and Professions Code section 26013 authorizes the Department to adopt these proposed regulations. Pursuant to Business and Professions Code section 26100, the Department shall establish a standard cannabinoids test method, including standard operating procedures, that shall be utilized by all testing laboratories, on or before January 1, 2023. The proposed regulations implement, interpret, and make specific the requirements for the standard cannabinoids test method to be used by all licensed laboratories pursuant to Business and Professions Code section 26100.

Informative Digest / Policy Statement Overview

The purpose of these regulations is to implement, interpret, and make specific requirements for a standard cannabinoids test method, including standard operating procedures, that shall be utilized by all licensed testing laboratories.

Existing Law

Pursuant to the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), the Department regulates commercial cannabis license holders in California including testing laboratories. MAUCRSA prohibits cannabis and cannabis products from being sold unless a representative sample of specified batches has been tested by a licensed testing laboratory. MAUCRSA requires the testing laboratory to issue a certificate of analysis to report specified information, including the content of specified compounds and contaminants. Requirements for testing laboratories are contained in Chapter 6, Division 19, of Title 4 of the CCR. Business and Professions Code section 26100, subsection (f)(2) requires the Department to establish a standard cannabinoids test method, including standard operating procedures, on or before January 1, 2023. All licensed laboratories will be required to use the method established by the Department.

Policy Statement

The purpose of these regulations is to implement and make specific Business and Professions Code section 26100(f)(2) pertaining to the establishment of a standard cannabinoids test method, including standardized operating procedures, that shall be utilized by all testing laboratories.

The rulemaking action would specify the standardized cannabinoids test method to be used by all licensed laboratories. The proposed regulations would specify that testing laboratories must use the standard operating procedure for the determination of cannabinoids concentration by high performance liquid chromatography (HPLC). The proposed regulations would specify the equipment to be used and the procedures to follow for the determination of cannabinoid concentration. The proposed regulations would clarify the requirements for method validation and method verification by the licensed laboratories. The proposed regulations would specify the method verification procedures and documentation requirements and the submission of documentation to the department. The proposed regulations would also inform licensed laboratories of the timeline for laboratories to commence utilizing the cannabinoid test method.

Regulation Objectives and Anticipated Benefit of the Proposed Regulations

The objective of proposed regulations is to implement and make specific Business and Professions Code section 26100(f)(2) pertaining to the establishment of a standard cannabinoids test method on or before January 1, 2023. Through the proposed regulations, the Department aims to ensure all licensed laboratories are using the same standardized cannabinoid test method which will ensure consumers receive accurate and consistent information regarding the cannabinoid content of the cannabis and cannabis product they use or consume.

An inherent challenge in regulating an industry that has not been federally regulated is the lack of standardized, generally accepted and validated methods for the testing of cannabis and cannabis products. If a standard test method is not available for an

analysis, new methods must be developed and validated. Accordingly, section 15712 of the Department's existing regulations require licensed laboratories to develop, validate and implement test methods for the required analyses and, to the extent practicable, requires the test methods developed to comport with established guidelines such as those from the U.S. Food and Drug Administration, the Association of Analytical Communities (AOAC) International, and United States Pharmacopeia. Due to the lack of generally accepted standardized methods, each licensed laboratory has developed and implemented its own test method for cannabinoid content analysis. The use of different methods by individual licensed laboratories can produce inconsistent analytical results between the laboratories, thus resulting in inconsistent reporting of cannabinoid content of cannabis and cannabis products among licensed laboratories.

The proposed regulations implement the requirement that the Department develop a standardized test method for cannabinoids for use by all licensed laboratories. The proposed regulations establish and make specific the standardized cannabinoids test method that all licensed laboratories must use. The proposed regulations inform the licensed laboratories of the standard operating procedures that they must follow and the instructions for the determination of cannabinoid concentrations using high performance liquid chromatography systems (HPLC). The proposed regulations also inform licensed laboratories of the timeline to commence utilizing the cannabinoid test method.

The proposed regulations are expected to benefit the health and welfare of California residents. The specific benefits anticipated are increased protection of the public from the harms associated with inconsistent laboratory testing methods for cannabinoids that can result in inconsistent reporting of the cannabinoid content of cannabis and cannabis products by licensed laboratories. The proposed regulations aim to provide uniformity and transparency for cannabinoid testing by establishing standard operating procedures and instructions for licensed laboratories to determine cannabinoids concentration. More specifically, the standard operating procedures provide instruction on sample preparation, sample extraction, proper dilution, necessary apparatus and materials, reagents, calibration standards, instrumental parameters, instrument analysis, method limit of quantification and reporting limit, quality control, acceptance criteria, and method verification. These factors can affect testing results, thus standardization of all these factors within a standard operating procedure will result in more accurate and consistent reporting of cannabinoid content by licensed laboratories.

The proposed regulations will also increase the Department's ability to effectively regulate licensed laboratories. A well organized, clearly written set of procedures will allow the Department to better educate licensees regarding the testing method as well as provide consistency in enforcement. Effective education and enforcement regarding the requirements found in the regulations are essential to the Department's goal of ensuring that California's licensed laboratories operate in a manner that benefits the state of California while reducing or eliminating the risks of harm to the people of the

state. The increased clarity and efficiency obtained by the proposed regulation will further increase the Department's ability to carry out this mission.

Section 15712.1. Test Method for Cannabinoids.

This proposed section would specify the cannabinoids test method that must be used by licensed laboratories. The section would specify that testing laboratories must use the standard operating procedure developed by the Department and incorporated by reference for the determination of cannabinoids concentration by HPLC. The section would specify the equipment to be used and the procedures to follow for the determination of cannabinoid concentration. The proposed section would clarify that a licensed laboratory does not need to perform method validation but must perform method verification. The proposed section would clarify the requirement for submission of the standard operating procedures to the Department. The proposed section would also inform testing laboratories that they must commence using the specified test method no later than July 1, 2023.

Section 15712.2. Verification of Test Methods for Cannabinoids.

This proposed section would specify the procedures and documentation requirements for method verification by the licensed laboratories. The proposed section would require the licensed laboratories to perform method verification prior to use of the method for regulatory compliance testing and submit the verification documentation to the department.

Incorporated by Reference

Determination of Cannabinoids Concentration by HPLC, Standard Operating Procedures (New 05/15/2022)

Evaluation of Inconsistency/Incompatibility with Existing State Regulations:

As required by Gov. Code section 11346.5(a)(3)(D), the Department has conducted an evaluation of these proposed regulations and has determined that they are not inconsistent or incompatible with existing regulations.

Evaluation of Inconsistency with Federal Regulation Statute

The United States Drug Enforcement Administration (DEA) under the Controlled Substances Act lists cannabis as a Schedule 1 Drug. This means that commercial cannabis activity is illegal under federal law. However, California, through the MAUCRSA and other laws, has decriminalized the cultivation, sale, and possession of cannabis and cannabis products for persons aged 21 or older and for medicinal patients.

Plain English Requirement

Department staff prepared these proposed regulations pursuant to the standard of clarity provided in Government Code section 11349 and the plain English requirements of Government Code sections 11342.580 and 11346.2, subsection (a)(1). The proposed regulations are written to be easily understood by the persons that will use them.

Disclosures Regarding the Proposed Action

The Department has made the following initial determinations:

Local mandate: There will be no local mandate.

Cost to any local agency or school district requiring reimbursement pursuant to Gov. Code section 17500, et seq: None.

Any other non-discretionary cost or savings imposed upon local agencies: None.

Cost or savings to any state agency: None.

Cost or savings in federal funding to the state: None.

Effect upon housing: There is no effect on housing.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses: The Department has determined there will not be a significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

Small Business Determination: The proposed regulations would affect approximately 48 licensed laboratories. The businesses impacted by the regulation all meet the criteria for being classified as small businesses. The cost associated with the proposed regulations for a small business is anticipated to be minimal for most licensed laboratories as most laboratories currently use similar testing methods and are in possession of all relevant apparatus and materials necessary to comply with the proposed regulations. However, if a licensed laboratory needed to purchase the required equipment and supplies the upper range of initial costs would be $108,300. The annual ongoing costs would amount to approximately $11,300.

Cost Impacts on a Representative Private Person or Business: The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Economic Impact and Fiscal Impacts

Business Impact

The Department of Cannabis Control has 48 licensed laboratories as of May 13, 2022. The businesses impacted by the regulation are all licensed testing laboratories.

Estimated Costs to Businesses

The proposed regulations require licensees to commence utilizing the Department established cannabinoid test method no later than six months following the Department's adoption of the test method through these proposed regulations. Many of the licensed laboratories currently use an HPLC system consisting of a column module, solvent delivery module, photodiode-array detection module and sampling module that is capable of separating the cannabinoids of interest to achieve a minimum resolution of 1.3 because the system is a basic instrument that is used to separate cannabinoids effectively and efficiently. The cost of a an HPLC system that meets the proposed regulatory requirements is approximately $60,000. Additionally, the grinding and homogenization procedures in the proposed regulations would require licensed laboratories to have a grinder capable of grinding samples to less than 1 mm. If the licensees do not have an existing grinder that is sufficient, the cost of a grinder would range from approximately $20,000 to $35,000. Further, the proposed regulations would also require the licensed testing laboratories to freeze grind edible samples and the associated cost for the liquid cryogens is approximately $10,000 per year. Licensed laboratories also purchase solvents and standards in the ordinary course of business, but in varying quantities depending on the volume of samples being processed. On average, a licensed laboratory may spend $800 for standards and $500 for solvents in a year and $2,000 for a column. However, the costs of standards, solvents, and columns would be incurred even if the proposed regulations were not in effect as they are necessary supplies to operate a licensed laboratory.

It is anticipated that the cost for most licensed laboratories to comply with the proposed regulations are minimal as most laboratories currently use similar testing methods and are in possession of all relevant apparatus and materials necessary to comply with the proposed regulations. The lowest range of initial costs for a licensed testing laboratory to comply with the proposed regulations would be approximately $1,300.00 reflective of purchasing $800 for standards and $500 for solvents, assuming the licensed laboratory already possessed a LC column, adequate grinder, and HPLC system.

However, if a licensed laboratory needed to purchase the required equipment and supplies the approximate costs are as follows: a new HPLC system for $60,000, a grinder for $35,000, liquid cryogens for $10,000, standards at $800, solvents for $500, and a LC column for $2,000.00, the upper range of initial costs would be $108,300. The annual ongoing costs would amount to approximately $11,300 including $800 for standards, $500 for solvents, and $10,000 for liquid cryogens though costs may vary depending on the volume of samples a particular licensed laboratory processes each year.

To calculate the approximate total statewide costs a business may incur to comply with this regulation over its lifetime, the upper range of costs is approximately $108,300 added to the annual ongoing costs of $11,300 yields a sum of $119,600.00. $119,600 multiplied by ten years results in a grand total of $1,196,000.00.

The proposed regulations will not have a significant adverse economic impact on businesses because the cost of compliance described above is anticipated to be absorbable by existing licensees.

Results of the Economic Impact Assessment

Based on the analysis below, the Department concludes that it is (1) unlikely that the proposal will eliminate any jobs, (2) unlikely that the proposal will create an unknown number of jobs, (3) unlikely that the proposal will create an unknown number of new businesses, (4) unlikely that the proposal will eliminate any existing businesses, and (5) unlikely that the proposed regulations will result in the expansion of businesses currently doing business within the state.

The proposed regulations will not have a significant adverse economic impact on businesses.

The Department does not anticipate the creation or elimination of jobs as a result of the proposed regulations. The proposed regulations are standardizing an HPLC cannabinoid test method which is already used by a majority of licensed laboratories, thus it is anticipated that existing laboratory personnel can perform the procedure proposed by the regulation and there will be no creation or elimination of jobs. The proposed regulations would not affect worker safety.

The proposed regulations would affect approximately 48 licensed laboratories. The businesses impacted by the regulation all meet the criteria for being classified as small businesses. The cost associated with the proposed regulations for a small business is anticipated to be minimal for most licensed laboratories as most laboratories currently use similar testing methods and are in possession of all relevant apparatus and materials necessary to comply with the proposed regulations. However, if a licensed laboratory needed to purchase the required equipment and supplies the upper range of initial costs would be $108,300. The annual ongoing costs would amount to approximately $11,300.

The Department does not anticipate the creation or the elimination or expansion of existing businesses, as a result of the proposed regulations. The proposed regulations would not affect the ability of businesses in the State to compete.

The proposal does not benefit or negatively impact the State's environment because the proposed regulatory action does not involve any topic that induces harm or benefit to the environment in the State.

Benefits of the Proposed Regulation

The total statewide economic benefit of this regulation is difficult to quantify in dollars because many of the benefits are fiscally intangible. The primary benefit of the proposed regulations is to protect the health and welfare of California residents by ensuring that licensed laboratories are properly testing cannabis and cannabis products

and reporting accurate results. This will allow consumers to receive accurate information regarding the level of cannabinoids in cannabis and cannabis products, while ensuring that the labeling of cannabis and cannabis products is accurate. Additionally, the proposed regulations reduce the ability to select licensed laboratories to achieve more favorable testing results.

The proposal does not benefit or negatively impact worker safety or the State's environment because the proposed regulatory action does not involve any topic that induces harm or benefit to worker safety or the environment in the State.

Fiscal Effect on State Government

The proposed regulations govern licensed laboratories while implementing the statutory requirement for the Department, on or before January 1, 2023, to establish a standard cannabinoids test method, including standardized operating procedures that shall be utilized by all testing laboratories. There is no impact on the Department's workload created by the proposed regulations. Thus, there is no fiscal impact on state government resulting from the proposed regulations.

Consideration of Alternatives

In accordance with Government Code section 11346.5, subdivision (a)(13), the Department must determine that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the agency would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

The first alternative considered by the department was to not adopt the proposed regulations. This alternative was rejected because SB 544, as codified in Business and Professions Code section 26100(f)(2), requires the Department to establish a standard cannabinoids test method, including standardized operating procedures, that shall be utilized by all testing laboratories. If the Department does not adopt the proposed regulations, there will be no standardized test method for licensees to follow to test cannabinoids and the Department will not have complied with its statutory mandate.

The second alternative considered was developing a method that uses liquid chromatography/ mass spectrometry (LCMS or LCMSMS). These methods use the separating power of liquid chromatography but use a different detector called mass spectrometry that is highly sensitive. The LC method specified in the reference method can be used with the LCMS or LCMSMS method. The advantage to this method is that

it can uniquely identify compounds by mass or a mass fragment spectrum. The disadvantage is the cost as these instruments are approximately $200,000 to $800,000. The Department did not adopt this method because only a small number of licensed laboratories currently utilize this method and it would be very costly for licensees.

The third alternative considered was developing a method that uses gas chromatography/mass spectrometry (GCMS). This method is rarely used for cannabinoids as the heating routine used by GCMS causes chemical changes of the cannabinoids. These chemical changes will give inaccurate results for cannabinoid analysis. There are variations to this method that allow derivatization of the sample to protect it from degradation in analysis. However, licensed laboratories that have undergone method validations do not use this method, and the additional cost of a GCMS instrument, slower analysis time, and added steps of derivatization make it unfeasible for routine testing. Additionally, the Gas Chromatography Mass Spectrometry instruments cost approximately $170,000. The Department did not adopt this method as it is rarely used for cannabinoids testing and costly.

Contact Person

Inquiries concerning the proposed administrative action may be directed to:

Charisse Diaz
Department of Cannabis Control
Legal Affairs Division
2920 Kilgore Road
Rancho Cordova, CA 95670
916-465-9025
Charisse.Diaz@cannabis.ca.gov

The backup contact person for these inquiries is:

Kaila Fayne
Department of Cannabis Control
Legal Affairs Division
2920 Kilgore Road
Rancho Cordova, CA 95670
916-251-4544
Kaila.Fayne@cannabis.ca.gov

Please direct requests for copies of the proposed text (the “express terms”) of the regulations, the initial statement of reasons, the modified text of the regulations, if any, or other information upon which the rulemaking is based to the contact persons listed above.

Availability of Statement of Reasons, Text of Proposed Regulations, and Rulemaking File

The Department will have the entire rulemaking file available for inspection and copying, throughout the rulemaking process, at its office at the address above. As of the date this Notice is published in the Notice Register, the rulemaking file consists of this Notice, the proposed text of the regulations, and the Initial Statement of Reasons. Copies of materials may be obtained by contacting the contact person at the address, email or phone number listed above.

Availability of Changed or Modified Text

After considering all timely and relevant comments received, the Department may adopt the proposed regulations, substantially, as described in this Notice. If the Department makes modifications that are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Department adopts the regulations, as revised. Please send requests for copies of any modified regulations to the attention of the contact person at the address, email, or phone number indicated above.

The Department will accept written comments on the modified regulations for at least 15 days after the date on which they are made available.

Availability of The Final Statement of Reasons

Upon its completion, copies of the Final Statement of Reasons may be obtained by contacting the contact person at the above address, email, or phone number indicated above.

Availability of Documents on the Internet

Copies of the Notice of Proposed Action, the Initial Statement or Reasons, and the text of the regulations can be accessed through the Department's website at: https://cannabis.ca.gov/cannabis-laws/rulemaking/.