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

Notice of Additional Modifications to Text of Proposed Regulations

Notice Date: May 8, 2023

Subject Matter of the 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.

Pursuant to the requirements of Government Code section 11346.8(c) and section 44 of title 1 of the California Code of Regulations, the Department of Cannabis Control (Department) hereby provides notice of additional modifications made to the proposed regulation sections listed above which were the subject of public hearing on August 1, 2022. The text of the regulation with additional proposed modifications is attached to this Notice.

The Department will accept written comments on the additional proposed changes from May 8, 2023 to May 23, 2023. All written comments received by or on May 23, 2023, will be summarized and responded to in the Final Statement of Reasons. **Please limit your comments to the modifications to the text.**

Additional modifications proposed to be added to the rulemaking in this 15-day comment period are displayed as **bold text surrounded by a bold box**. Additional modifications proposed to be deleted from the rulemaking in this 15-day comment period are displayed as ~~**bold, double strikethrough text surrounded by a dashed box**~~.

Text that is single underline, **double underline**, ~~**double strikethrough,**~~ *italic, double wave underline,* or ~~*italic, single strikethrough, double wave underline*~~ were prior proposed modifications for which the comment periods have ended.

Written Comment Period

Written comments may be submitted by mail or e-mail to the address listed below. **Comments submitted must be received by the Department at its office by or on May 23, 2023.**

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.

Updated Informative Digest

The primary modifications to the proposed regulations would provide additional clarity regarding mandatory actions, make conforming changes in the regulatory text and the standard operating procedure (SOP) incorporated by reference, and make non-substantive edits for syntax.

Section 15712.1. Cannabinoid Test Method for Dried Flower, including Non-Infused Pre-Rolls.

The title of the section has been amended to “Cannabinoid Test Method for Dried Flower, including Non-infused Pre-Rolls” for syntax. Additionally, “non-infused” has been added to “pre-rolls” throughout for greater accuracy as the proposed cannabinoid test method is only applicable to non-infused pre-rolls and does not apply to infused pre-rolls. Further, the phrase “test method” has been revised throughout to “cannabinoid test method” to provide additional clarity regarding the subject of the test method and “High Performance Liquid Chromatography (HPLC)” has been added to ensure both the full term and acronym are identified.

The date in proposed section 15712.1(b) was updated to 4/10/2023. The edit is necessary for clarity as the SOP was updated on April 10, 2023. Lastly, the date for licensed laboratories to implement the cannabinoid test method has been amended to three months after the effective date of the regulation.

The phrase “and obtain Department approval prior to use of the proposed method” has been removed from proposed section 15712(i).

Section 15712.2. Verification of Test Method for Dried Flower, including Non-Infused Pre-Rolls.

Consistent with edits made in proposed section 15712.1, this section has been renamed "Verification of Cannabinoid Test Method for Dried Flower, including Non-Infused Pre-Rolls." A new subsection (c) has been added to incorporate the definition for "reagent blank" which has been moved from the SOP to provide greater clarity as the term is not used in the SOP but is used in this regulatory section. The remaining subsections have been renumbered accordingly. Lastly, non-substantive syntaxial edits were made to the section to provide additional clarity regarding method verification.

Determination of Cannabinoids Concentration by High Performance Liquid Chromatography (HPLC) for Dried Flower, including Non-Infused Pre-Rolls, (New 04/10/2023) (incorporated by reference in CCR, tit. 4, §15712.1(b)).

Consistent with edits made in sections 15712.1 and 15712.2, the title of the SOP has been amended to add the term "non-infused" to "pre-rolls" to provide additional clarity regarding the applicability of the SOP to non-infused pre-rolls.

The date has been updated to 04/10/2023 for accuracy.

SOP Definitions.

The definitions section has been amended by removing the definition for "certified reference material" as the term is no longer used in the SOP. The definition for "liquid chromatography" has been removed as the term is no longer used in the SOP and all areas where it was used have been replaced by HPLC for greater accuracy. The definition of "method blank" has been revised by adding the phrase "or proportions" to align with the definition in section 15700. Lastly, the definition for "reagent blank" has been removed from the SOP as the term is not used in the SOP and it has been added to section 15712.2 because the term is used in section 15712.2. The remaining definitions have been renumbered accordingly.

SOP §I. Safety.

The Safety section of the SOP has been amended to remove the first three sentences related to limiting health hazards and exposure to chemical compounds as well as compliance with the "Laboratory Safety Guidance" established by the Occupational Safety and Health Administration (OSHA).

SOP §II. Apparatus and Materials.

Subsection H has been amended to remove the term "effectively."

Subsection M has been amended to replace "LC" with "HPLC" for consistency of terms used throughout the SOP.

Subsection Q has been amended to remove the descriptor of an analog vortex mixer and refer only to vortex mixer for accuracy as any vortex mixer is permissible under this SOP.

SOP §V. Procedure.

Subsection B.1. has been amended to add “any size reduction equipment” as an option for homogenizing samples.

Subsection C.6. has been amended for clarity by removing the statement “[t]he expected concentration can be calculated based on labels of samples or past experience on similar samples.”

Subsection C.7. has been amended to align with the intent of this subsection which requires the specific action to obtain a concentration within the range of calibration curve. To clarify that this step is mandatory, the word “should” has been replaced with “shall.” Subsection D.1. has been amended to replace “LC” with “HPLC” for consistency of terms used throughout the SOP and regulatory sections.

Subsection E.5. has been amended to add the term “mid-range” to Continuing Calibration Verification (CCV) for accuracy and to align requirements for all CCV to be in the mid-range. This subsection has also been amended to update the cross-reference to Section VII.A.3.

SOP §VII. Quality Control.

The section has been amended to replace the word “should” with “shall” in the first sentence and subsections A.2., A.3., and B., to align with the intent of this section which is to require licensees to meet existing requirements regarding the use of quality control samples.

Subsection A.3. has also been amended to update the cross-reference to Section IV.C.

Subsection B has been amended to replace the word processed with prepared.

Subsection B.1. has been amended to remove the last sentence regarding other plant material cannabis matrices.

Subsection B.2. has been amended to add that mid-range is the amount to be spiked into the blank matrix.

Subsection E. has been amended to clarify that if the laboratory is unable to deconvolve the cannabinoid from the interference the sample shall be re-analyzed in accordance with the requirements of section 15730 of the Department’s regulations.

SOP §VIII. Acceptance Criteria for Quality Control Samples.

This section has been amended for syntax to replace “need to” with shall.

SOP §IX. Reporting Results.

This section has been amended to remove subsection B. as it is repetitive and unnecessary as subsection A. contains all requirements for reporting results.

Updated Initial Statement of Reasons

Section 15712.1. Cannabinoid Test Method for Dried Flower, including Non-Infused Pre-Rolls.

The title of the section has been amended to “Cannabinoid Test Method for Dried Flower, including Non-Infused Pre-Rolls” to for syntax. Additionally, “non-infused” has been added to “pre-rolls’ throughout for greater accuracy as the proposed cannabinoid test method is only applicable to non-infused pre-rolls and does not apply to infused pre-rolls. Further, the phrase “test method” has been revised throughout to “cannabinoid test method” to provide additional clarity regarding the subject of the test method and “High Performance Liquid Chromatography (HPLC)” has been added to ensure both the full term and acronym are identified. The Department determined that HPLC and Liquid Chromatography (LC) are used interchangeably in the laboratory testing industry and throughout this SOP, thus amending to HPLC for all is necessary for consistency. These edits are also necessary to provide further clarity and accuracy of terms.

The date in proposed section 15712.1(b) was updated to 4/10/2023. The edit is necessary for clarity as the SOP was updated on April 10, 2023. Lastly, the date for licensed laboratories to implement the cannabinoid test method has been amended to three months after the effective date of the regulation. This change is necessary due to the extended rulemaking period and ensures licensees have enough time to implement the cannabinoid test method. As licensees will need time to acquire equipment and train staff on the new test method, a date beyond the effective date for the regulation is necessary.

The phrase “and obtain Department approval prior to use of the proposed method” has been removed from proposed section 15712(i) as it is unnecessary and does not provide additional clarity. The Department has determined that the cross reference to section 15713 which precedes the phrase sufficiently informs licensees of the requirement.

Section 15712.2. Verification of Test Method for Dried Flower, including Non-Infused Pre-Rolls.

Consistent with edits made in proposed section 15712.1, this section has been renamed “Verification of Cannabinoid Test Method for Dried Flower, including Non-Infused Pre-Rolls.” A new subsection (c) has been added to incorporate the definition for “reagent blank” which has been moved from the SOP and is necessary to provide greater clarity because the term is used in this regulatory section, not the SOP. The remaining

subsections have been renumbered accordingly. Lastly, non-substantive syntaxial edits were made to the section to provide additional clarity regarding method verification.

Determination of Cannabinoids Concentration for Dried Flower, including Non-infused Pre-Rolls, by High Performance Liquid Chromatography (HPLC) (New 04/X/2023) (incorporated by reference in CCR, tit. 4, §15712.1(b)).

Consistent with edits made in sections 15712.1 and 15712.2, the title of the Standard Operating Procedure (SOP) has been amended to add the term "non-infused" to "pre-rolls" to provide additional clarity regarding the applicability of the SOP to non-infused pre-rolls. Additionally, this change is necessary as pre-rolls may be both infused and non-infused. Including "non-infused" here ensures that licensees have clear direction regarding the applicability of the test method.

The date has been updated to 04/10/2023 for accuracy and identifies that the SOP was updated in April of 2023.

SOP Definitions.

The definitions section has been amended by removing the definition for "certified reference material" as the term is no longer used in the SOP. The definition for "liquid chromatography" has been removed as the term is no longer used in the SOP and all areas where it was used have been replaced by HPLC for greater accuracy and consistency in use of terms as discussed above. The definition of "method blank" has been revised by adding the phrase "or proportions" to align with the definition in section 15700. This edit is necessary for accuracy and consistency in defined terms. Lastly the definition for "reagent blank" has been removed from the SOP as the term is not used in the SOP and added to section 15712.2 because the term is used in section 15712.2. The remaining definitions have been renumbered accordingly.

SOP §I. Safety.

The Safety section of the SOP has been amended to remove the first three sentences related to limiting health hazards and exposure to chemical compounds as well as compliance with the "Laboratory Safety Guidance" established by the Occupational Safety and Health Administration (OSHA). This revision is necessary to avoid duplication of requirements. Laboratories are already required to comply with Title 29 of the Code of Federal Regulations, section 1910.1450 (OSHA 3404-11R (2011), thus including the requirement here is duplicative and unnecessary.

SOP §II. Apparatus and Materials.

Subsection H has been amended to remove the term "effectively." This is necessary for consistency of terms and alignment with phrasing in subsection M.

Subsection M has been amended to replace "LC" with "HPLC" for consistency of terms used throughout the SOP as discussed above.

Subsection Q has been amended to remove the descriptor of an analog vortex mixer and now refers only to vortex mixer for accuracy as any vortex mixer is permissible under this SOP. The Department determined that the additional descriptor language was unnecessary as any vortex mixer will meet the requirements of this section.

SOP §V. Procedure.

Subsection B.1. has been amended to add “any size reduction equipment” as an option for homogenizing samples. This is necessary to clarify the equipment that may be used to grind the samples.

Subsection C.6. has been amended for clarity by removing the statement “[t]he expected concentration can be calculated based on labels of samples or past experience on similar samples.” The Department determined this sentence was unnecessary and did not supply additional direction to licensees. As the sentence is unnecessary it has been deleted.

Subsection C.7. has been amended to align with the intent of this subsection which requires the specific action to obtain a concentration within the range of calibration curve. To clarify that this step is mandatory the word “should” has been replaced with “shall.” This edit is necessary as the original ISOR provide that subsection C provides the specific instructions for sample extraction. As the specific steps were verified in the Department’s method validation, the Department has determined that the steps contained in this section must be conducted as specified. The edit benefits licensees by ensuring they have accurate instruction on the steps they must take and ensures accuracy in the test results.

Subsection D.1. has been amended to replace “LC” with “HPLC” for consistency of terms used throughout the SOP and regulatory section as discussed above.

Subsection E.5. has been amended to add the term “mid-range” to Continuing Calibration Verification (CCV) for accuracy and alignment with requirements for all CCV to be in the mid-range. This change is necessary to ensure accuracy in testing by providing specific direction regarding the appropriate range for CCV. This subsection has also been amended to update the cross-reference to Section VII.A.3. This is necessary for accuracy as section VII.A.3. contains the calibration standards.

SOP §VII. Quality Control.

The section has been amended to replace the word “should” with “shall” in the first sentence and subsection A.2., A.3., and B., to align with the intent of this section which is to require licensees to meet existing requirements regarding the use of quality control samples. This edit is necessary to clarify that licensed laboratories are required to meet existing requirements regarding use of quality control samples. Quality control samples are used to measure method accuracy, precision, contamination, and matrix effects. Quality control samples are necessary because quality control sample results are used to ensure that data released by the license laboratory is valid, reliable and reproducible.

Thus, providing specific clarity to licensees regarding the requirements is necessary to ensure accuracy and ensures public health and safety is protected through accurate testing.

Subsection A.3. has also been amended to update the cross-reference to Section IV.C. This is necessary as Section IV.C. contains the calibration licensees must use for this step of the method.

Subsection B has been amended to replace the word processed with prepared. This is necessary for consistency with Section 15700(f) and accuracy as a batch is defined as samples that are prepared together.

Subsection B.1. has been amended to remove the last sentence regarding other plant material cannabis matrices. This is necessary for accuracy as the test method only applies to dried flower, including non-infused pre-rolls, thus there are no other matrices that apply.

Subsection B.2. has been amended to add that mid-range is the amount to be spiked into the blank matrix. This is necessary for accuracy and consistency with the definition of laboratory control samples (LCS) in section 15700(ff) which specifies LCS is required to be at mid-range. This is also consistent with edits made to CCV which also require mid-range.

Subsection E. has been amended to clarify that if the laboratory is unable to deconvolve the cannabinoid from the interference the sample shall be re-analyzed in accordance with the requirements of section 15730 of the Department's regulations. This is necessary as the section previously provided that a licensed laboratory may deconvolve a cannabinoid from interference but did not include what the licensee's options would be if unable to deconvolve. This edit provides clarity and direction to licensed laboratories and is necessary to ensure accuracy of testing.

SOP §VIII. Acceptance Criteria for Quality Control Samples.

This section has been amended for syntax to replace "need to" with shall. No substantive changes have been made however the Department determined the edit was necessary for consistency of terms used.

SOP §IX. Reporting Results.

This section has been amended to remove subsection B. as it is repetitive and unnecessary as subsection A. has all requirements for reporting testing results. Removal of this subsection is necessary to ensure the SOP is readily understandable by licensees so that they can accurately report the results of testing. This edit also ensures that licensees are using the same reporting parameters for all test methods used by the laboratory.

Incorporated by Reference

The following documents are incorporated into the regulations by reference:

Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Non-Infused Pre-Rolls, Standard Operating Procedures (New 04/10/2023).

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. Copies of materials may be obtained by contacting Charisse Diaz 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 Charisse Diaz 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 Charisse Diaz 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, the original proposed text of the regulations, the Notices of Modifications, and modified proposed text can be accessed through the Department's website at: https://cannabis.ca.gov/cannabis-laws/rulemaking/.