State of California

Department of Cannabis Control

California Code of Regulations, Title 4, Division 19

Initial Statement of Reasons:

Pesticide Testing

INTRODUCTION

The Department of Cannabis Control ("Department" or "DCC") is responsible for administering and enforcing the provisions of the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA, Bus. & Prof. Code § 26000 et seq.), including the cultivation, manufacture, and testing of commercial cannabis and cannabis products.

BACKGROUND

The Department is specifically tasked with prioritizing the protection of the public in its regulatory activities (BPC §26011.5). MAUCRSA further specifies that the Department mandate only commercially feasible procedures, technology, or other requirements, and must not make compliance so onerous that the operation under a cannabis license is not worthy of being carried out in practice by a reasonably prudent businessperson (BPC §26013(c)).

Business and Professions Code section 26060(c) requires the Department of Pesticide Regulation (DPR) to develop guidelines for action levels for pesticide residues in harvested cannabis. Under Business and Professions Code section 26100(d)(2), DCC is responsible for establishing maximum allowable levels of contaminants and must consider guidelines set by DPR in establishing action levels for residual pesticides.

The Department's residual pesticide action levels have not been updated since their initial adoption in 2017. Since that time, the Department has developed a more thorough understanding of how pesticides are used in commercial cannabis cultivation. The Department has also continued to work with DPR as they conduct research and analysis to better assess appropriate risk-based action levels for pesticide residues in cannabis goods.

In December 2024, DPR issued a memorandum ("Memo") to the Department recommending updates to various existing action levels and inclusion of additional pesticides in the cannabis testing requirements. DPR's updated recommendations reflect a conservative approach using health- and risk-based methodologies. (Memo, pp.1-3, 6, 11.) However, DPR explicitly acknowledged that some proposed action levels may be below the detection limit of current analytical testing equipment, and that

whether to implement these action levels is a policy decision to be made by DCC. (Memo, p.11.)

PROBLEM STATEMENT

Laboratory testing of cannabis and cannabis products is an important aspect of a well-regulated cannabis industry. Medical patients and adult-use consumers must have access to products that are accurately labeled and free of dangerous contaminants and adulterants, including pesticide residues. Inhalation or ingestion of pesticides is unhealthy and can cause especially severe issues for medicinal consumers who are immunocompromised.

The Department is proposing to address three principal concerns in this rulemaking action. First, existing action levels for residual pesticides are outdated and do not reflect the most current analysis of risk. Second, assigning a pass/fail value of "non detect" for Category I pesticides provides opportunities for testing laboratories to manipulate test results and facilitate the harmful practice of lab shopping. Third, allowing multiple methods of establishing limits of detection (LOD) and limits of quantitation (LOQ) rather than one standardized method results in variability between testing laboratories and opens the door to "lab shopping."

"Lab shopping" is an industry term of art referring to the practice of selecting a testing lab based on favorability of results, rather than accuracy of testing. Under existing law, every batch of cannabis goods must be tested before it may be sold at retail. Manufacturers and distributors may realize significant financial losses if a batch of goods fails regulatory compliance testing, ranging from costs of remediation or relabeling to total loss of the goods if destruction is required. There is substantial incentive, therefore, for a licensee to seek out testing laboratories with less stringent standards. Labs with less rigorous methods to conduct testing will draw customers away from scientifically rigorous labs, placing the labs most committed to public safety at a competitive disadvantage and potentially driving them out of business.

ANTICIPATED BENEFITS

The Department anticipates that this regulatory package will benefit consumers and the regulated market through updated pesticide action levels and more rigorous and scientifically valid requirements that will increase standardization between testing laboratories. Testing requirements that prioritize human health and that mandate scientifically rigorous testing practices support the Department's goal of a safe, well-regulated market.

Consumers will benefit from reduced risk of pesticide exposure as a result of updated action levels. This is especially beneficial for medical cannabis patients who may be immunocompromised and face greater risk from exposure to residual pesticides due to underlying health conditions.

Increased standardization between licensed laboratories reduces the opportunities for lab shopping, which benefits both consumers and the regulated cannabis industry. Lab shopping results not only in skewed pesticide residue results, but also implicates the results of all tests that affect health and safety, including THC concentration, heavy metals, dangerous solvents, and molds. Removing opportunities for lab shopping results in more accurate and transparent test results leading to a safer cannabis market.

When cannabis and cannabis products sold in the legal market are reliably tested, accurately labeled, and shown to be free from contaminates, consumers have greater incentive to purchase through licensed retailers rather than risking their health on cannabis sold in the illicit market. Offering safe cannabis and cannabis products gives licensed businesses an advantage in the marketplace and incentivizes participation in the regulated cannabis market.

SPECIFIC PURPOSE OF, AND RATIONALE FOR, EACH PROPOSED AMENDMENT

Global Amendments

Use of "shall."

> Shall. This word runs afoul of several basic principles of good drafting. The first is that a word used repeatedly in a given context is presumed to bear the same meaning throughout. (Shall commonly shifts its meaning even in midsentence.) The second principle is strongly allied with the first: when a word takes on too many senses and cannot be confined to one sense in a given document, it becomes useless to the drafter. (Shall has as many as eight senses in drafted documents.) The third principle has been recognized in the literature on legal drafting since the mid-19th century: good drafting generally ought to be in the present tense, not the future. (Shall is commonly used as a future-tense modal verb.) In fact, the selfsame quality in shall—the fact that it is a chameleon-hued word—causes it to violate each of those principles.
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> (Garner, Garner on Language and Writing (2009) p. 174.)

The Department is removing the word "shall" from its regulations for the reasons described above and to eliminate any potential for misinterpretation due to inconsistent or incautious drafting. These are non-substantive changes under CCR, title 1, section 100(a)(4). In every instance of its usage to indicate or impose a mandatory requirement, "shall" is being replaced with "must." In every instance of its usage to disallow or prohibit an action, "shall not" is being replaced with "may not." The meaning of each provision being amended as described is not being altered by the change in verbiage. In other words, existing mandatory provisions are not being made permissive or optional, and existing prohibitions remain in effect.

Chapter 10. Testing Laboratories

Amend §15719. Residual Pesticides Testing.

Existing subsection (b) is amended to remove requirements regarding Category I pesticides because each pesticide listed in the consolidated table (discussed below) is being assigned a numerically quantifiable action level and the distinction between Category I and Category II pesticides is no longer relevant.

Existing subsection (c) is amended to remove the LOQ requirement for Category I pesticides because each pesticide listed in the consolidated table (discussed below) is being assigned a numerically quantifiable action level and the distinction between Category I and Category II pesticides is no longer relevant. This subsection is further amended to require licensed laboratories to establish an LOQ for each pesticide in the consolidated table. The LOQ, defined in section 15700(kk) as the minimum concentration of an analyte in a specific matrix that can be reliably quantified, is critical for ensuring that a given test is capable of accurately reporting the amount of a substance. The Department determined that requiring laboratories to be able to accurately quantify the presence of each pesticide at half of that pesticide's respective action level will ensure that testing results are accurate. The Department considered requiring LOQs between 50-100% of the action level, which would be easier for laboratories to achieve, but determined that due to existing allowable margins for error in accuracy and recovery, allowing higher LOQs may result in samples passing pesticide testing despite the presence of pesticides above the stated action levels. Requiring laboratories to establish LOQs at or below 50% of action levels eliminates this potential danger.

Existing subsection (d) is amended to refer only to the pesticide action levels in the consolidated table (discussed below). Subsections (d)(1) and (d)(2) are repealed. This is necessary because each pesticide listed in the consolidated table is being assigned a numerically quantifiable action level and the distinction between Category I and Category II pesticides is no longer relevant.

Existing subsection (e) is non-substantively reworded and relocated to appear before the consolidated pesticide table.

Finally, the two existing tables in section 15719 are being consolidated. The consolidated table includes the names of all pesticides required to be tested (column 1) and each pesticide's respective CAS number (column 2), action level for inhalable cannabis and cannabis products (column 3), and action level for non-inhalable cannabis products (column 4). Column 1 includes all 66 pesticides (Category I + Category II) listed in the existing tables, plus 11 additional pesticides for which DPR recommended testing and provided action levels. (Memo, Table 4, pp.15-19.) Further, DPR revised the action levels for 31 of the 66 existing pesticides. (Memo, p.20.) The Department defers to DPR's subject matter expertise regarding pesticide exposure and accordingly relies

on and incorporates the justifications provided in the Memo regarding the need to test for these 77 pesticides and to establish or revise their respective action levels, as applicable.

Column 1 also includes three pesticides (Fenobucarb (BPMC), Isoprocarb (MIPC), and Procymidone) for which DPR recommended testing but did not provide action levels. (Memo, Table 2, p.10.) DPR instead recommended that DCC prohibit the sale or distribution of cannabis with "any detectable residue of these pesticides." (Memo, p.10.) One of DPR's recommendations is to eliminate the "two-category system" in section 15719 in favor of establishing specific action levels for each pesticide. (Memo, p.11.) DPR explains that inherent in "detect/non-detect" testing is an increased chance of disparity between testing laboratories, as one laboratory may use analytical equipment that is less precise than another. (Id.) As previously stated, DPR recommended specific numerical action levels for 77 of the 80 pesticides for which the Department should require testing. However, the remaining three pesticides are essentially recommended to be treated as "Category I" pesticides. The Department considered postponing inclusion of these three pesticides in section 15719 until DPR provides numerical action levels but instead determined it necessary to include them now in furtherance of protecting public health. The Department believes it is reasonable and logical to establish these action levels using existing Category I testing requirements as a guide. Accordingly, since Category I pesticides currently have a required LOQ of 0.1 ppm, the Department is proposing to set the action level for these three pesticides at 0.1 ppm.

Amend §15731. Limits of Detection (LOD) and Limits of Quantitation (LOQ) for Quantitative Analyses.

Existing subsections (a) and (b) provide three optional methods of calculating the LOD and LOQ, respectively, for a given chemical analysis. When these options were adopted in 2017, California's commercial cannabis industry, including laboratory testing of cannabis and cannabis products, was in its infancy. At that time, options for calculating limits of detection and quantitation were considered necessary because there was insufficient evidence to support the adoption of one uniform, robust method. However, over the past eight years the Department has come to realize that the broad scope of the existing rule leads to variability in test results and increased disparity in the testing industry.

For example, the Department has determined that the calculation options in existing subsections (a)(1) and (b)(1) do not consider a test method's total performance, and that signal-to-noise ratio analysis is better employed in verifying the accuracy of LOD and LOQ values calculated pursuant to subsections (a)(2) and (b)(2), respectively. Similarly, existing subsections (a)(3) and (b)(3) reference federal "guidelines" that were useful tools available and loosely adaptable to the burgeoning commercial cannabis testing industry in 2017 but not designed or intended to be applied to cannabis testing. In general, these guidance documents provide examples and recommendations in lieu

of specific calculations or laboratory test procedures. The downside to offering broad guidelines and recommending best practices is that it allows for wide variation in laboratory operating procedures, which is antithetical to the Department's goals of standardizing and efficiently regulating all licensed cannabis testing activity in the state.

Another concern stemming from existing section 15731 is that some licensed laboratories use less rigorous methods of calculating LODs and LOQs. This practice represents a potential threat to public health from exposure to elevated levels of residual pesticides in cannabis goods.

Anecdotally, the Department has received stakeholder feedback echoing these concerns and requesting the adoption of standardized LOD and LOQ calculations. The Department is accordingly amending this section to ensure consistency and fairness in the industry by establishing one method of calculating an LOD, one method of calculating an LOQ, and additional verification requirements for both calculations.

Amended subsection (a) incorporates existing subsection (a)(2) to clearly require use of a single calculation for determining the LOD. The calculation is based on the test method's total performance, including the process of extraction of the analytes from a given matrix. The calculation is scientifically rigorous because it uses a statistical measure of the test method's total variability to determine the concentrations at which the test method will be able to detect a given analyte with 95% confidence. The calculation uses the statistical difference of the signals, as demonstrated by the required seven spiked blank samples and standard deviation, to predict the LOD concentration with 95% probability that analytes at the calculated concentration will be detected.

New subsection (b) establishes additional ongoing acceptance criteria requirements for LODs based on whether the chemical analysis is chromatographic. The Department is requiring an additional verification that the calculated LOD values meet a minimum signal-to-noise ratio of 3:1 because the generally accepted definition of a detectable signal in analytical chemistry is a signal that is distinguishable from noise in a ratio of 3:1. It is important that the LOD values that have been determined by the laboratory in the LOD calculation are reviewed against the signals produced by the instrument to ensure the values are achievable with the chosen instrumentation. In chromatographic analyses, signals from instrumentation are graphically represented as peaks that must be verified by visually comparing them to the noise at their respective heights. In non-chromatographic analyses, signals are displayed as numerical values and therefore must be verified by software analysis or mathematical calculation. The failure to maintain a signal-to-noise ratio of 3:1 at the LOD significantly impairs the ability of the laboratory to report when an analyte is present and undermines the accuracy of the test method. Regular attention from laboratory staff is needed to maintain the required ratio, which is the basis for determining whether an analyte is present or not, both at the initial LOD determination and subsequently.

New subsection (c) incorporates existing subsection (b)(2) to clearly require use of a single calculation for determining the LOQ. The calculation is based on the test method's total performance, including the process of extraction of the analytes from a given matrix. The calculation is scientifically rigorous because it uses a statistical measure of the test method's total variability to determine the concentrations at which the test method will be able to measure a given analyte with 95% confidence. The calculation uses the statistical difference of the signals, as demonstrated by the required seven spiked blank samples and standard deviation, to predict the LOQ concentration with 95% probability that analytes at the calculated concentration are measurable.

New subsection (d) establishes additional ongoing acceptance criteria requirements for LODs based on whether the chemical analysis is chromatographic. The Department is requiring an additional verification that the calculated LOQ values meet a minimum signal-to-noise ratio of 10:1 because the generally accepted definition of a measurable signal in analytical chemistry is a signal that is distinguishable from noise in a ratio of 10:1. It is important that the LOQ values that have been determined by the laboratory in the LOQ calculation are reviewed against the signals produced by the instrument to ensure the values are achievable with the chosen instrumentation. In chromatographic analyses, signals from instrumentation are graphically represented as peaks that must be verified by visually comparing them to the noise at their respective heights. In non-chromatographic analyses, signals are displayed as numerical values and therefore must be verified by software analysis or mathematical calculation. The failure to maintain a signal-to-noise ratio of 10:1 at the LOQ significantly impairs the ability of the laboratory to report when an analyte is measured and undermines the accuracy of the test method. Regular attention from laboratory staff is needed to maintain the required ratio, which is the basis for determining whether an analyte is measurable or not, both at the initial LOQ determination and subsequently.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS, OR DOCUMENTS

1. Department of Pesticide Regulation Memorandum, Recommended Revisions to the Pesticide Action Levels for Testing Cannabis Products in California, December 18, 2024.

STANDARDIZED REGULATORY IMPACT ASSESSMENT

The Standardized Regulatory Impact Assessment ("SRIA") for this proposed action was performed by ERA Economics, LLC and is included as Attachment 1 to this statement of reasons.

CONSIDERATION OF ALTERNATIVES

The Department considered requiring laboratories to obtain ISO accreditation to test the 14 new pesticides and reaccreditation to test only those of the existing 66 pesticides that have revised action limits lower than the previous action limit of 0.1 µg/g. This alternative was rejected because the primary goals of this proposed action are to prevent licensed laboratories from falsifying or manipulating pesticide residue test results and ensure that products that reach consumers are safe for consumption. This alternative proposal would focus on the 14 new pesticides while maintaining the status quo for nearly all of the 66 existing pesticides, and as identified and discussed at length in this statement of reasons, maintaining the status quo ignores DPR's recommendations and is inadequate to regulate laboratories and protect consumers.