COMMENTS REGARDING PROPOSED REGULATION § 15712.2

Submitted by: Coverton Labs LLC, 31 Upper Ragsdale Drive, Suite 1, Monterey, CA 93940

I. SUMMARY

The Department of Cannabis Control (the "Department") proposes this new regulation "to ensure all licensed testing laboratories are using the same standardized cannabinoid test method to ensure consumers receive accurate and consistent information regarding the cannabinoid content of the cannabis and cannabis product they use or consume."

However, it is an open "secret" in California that cannabis product potency and possibly safety claims are routinely and sometimes wildly inaccurate, and that differing scientifically accepted methods are not the reason for inaccurate test results. Instead, inaccurate results are often due to labs purposefully using non-scientific methods to inflate results, mislead consumers, and create potentially unsafe products; these labs also use the inflated or fraudulent results to gain an unfair advantage in the marketplace and essentially price gouge the consumers. Certain labs simply fail, either willfully or negligently, to adhere to Department-approved SOPs. The Department has already developed and implemented processes through which it approves lab SOPs before a lab can begin operation, and those processes are suitable and adequate, provided the Department holds labs accountable for failing to adhere to them.

Furthermore, the regulation insufficiently accounts for the economic cost to currently operating labs of implementing the new rule. Not only does the Department's economic analysis underestimate the true cost of the proposed regulation, but it would moreover require many labs, including Coverton Labs, to purchase and employ equipment that is unnecessary under approved SOPs.

Coverton has concerns that this proposed rule is overly restrictive, discourages competition in a vibrant and varied marketplace, and is not sufficiently based on facts that are available to the Department but appear not to have been considered by the Department in formulating the proposed regulation. Promoting a uniform method may stifle innovation in a field of lab science that is at its beginning and is not necessary where various scientific methods produce sound results under the current regulation and approved SOPs.

Rather, greater consistency in testing results would be achieved by increased and regular inspection and accountability measures, including required access by consumers to the certificate of analysis ("CoA") on the product packaging at the dispensaries via QR codes, as well as severe penalties for labs that fail to adhere to their SOPs. In addition, the Department should require retesting above certain specified potency levels. The Department should actively monitor, sample, and test retail products and remove non-compliant products, holding their manufacturers,

testing labs, and distributors accountable for their non-compliance, or outsource verification and compliance measures to an independent third-party lab. Increased and regular inspection and sample testing by the Department will also lead to more consistent results by rooting out inaccurate or fraudulent testing results.

II. IMPLICATIONS OF THE PROPOSED RULE

Coverton Labs has several significant concerns about the proposed regulation. Although the regulation purports to resolve major discrepancies in results due to testing methods, the proposed regulation fails to sufficiently account for purposeful manipulation of data and use of improper deviations. Many labs that generate inaccurate or inconsistent testing results purposely or negligently fail to follow their SOPs. Such unscrupulous methods permit customers to "forum shop" and use only the labs that will guarantee a more favorable test result, regardless of the true cannabinoid measure. Given the higher price of higher potency cannabis, the end result of this fraudulent conduct is consumers paying higher prices. Improved inspections that account for varying methods would be a better method for protecting the public.

The Department purports to enact this regulation since, "[d]ue 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." While some variation in lab results will depend on the efficiency of the extraction, the brand of equipment, the individual technicians, and calibration of instruments, these slight differences do not amount to the drastic differences seen between the honest labs and the labs manipulating results.

Boiling down the solution to a single one-size-fits-all approach will stifle ongoing use of the several methods accepted by the scientific community for the accurate analysis of cannabinoids. For example, cannabinoids are terpenes which have been accurately and scientifically measured with chromatography for decades. This new regulation would curtail a tried-and-true method. Any lab that follows its SOPs – as approved by the Department after the Department's intensive review – and passes its proficiency tests should be deemed to be applying accurate and effective testing methods.

Coverton Labs furthermore has concerns that the methods required by the regulation are inefficient. This is important because in its current form the method required by the proposed regulation would at least double chemical waste production for many laboratories. Acetonitrile

has a poor extraction efficiency for cannabinoids compared to Methanol,[1] and sonicating in ice water will further inhibit the extraction efficiency. Currently our laboratory can achieve satisfactory extraction efficiency with lower levels of methanol per sample, so increasing this to 40mL extraction solvent would increase the volume of chemical waste produced during sample preparation for our laboratory substantially.

A. <u>The Department has miscalculated the economic impact of the regulation.</u>

The Department claims that "[t]he 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." This does not account for differences in test method resource efficiency.

For example, the proposed regulation would impose upon Coverton Labs an additional cost of 9.8mL of solvent per sample. Additionally, the solvent to be used according to the proposed SOP is 80% Acetonitrile compared to the 100% Methanol Coverton Labs uses. Methanol costs about $31/L and Acetonitrile costs about $140/L. An 80/20 ACN/MeOH mixture means the cost of the proposed solvent is 3.81x more expensive than our current solvent for the same amount of volume used. To test 100 samples a day for a year with our current methods this will require about 273L of Acetonitrile, 91L Water, and 546L Methanol. The same volume of testing with the proposed method will require about 931L Acetonitrile 25L Water 208L Methanol. This equates to an additional 254L of solvent throughout the year at an increased cost of $87.2/L. This would create an additional $81,642 annual cost for just solvent alone.

The proposed regulation also fails to fully account for any increased labor costs. Sample preparation in accordance with the proposed regulation would require Coverton technician to expend an additional 104 minutes for each analytical batch. Given five batches a day, this would equate to an additional 2,253.33 hours of additional time throughout the year. At an average technician cost of $25/hour, this would create at least an additional $56,333 increase in labor costs. Coverton would also have to pay increased energy costs. The proposed regulation would require Coverton to run its equipment three- to six-times longer than current methods.

If you also add the Department-projected additional cost of the liquid cryogens at around $10,000 per year, the minimum total increase in cost of testing cannabinoids would be $147,975/year given 100 samples/day. This is a conservative estimate, considering that many labs test more than 100 samples/day, and this does not include any of the additional consumables and equipment that should also be factored in – at minimum an increase of $3.57 each sample, burdening many ethical, compliant labs with a competitive disadvantage.

---

[1] Medical Marijuana Solvent Extraction Efficiency – Potency Determinations with GC-FID: https://www.restek.com/en/chromablography/chromablography/medical-marijuana-solvent-extraction-efficiency--potency-determinations-with-gc-fid/.

Additionally, the proposed regulation's requirements would increase hazardous chemical waste produced by laboratories because of implementation of the proposed method. For our laboratory this would be approximately 9.8mL per sample additional waste.

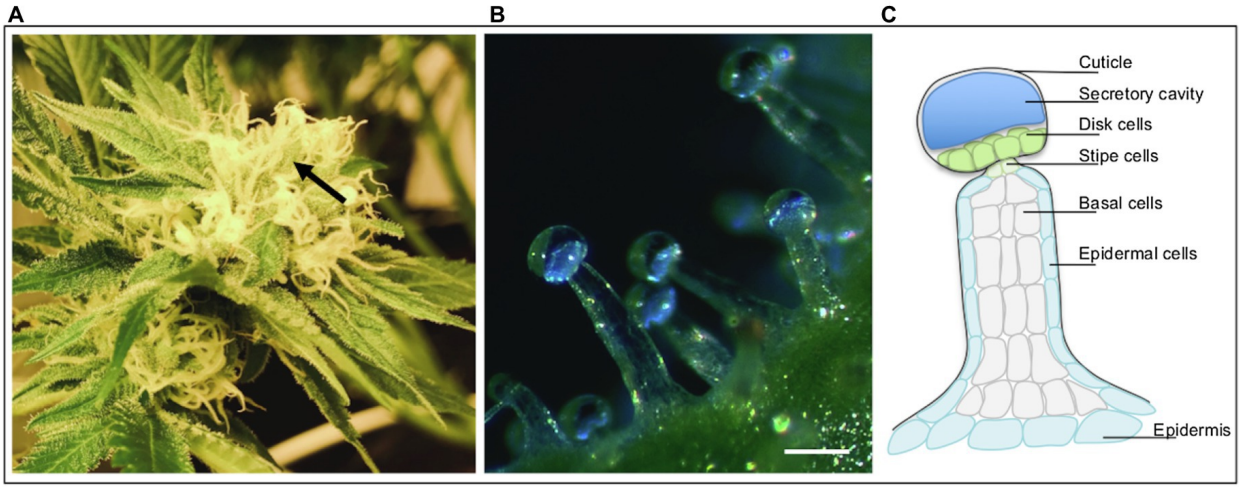
B. <u>The proposed regulation fails to consider the established science.</u>

Every licensed laboratory already has "[a] well organized, clearly written set of procedures" that has been reviewed and approved by the Department pursuant to Article 4 of Standard Operating Procedures §15711 of Laboratory Analyses Standard Operating Procedures. Most laboratories are likely using far more efficient cannabinoid extraction methods that are faster and more cost effective without sacrificing accuracy.

To catch bad actors, spot tests of products in dispensaries must be retested to show the major discrepancies between actual numbers and bad player lab results. There are many ways for laboratories to cheat outside the boundaries of the standardized method proposed. For example: if the technician preparing the calibration curves mixes them at lower levels, but reports mixing them at the correct levels, then all results produced will be inflated.

Based on our experience, there is an exceedingly low probability that 30% or more of the total mass of a non-concentrated flower product is THC when the active cannabinoids are only found in the small glandular trichomes on the flower sample. While it is possible to have different trichome concentrations across different cultivars, having a sample containing a majority amount of THC is unlikely. Cannabis plants produce a number of cannabinoids, terpenoids, and flavonoids, all located in the trichomes growing out of the cannabis flower. These molecules are all located in the secretory cavity of the trichomes of the flower.

As shown in the diagram below, these trichomes make up an incredibly small percentage of the overall inflorescence. There are 110 known different cannabinoids, over 120 different terpenes identified in cannabis plants, and over 20 different flavonoids. It is unrealistic to expect that genuine, correct lab methods would reveal that the small secretory cavities of the trichomes of the inflorescence of the plant contain enough of just two compounds – THC and THCA – to equal 30% of or more of the total weight of the flower.



https://www.frontiersin.org/articles/10.3389/fpls.2021.721986/full

A simpler method of catching bad actors would be if the state were to spot check packaged cannabis and remove products with fraudulent results from the shelves so they can be retested and relabeled with their true cannabinoid results, and the residents of California can receive honest and true reports of the levels of cannabinoids in their products.

Laboratories such as clinical laboratories performing toxicology, hematology, molecular and genetics testing and more, agricultural laboratories, soil and water testing laboratories, and water treatment laboratories all are allowed to have their own approved individual, non-standard testing methods. Why should the burgeoning field of cannabis science be any different?

C. Alternative compliance and accountability methods would be more easily implemented.

There is an "understanding" in the California market that distributors will not accept flower product with potency labeled less than 24%. A uniform testing method will not, therefore, necessarily yield accurate results but would burden labs with higher costs without any benefit to consumers. The Department should instead employ vigorous inspection and compliance regimes to ensure honest application of approved SOPs and to verify that labels and CoAs contain accurate information. In this connection, below are suggested methods for improved monitoring and enforcement of labs.

The first-proposed, more effective method to hold dishonest labs accountable would be to randomly test products taken directly off dispensary or wholesaler shelves to confirm that the value of cannabinoids falls within reasonable limits. The Department may choose to contract or partner with an independent lab or a group of laboratories to establish the known range of acceptable limits for cannabinoid test results. For samples falling outside these limits, suggesting

above ~30-32%THC, a retest by a different lab, and possibly an investigation, should be required.

Another alternative would be to assign Department employees to oversee specific labs to ensure proper quality control documentation and adherence to the approved SOPs. The Department employee could otherwise spot-check the lab processes during frequent and random inspections to ensure technicians are using the correct amount of sample and solvent. These inspections should also verify instrument calibrations and the homogenization process. Checks could be as often as one week, one month, or one quarter, and would occur at random.

Various other industries have third party "seals of approval" that are given to companies that adhere to industry standards. The cannabis industry could benefit from a program like this to allow consumers to see which brands and laboratories are within regulation. Seals of approval could be issued based on random spot testing of dispensary products. Instead of putting exact potency on the label, processors should be required to instead label product with different categories that indicate a range of potency, which would be also helpful to the consumer. The current requirements to declare a fixed potency are not especially helpful or realistic – as a natural product, percentages of various cannabinoids will inevitably vary from plant to plant, crop to crop.

See table below for possible format suggestions:

Potency Label on Product	Potency Range
Very Low	<7%
Low	7-13%
Average	13-20%
High	20-30%
Very High	>30%

While spot tests must be done at all labeled potency levels, if a flower sample tests above a certain threshold, ~30-32% THC, an automatic retest or investigation should be initiated.

Some manufacturers will print the label for the product and base the potency percentage on an QA CoA. Then a compliance CoA is issued, and as long as it is in 10% deviation from the label, the product is approved to be on the shelf. If a QR code that is linked to the compliance CoA is placed on the product (which was generally the practice until just recently, seemingly coinciding with the rapid escalation of sometimes wildly inaccurate potency claims), the

consumer could see the actual compliance CoA that is associated with the product rather than the label that could have been printed based on an QA CoA.

As the Department is aware, various constituent organizations have been requesting enforcement of existing regulations through third party testing and sampling for quite some time. *See* letter, dated December 17, 2021, from the Chairman of the American Council of Independent Laboratories and Member of the California Cannabis Working Group, attached hereto. Action on this front is long overdue.

III. CONCLUSION

The proposed regulations will not benefit California residents but will only further damage an already struggling market by causing excessive and unnecessary cannabinoid testing costs without achieving the touted benefit. Not only will the proposed regulation not help the problem of fraudulent THC results, it will create unnecessary excessive costs in energy, resources, and time for many laboratories. Many different methods are valid for the testing of cannabinoid percentages in cannabis, and differences in method efficiency are what allow for free market competition. Optimization of methods is what allows laboratories to increase their efficiency and reduce consumption of hazardous materials. Greater oversight and enforcement by the Department will result in scientifically reliable and accurate testing, and remove potency fraud from the market, thereby protecting consumers from artificially high pricing and potentially adverse health consequences.

ACIL
CALIFORNIA CANNABIS WORKING GROUP

December 17, 2021

Nicole Elliott
California Department of Cannabis Control
2920 Kilgore Road
Rancho Cordova, CA 95670

Dear Director Elliott,

I write today regarding California's Cannabis Advisory Committee (CAC) and the current application and selection process. We were gratified to see notice of the opening of the application for all current seats on the Committee from the Department of Cannabis Control (DCC) this month.

In a message earlier this year to the Director of Consumer Affairs, we advocated for the inclusion of independent or third-party testing, sampling, accreditation, or certification entities on the Committee. The absence of participation from any of these critical consumer safeguard bodies presents a significant "hole" in the ability of the Committee to fulfill its mission.

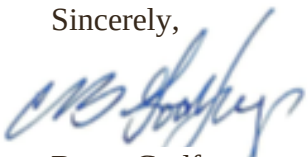
As you know from our previous interactions with the DCC, American Council of Independent Laboratories (ACIL) California Cannabis Working Group (CA-CWG) is dedicated to the highest testing and safety standards in the cannabis industry. Building upon decades of experience in the laboratory testing space nationwide, our members are involved in testing, product certification, consulting, and research and development to enhance public health and safety. ACIL members are accredited, periodically inspected laboratories that have high-level quality management systems in place to ensure that they generate quality data and have demonstrated a long history of operating in a professional manner.

We are aware that the Cannabis Advisory Committee advises the DCC on the development of regulations that help protect public health and safety and reduce the illegal market for cannabis. The Committee's role directly aligns with CA-CWG's purpose and the participation of any of our members would greatly enhance that mission for the state. In fact, we believe that the omission of participation from any of the bodies tasked with the independent verification of the safety and quality standards of cannabis products on the market was an error in the formation of the original CAC.

Our members would contribute a perspective that is currently absent on the Committee as you work to advance the health and safety of public in California. We strongly encourage the DCC to include our members, who have gone above and beyond to advocate for the highest standards with their involvement in the CA-CWG, in the newly appointed 2022 Cannabis Advisory Committee.

Thank you for your time and attention. Please do not hesitate to call upon us.

Sincerely,



Bruce Godfrey
Chairman, ACIL
CA-CWG Member