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

Notice of Further Modifications to Text of Proposed Regulations

Notice Date: October 4, 2022

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 further 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 further proposed modifications is attached to this Notice.

The Department will accept written comments on the further proposed changes from October 4, 2022, to 5:00 p.m. on October 20, 2022. All written comments received by 5:00 p.m. on October 20, 2022, will be summarized and responded to in the Final Statement of Reasons. **Please limit your comments to the modifications to the text.**

Further modifications proposed to be added to the rulemaking in this 15-day comment period are displayed in *italic, double wave underlined type font.* Further modifications proposed to be deleted from the rulemaking in this 15-day comment period are displayed in ~~*italic, single strikethrough, double wave underlined*~~ type font.

Text that is single underline, **bold double underlined**, or ~~**bold double strikethrough**~~ 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 5:00 p.m. on October 20, 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.

Updated Informative Digest

The primary modifications to the proposed regulations limit applicability of the proposed cannabinoid test method and reporting requirements to the testing of dried flower, including pre-rolls. The Department received multiple comments requesting further study of the method's use for infused products. As a result, the Department has determined that limiting the applicability of the method to dried flower, including pre-rolls, is appropriate at this time to allow for further research and development related to the appropriate standardized method for the testing of cannabis products.

Section 15712.1. Test Method for Cannabinoids.

The phrase "for Dried Flower, including Pre-Rolls" was added to proposed section 15712.1. The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the cannabinoid test method established by these regulations to be the only cannabinoid test method that may be utilized by licensed testing laboratories for purposes of regulatory compliance testing and reporting for dried flower, including pre-rolls.

The phrase "results for dried flower, including pre-rolls" was added to proposed section 15712.1(a) so the sentence reads as follows: "Notwithstanding section 15712, a licensed laboratory shall utilize the cannabinoids test method required by this section and shall not utilize any other cannabinoid test method for the purpose of regulatory compliance testing and reporting results for dried flower, including pre-rolls." The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoids for dried flower, including pre-rolls. This amendment is necessary to further clarify that the cannabinoid test method established by these regulations to be the only cannabinoid test method that may be utilized by licensed testing laboratories for purposes of regulatory compliance testing and reporting for dried flower, including pre-rolls.

The sentence, “a licensed laboratory is not required to use the method required by this section for cannabis products, including infused pre-rolls” was added to proposed section 15712.1(a). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoids for dried flower, including pre-rolls. The addition of this sentence clarifies that the proposed testing method is not required for cannabis products, including infused pre-rolls.

The phrase “for Dried Flower, including Pre-Rolls” was added to proposed section 15712.1(b) to provide clarity in the title of the Standard Operating Procedures. This addition is necessary, so it is clear the Determination of Cannabinoids Concentration by HPLC is for dried flower, including pre-rolls.

The date in proposed section 15712.1(b) was updated to 09/23/2022. The edit is necessary for clarity as the Standard Operating Procedures were updated on September 23, 2022.

The phrase “and in additional matrices beyond those covered in” was added to proposed section 15712.1(i). This edit is necessary to clarify that laboratories may test for additional matrices and ensures labs will still perform method validations for matrices and analytes not covered by the Standard Operating Procedures.

The word “of” was removed from proposed section 15712.1(i). This is a necessary grammatical change.

The phrase “and additional matrices” was added to proposed section 15712.1(i). This edit is necessary to clarify that laboratories may test for additional matrices and ensures labs will still perform method validations for matrices and analytes not covered by the Standard Operating Procedures.

<u>Section 15712.2. Verification of Test Method for Cannabinoids for Dried Flower, including Pre-Rolls.</u>

The phrase “for Dried Flower, including Pre-Rolls” was added to proposed section 15712.2. The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the verification of test method for cannabinoids applies to dried flower, including pre-rolls.

The row in the table in proposed subsection 15712.2(c) listing the criteria for sample matrices, number required, and notes has been removed. This amendment is necessary to further clarify that the verification of test method for cannabinoids applies to dried flower, including pre-rolls, rather than to both cannabis and cannabis products.

The phrase “of cannabis and cannabis products” was removed from proposed section 15712.2(h). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the verification of test method for cannabinoids applies to dried flower, including pre-rolls, rather than to cannabis and cannabis products.

Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-rolls, Standard Operating Procedures (New 09/23/2022) (incorporated by reference in CCR, tit. 4, §15712.1(b)).

The phrase “for Dried Flower, including Pre-Rolls” has been added to the title of the proposed Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-rolls, Standard Operating Procedures (New 09/23/2022). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed Standard Operating Procedures shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the Standard Operating Procedures for determination of cannabinoids concentration by HPLC apply to dried flower, including pre-rolls.

The date has been updated to 09/23/2022 in the title of the proposed Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-rolls, Standard Operating Procedures (New 09/23/2022) because the Standard Operating Procedures were updated on September 23, 2022. The edit is necessary for clarity as the Standard Operating Procedures were updated on September 23, 2022, and the previous date of August 23, 2022 is no longer the proposed version.

Scope.

The phrase “for Dried Flower, including Pre-Rolls” has been added to the proposed Scope section of the proposed Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-rolls, Standard Operating Procedures (New 09/23/2022). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the Standard Operating Procedures apply to dried flower, including pre-rolls.

Application.

The phrase “for dried flower, including pre-rolls” has been added to the proposed Application section of the proposed Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-Rolls, Standard Operating Procedures (New

09/23/2022). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the Standard Operating Procedures apply to dried flower, including pre-rolls.

The sentence “This method does not cover the determination of cannabinoid concentration in cannabis products, including infused pre-rolls” has been added to the proposed Application section of the proposed Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-Rolls, Standard Operating Procedures (New 09/23/2022). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the Standard Operating Procedures does not apply to cannabis products and infused pre-rolls.

A definition for “standard” has been added to the Definition section of the proposed Determination of Cannabinoids Concentration by HPLC for Dried Flower, including Pre-Rolls, Standard Operating Procedures (New 09/23/2022). The definition states, “”Standard” means a certified reference standard comprised of one or more of the target analytes prepared at a known concentration by a certifying body or a party independent of the laboratory with ISO/IEC 17034 accreditation.” This edit is necessary because it directly addresses several comments requesting greater clarity of the standards needed for analysis.

Standard Operating Procedures, Section II. Apparatus and Materials.

The apparatus in proposed section II(U) of the Standard Operating Procedures stating “cryogenic grinder capable of grinding samples to less than 1 mm. Any method of cryogrinding or size reduction equipment using liquid nitrogen, dry ice or other cryogens, that can lower the temperature to less than -70 Celsius is acceptable provided that it grinds the sample to less than 1mm” has been removed. The cryogenic grinder was only necessary to grind samples of manufactured cannabis products. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls and manufactured cannabis products are not included in the proposed test method. This amendment is necessary to further clarify that the Standard Operating Procedures does not apply to manufactured cannabis products.

Standard Operating Procedures, Section IV. Calibration Standard.

The sentence, “with the following analytes at the listed concentration. Mixtures or combined standard solutions of the listed analytes at their specified concentration or single standard solutions of the analytes at their specified concentrations may be used

for the following stock standard solution" has been added to proposed section (IV)(A). This edit is necessary to make clear standard mixes are okay.

The phrase, "mL" was added to proposed section (IV)(A)(6). This amendment is necessary for consistent nomenclature. This edit is non-substantive.

A period was added to proposed section (IV)(B)(1) for grammar. This edit is necessary and non-substantive.

A colon was deleted from proposed section (IV)(B)(1) for grammar. This edit is necessary and non-substantive.

The phrase "using single standard solutions of the target analytes," and the word "the" have been added to proposed section (IV)(B)(1). This edit is necessary to show that this is the procedure for single standard solutions.

The sentence, "For mixtures or combined standard solutions, add acetonitrile/methanol (80:20 Volume:Volume) as diluent. Vortex to mix well" has been added to proposed section (IV)(B)(1). This edit is necessary to provide clarity and specificity so laboratories have a clear procedure to make the stock solution in the event a mixture or combined standard is used. The public comments demonstrated a large demand from laboratories and vendors to ensure standard mixes, which are commonly used, are allowed in the proposed method.`

The phrase "second source:" and replaced with the following phrase was added to proposed section (VI)(B)(3): "different source of the calibration standards and source external to the laboratory." This edit is necessary for consistency as "second source" is not a defined term and the phrase replacing "second source" is more clear and instructive of what source is acceptable.

The phrase "using single standard solutions of the target analytes," was added to proposed section (IV)(B)(3). This edit is necessary to show that this is the procedure for single standard solutions. The public comments demonstrated a large demand from labs and vendors to ensure standard mixes, which are commonly used, are allowed in the proposed method.

The sentence, "For mixtures or combined standard solutions, add acetonitrile/methanol (80:20 Volume:Volume) as diluent. Vortex to mix well" has been added to proposed section (IV)(B)(3). This edit is necessary to provide clarity and specificity so laboratories have a clear procedure to make the stock solution in the event a mixture or combined standard is used. The public comments demonstrated a large demand from laboratories and vendors to ensure standard mixes, which are commonly used, are allowed in the proposed method.

The word "the" was added to proposed section (IV)(B)(3). This edit is necessary and non-substantive.

The phrase "or per the manufacturer's specifications." was added to proposed section (IV)(B)(5). This edit is necessary to address a request for further clarification on

standard storage. This amendment provides specificity to allow laboratories to preserve the condition of the standards by storing standards in the manner recommended by the manufacturer.

Standard Operating Procedures, Section V. Procedure.

The sentence, “Notes: Group samples by type (e.g., plant material, juice, oil, chocolate, hard candy, gummy and cookie)” has been removed from proposed section (V)(B). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to further clarify that the Standard Operating Procedures does not apply to cannabis products and infused pre-rolls.

Standard Operating Procedures, Section (V)(B). Sample Preparation.

The phrase “as follows” was removed and the phrase “by using” was added to proposed section (V)(B) so the sentence states, “Homogenize the samples by using”. This amendment is necessary for clarity, as the Standard Operating Procedures no longer apply to cannabis products and infused pre-rolls. As such, there is only one method to homogenize samples under the Sample Preparation section, as all samples will be plant material.

The phrase “For plant material, use” was removed from proposed section (V)(B)(1). This amendment is necessary for clarity, as the Standard Operating Procedures no longer apply to cannabis products and infused pre-rolls. As such, all samples will be plant material and it would be redundant to specify what one must use for a plant material sample.

The sentence “For pre-rolls, include the rolling paper in the homogenized samples” was added to proposed section (V)(B)(1). This amendment is necessary for clarity, as the paper in a pre-roll consumed and should be tested as part of the over sample product.

The sentence, “For chocolate, hard candy, gummy and cookie samples, use a cryogenic grinder which can grind the samples to less than 1 mm, following manufacturer’s instructions”, has been removed from proposed section (V)(B)(1). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to clarify that the Standard Operating Procedures does not apply to cannabis products such as chocolates, hard candy, gummy and cookie samples.

The sentence, “For beverage and cannabis infused edible oil samples, invert the container 3 or more times to ensure homogeneity of the liquids,” has been removed from proposed section (V)(B)(1). The Department received multiple comments

suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. This amendment is necessary to clarify that the Standard Operating Procedures does not apply to cannabis products such as beverages and cannabis infused edible oil.

The phrase “200 mg” was added and the phrase “appropriate amount” was removed first sentence of proposed section (V)(B)(2). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. As such, all samples for plant material should weigh 200 mg, as no other sample types will be used in the proposed test method. This amendment is necessary to clarify the sample weight for plant material, as the Standard Operating Procedures do not apply to other cannabis products.

The phrase “indicated below, that corresponds to the sample type” was removed from proposed section (V)(B)(2). This edit is necessary because there are no longer multiple sample types and masses determine by the sample type because the Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls.

The phrase “Plant material/concentrate/vape oil: 200 mg” was removed from proposed section (V)(B)(2). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. As such, all samples for plant material should weigh 200 mg, as no other sample types will be used in the proposed test method. This amendment is necessary to clarify that the sample weight does not include concentrate or vape oil samples.

The phrase “Cannabis infused edible oil: 0.5 g” was removed from proposed section (V)(B)(2). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. As such, no other sample types will be used in the proposed test method. This amendment is necessary to clarify that the sample weight does not include cannabis infused edible oil samples.

The phrase “Chocolate/hard candy/gummy/cookie/other edibles/topicals: 2 g” was removed from proposed section (V)(B)(2). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. As such, no other sample types will be used in the proposed test method. This

amendment is necessary to clarify that the sample weight does not include chocolate, hard candy, gummy, cookie, other edibles, or topical samples.

The phrase “Juice/water/beverage:5 mL” was removed from proposed section (V)(B)(2). The Department received multiple comments suggesting the proposed test method be limited to regulatory compliance testing and reporting results for dried flower and plant material. The Department determined that the proposed test method shall be limited to cannabinoid testing for dried flower, including pre-rolls. As such, no other sample types will be used in the proposed test method. This amendment is necessary to clarify that the sample weight does not include juice, water, or beverage samples.

Standard Operating Procedures, Section (V)(C). Sample Extraction.

The phrase “For plant material” was removed from proposed section (V)(C)(1). This amendment is necessary for clarity, as the Standard Operating Procedures only apply to plant material, and no longer apply to cannabis products and infused pre-rolls. As such, there is only one method for sample extraction in the Sample Extraction section, as all samples will be plant material.

The “u” in “use” was capitalized in proposed section (V)(C)(1). This amendment is necessary for grammar and clarity, as the word ‘use’ is the first word in the sentence.

The sentence “for everything else, use methanol as extraction solvent” was removed from proposed section (V)(C)(1). This amendment is necessary for clarity, as the Standard Operating Procedures only apply to plant material, and no longer apply to cannabis products and infused pre-rolls. As such, there is only one method for sample extraction in the Sample Extraction section, as all samples will be plant material.

The word “the” was added to proposed section (V)(C)(1). This amendment is necessary for grammar and clarity, as there is only one typical dilution for dried flower, including pre-rolls, as all samples will be plant material.

The phrase “at least” was added to proposed section (V)(C)(3). This amendment is necessary to address public comment and clarify that laboratories may sonicate for longer than thirty minutes.

The phrase “with acetonitirile/methanol (80:20 Volume:Volume) was added to proposed section (V)(C)(6) to address public comment and clarify what diluent is used to dilute the sample extract.

The “t” in “typical” in proposed section (V)(C)(6) has been changed to a lower case “l” in proposed section (V)(C)(1). This amendment is necessary for grammar and clarity, as the word ‘the’ is the first word in the sentence and “typical” is now the second word.

The “s” in “dilutions” in proposed section (V)(C)(6) has been removed. This amendment is necessary for grammar and clarity, as there is now only one typical dilution for dried flower.

The phrase “for dried flower, including pre-rolls, is 20” was added to proposed section (V)(C)(6). This amendment is necessary for clarity, as the Standard Operating Procedures only apply to dried flower, including pre-rolls. As such, there is only one typical dilution, as all samples will be plant material.

The phrase “are given in the following table” and the table providing sample matrix for flower/plant material, concentrate/vape oil, edibles, and beverages and respective dilution were removed from proposed section (V)(C)(6). This amendment is necessary for clarity, as the Standard Operating Procedures only apply to dried flower, including pre-rolls. As such, there is only one typical dilution, as all samples will be plant material and the other sample matrices listed are not included in this method.

Standard Operating Procedures, Section (V)(E). Instrument Analysis.

The word “replicate” was added to proposed section (V)(E)(3) to replace the word “duplicate”. This edit is necessary for consistency of nomenclature. The regulations refer to sample replicate rather than sample duplicate.

The sentence “6. Store samples and Standards in the HPLC autosampler or a refrigerator in dark at 4°C or lower” was removed from proposed section (V)(E)(6) and replaced with the following sentence: “After the run finishes, recap the standards and sample vials and store them in –20°C freezer”. This amendment is necessary to be consistent with previous standards storage instruction and provides clarity in storage of standards. Standard Operating Procedures, Section (VI). Method Limit of Quantification (LOQ).

The word “minimum” was added to the proposed section (VI). This edit is necessary for clarity and consistency. The calibration points listed are a minimum and laboratories may choose to add additional calibration points.

Standard Operating Procedures, Section (VII)(A). Quality Control.

The following sentences were added to proposed section (VI)(A)(1): “The solvent blank should be free of the target analytes such that no target analyte is present over the LOQ to meet acceptance criteria. If target analytes are present over the LOQ, rerun the solvent blank once or until the target analytes are no longer present over the LOQ. If the problem persists, locate the source of contamination and rerun the CCV or ICV.” This edit is necessary to set an acceptance criteria for the solvent blank to ensure accuracy of the testing results. The Department set this acceptance criteria because solvent blanks are used to flush instrumentation and monitor any carryover in analysis. If there is an analyte in the solvent blank above the LOQ concentration, this carryover could be reported as a result incorrectly.

The phrase “second source” was removed and replaced with the following phrase was added to proposed section (VI)(A)(2): “source external to the laboratory and different from the source of the calibration standards”. The phrase “second source” has not previously been used and this edit is necessary for clarity and consistency.

The phrase “percent recovery” was added to proposed section (VI)(A)(2-3). This edit is necessary to clarify what 30% refers to.

Standard Operating Procedures, Section (VII)(B). Quality Control.

The sentence “Use Deionized (DI) water as the Method Blank for beverage sample matrices and follow the same extraction procedures” has been removed from proposed section (VII)(B)(1). This amendment is necessary for clarity, as the Standard Operating Procedures only apply to dried flower, including pre-rolls. As such, there is only one blank matrix for this method, as juice and beverage sample matrices are not included in this method.

The word “other” has been removed from proposed section (VII)(B)(1) because this method only applies to one type of sample matrix. This amendment is necessary for clarity, as the Standard Operating Procedures only apply to dried flower, including pre-rolls and no other matrices would be included.

The word “plant material” was added to proposed section (VII)(B)(1). This amendment is necessary for clarity, as the Standard Operating Procedures only apply to dried flower, including pre-rolls and all matrices would be for plant material.

Both instances of the word “methyl” were removed from proposed section (VII)(B)(1) because cellulose powder was used as a blank matrix and cellulose was used as the Method Blank in the method, not methyl cellulose.

The word “methyl” was removed from proposed section (VII)(B)(2) because cellulose powder was used as a blank matrix in the method, not methyl cellulose.

The word “matrix” has been added to proposed section (VII)(B)(4) for clarity and consistency. This amendment is necessary because it must be clear that the “post-dilution” spike refers to the “matrix post-dilution spike”.

Standard Operating Procedures, Section (VII)(D). Retention Time (RT) Acceptance Window.

The phrase “calibration standards” was removed from proposed section (VII)(D) and replaced with the following phrase “target analytes in the CCVs and calibration curve standards injected during”. This edit is necessary to clarify that a calibration curve is not injected every run or analytical sequence. This amendment is necessary because without this amendment, a laboratory would have no retention times to average in the event that they only ran CCVs in the analytical sequence. The intent is that the laboratory averages the retention time of known standards during the analytical sequence. These retention times will be the metric that the laboratories use to evaluate

the identity of the analytes so therefore it is critical to ensure that the labs are able to collect this information from CCVs (which are known standards) to comply with the regulations.

The word “run” was removed and replaced with “analytical sequence” in proposed section (VII)(D). This edit is necessary to clarify that a calibration curve is not injected every run or analytical sequence and to instruct laboratories to use CCVs for the average retention time when a calibration curve has not been injected in the analytical sequence.

The sentences “of the calibration curve standards injected during the same analytical sequence of the samples. Calibration curve standards injected during the same analytical sequence include CCVs and the calibration curve standards. If no calibration curve was injected during the same analytical sequence as the samples, use the CCVs injected during the same analytical sequence as the samples” were added to proposed section (VII)(D). This edit is necessary to clarify that a calibration curve is not injected every run or analytical sequence. This amendment is necessary because without this amendment, a laboratory would have no retention times to average in the event that they only ran CCVs in the analytical sequence. The intent is that the laboratory averages the retention time of known standards during the analytical sequence. These retention times will be the metric that the laboratories use to evaluate the identity of the analytes so therefore it is critical to ensure that the labs are able to collect this information from CCVs (which are known standards) to comply with the regulations.

The word “curve” was added to proposed section (VII)(D). This edit is necessary to clarify there are 7 calibration curve standards in a calibration curve.

The words “the run” were removed from proposed section (VII)(D) and replaced with “a calibration curve”. This edit is necessary for clarity and consistency.

The word “can be” were added to replace the word “are” in proposed section (VII)(D). This edit is necessary to clarify that seven retention times can be collected.

The phrase “along with 1 retention time of each cannabinoid from every CCV injected in the analytical sequence was added to replace the phrase “from the standards” in proposed section (VII)(D). This amendment is necessary because without this amendment, a laboratory would have no retention times to average in the event that they only ran CCVs in the analytical sequence. The intent is that the laboratory averages the retention time of known standards during the analytical sequence. These retention times will be the metric that the laboratories use to evaluate the identity of the analytes so therefore it is critical to ensure that the labs are able to collect this information from CCVs, which are known standards to comply with the regulations. One retention time of each cannabinoid from every CCV injected in the analytical sequence because there will be one retention time for each cannabinoid in the CCV. The separation gives one retention time for each cannabinoid.

The word “total” was added to replace the word “7” in proposed section (VII)(D). This amendment is necessary because without this amendment, a laboratory would have no retention times to average in the event that they only ran CCVs in the analytical sequence. The intent is that the laboratory averages the retention time of known standards during the analytical sequence. These retention times will be the metric that the laboratories use to evaluate the identity of the analytes so therefore it is critical to ensure that the labs are able to collect this information from CCVs (which are known standards) to comply with the regulations.

Incorporated by Reference

The following documents are incorporated into the regulations by reference:

Determination of Cannabinoids Concentration by HPLC, Standard Operating Procedures (New 09/23/2022)

Updated Economic Assessment

Economic Impact Assessment

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 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. The cost of a grinder is estimated to be $25,000. 100 samples was chosen as a basis for estimating costs for laboratories as, based on its experience, the Department estimates a range of 40-100 flower and pre-roll samples are analyzed on average each week by a given laboratory. It is estimated based on 100 samples per week that laboratories would use 100 filter tips, 100 syringes totaling 10,400 syringes and filter tips per year at an average cost of $1.12 per filter and $0.215 per syringe resulting in a cost of $6,942 for filtering samples in a year. The total number of Matrix Post-dilution spikes needed per week is five based on an estimate of 100 samples per week, and the total spike material needed per week assuming the lowest spike amount of 50 uL yields a total of 250 microliters of total spike material per week, and a total of 13 mL per year to run samples using the new method. The estimated cost per combination standard vial is $879. Estimating 13 vials are needed each year, the estimated cost is $11,427 per year of combination standard vial. Solvent blanks are not estimated to cost an additional amount as most laboratories are already running solvent blanks. The solvent required

for each sample extraction is 40 mL, not including dilutions which are already performed by laboratories. The increased use of the extraction solvent requires an estimated additional 26 4L bottles of solvent a year, the estimated cost is $3796. A licensed laboratory may also purchase a column with an estimated cost of $937.

Further, the estimated costs for hazardous waste disposal are estimated to be $9.70 per liter of solvent. The cost of a five-gallon drum of either waste stream (acetonitrile or methanol) is an estimated cost of $158.13 plus the estimated cost of the five-gallon drum at $26 totaling $184.13 per five-gallon drum. The proposed method would generate roughly 104 liters of solvent per year based on 100 samples per week, totaling an estimated hazardous waste disposal cost of $1,008.80 per year.

To calculate the approximate costs a business may incur annually to comply with this regulation, the upper range of costs to run 100 samples is $84,110.80 if a laboratory must purchase a column, grinder, and HPLC system, while the lower end of annual costs is estimated to be $23,118.80 if a laboratory does not need to purchase a column, grinder, and HPLC system.

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 $841,108.00 and the lowest range estimate of complying with this proposed method for a total 10 year lifetime cost is $231,118.00.

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

The Department does not anticipate the creation or elimination of jobs or licensed businesses, or the expansion of existing businesses, as a result of the proposal. 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 regulation does not add or increase testing requirements, thus it is anticipated the regulation will not result in the creation, expansion, or elimination of businesses.

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.

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
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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/.