CALIFORNIA CANNABIS INDUSTRY ASSOCIATION

**PUBLIC COMMENTS TO BCC**

The California Cannabis Industry Association (CCIA) was formed to unite the legal cannabis industry to help educate and act as a resource to lawmakers and our members. Our unified voice includes over 460 California businesses representing nearly 650 brands and approximately 10,000 employees. We would like to thank the California Bureau of Cannabis Control (BCC) for their hard work in crafting the proposed draft permanent regulations. We appreciate the time and diligent efforts the BCC has extended to address the concerns of the cannabis industry as well as ensuring the safety of patients and consumers of cannabis products.

Among the key priorities addressed under the leadership of the BCC are the elimination of the A-Type and M-type licenses and, more recently, the BCC's clarification that licensed delivery operators may deliver to patients and consumers residing in banned jurisdictions.

The elimination of A-Type and M-Type licensure requirement was a critical priority for CCIA. Allowing licensees to engage in commercial cannabis activities with any licensee, regardless of designation, reduces operator costs; improves efficiency; and promotes access by ensuring cannabis and cannabis products are available to patients. We are grateful the regulators and the administration demonstrated the leadership to make this change in the re-adoption of the emergency regulations in June 2018.

We are also grateful that the BCC has taken the necessary steps to eliminate "access deserts" across the state by the expansion of delivery to all jurisdictions under proposed Chapter 3 section 5418 (c). We appreciate the fact the regulators and the state are meeting the needs of the industry while providing access to patients and consumers across the state.

CCIA, representing a collective group of California cannabis industry businesses and its customers, along with our supply chain committees and Board of Directors, would like to take this opportunity to submit this comment to the draft permanent regulations.

These comments seek to optimize the draft permanent regulations by addressing the business concerns of the cannabis industry as well as clarify public safety issues. The objective is not to reject regulation but rather to enhance regulations to combat the illicit market and support the newly regulated cannabis industry, pushing it towards success both commercially as well as maintaining patient and consumer safety.

In implementing the draft permanent regulations we ask that the BCC be thoughtful of the industry as a whole. While there are some large commercial cannabis businesses, many are small and independently operated, and new to regulated markets. CCIA has found its members are eager to comply with issued regulations but at the same time overwhelmed by the financial and logistical burdens of implementation.

We thank the BCC for its review and objective consideration of these comments.

**SUMMARY of COMMENTS**

1. Section 5040. "Advertising Placement"
2. Section 5407. "Sale of Non-Cannabis Goods on Premises"
3. Section 5413. "Exit Packaging"
4. Section 5416 (d). "Delivery to a physical Address"
5. Section 5418 (c). "Cannabis Goods Carried During Delivery"
6. Section 5427 (a). "Retailer Premises to Retailer Premises Transfer"
7. Section 5050 (d). "Loss of Access"
8. Section 5730 (h)."Eliminate requirement for replicate re-tests of failed samples if laboratory quality control (LQC) samples meet acceptance criteria"
9. Section 5726(e)(5). "Eliminate the requirement for testing laboratories to substantiate label claims"
10. Section 5713(H). (2) "Revise acceptance criteria for percent recovery to 70%-130% for all LQC samples"
11. Section: 5718(c). "Eliminate minimum limits of quantification (LOQ) and replace with specific action levels (pass/fail)"
12. Section 5705. "Bulk batches of concentrate/distillate should be considered to be in final form prior to packaging to avoid issues of packaging breakdown"
13. Section 5726(d)(10). "Eliminate product density requirements from testing labs"
14. Section 5724(d)(1). "Increase variability requirements regarding acceptance criteria (20% for cannabinoids; 25% for terpenoids)"
15. Provide basic guidelines for visual inspection testing
16. Section 5728(a). "Reduce sample storage time until it can be established that all analysis can be performed reproducibly on samples stored beyond this time frame"
17. Section 5705(a). "Remove constraints on testing laboratories to conduct all required testing in a single licensed facility"
18. Additional Recommendations:
    a. Supply Chain Sampling
    b. Compassionate Care Programs
    c. Research & Development

**1. Section 5040. "Advertising Placement"**

Section 5040 states the following:

*(a) Any advertising or marketing, as defined in Business and Professions Code section 26150, that is placed in broadcast, cable, radio, print, and digital communications:*

*(1) Shall only be displayed whereafter a licensee has obtained reliable up-to-date audience composition data demonstrating that at least 71.6 percent of the audience viewing the advertising or marketing is reasonably expected to be 21 years of age or older, as determined by reliable up-to-date audience composition data; and;*

*(2) Shall not use any depictions or images of minors under 18 years of age.*

*(b)(3) Shall not contain the use of objects, such as toys, inflatables, movie characters, cartoon characters, or include any other display, depiction, or image designed in any manner likely to be appealing to minors under 18 years of age; and*

*(4) Shall not advertise free cannabis goods or giveaways of any type of products. This includes promotions such as:*

*(A) Buy one product get one free;*

*(B) Free product with any donation; and*

*(C) Contests, sweepstakes, or raffles.*

*(b) In addition to the requirements for advertising and marketing in subsection (a) of this section, all outdoor signs, including billboards, must be affixed to a building or permanent structure. All outdoor advertising must be in compliance with the Outdoor Advertising Act, commencing with section 5200 of the Business and Professions Code.*
*(c) For the purposes of this section, "reliable up-to-date audience composition data" means data regarding the age and location demographics of the audience viewing a particular advertising or marketing medium. "Reliable up-to-date audience composition data" does not include data from the most recent United States decennial or special census, or the annual population estimate for California counties published by the Demographic Research Unit, State Department of Finance.*
*(d) Immediately upon request, a licensee shall provide to the Bureau audience composition data as required in subsection (a) of this section for advertising or marketing placed by the licensee. This information shall be provided to the Bureau within the time specified by the Bureau.*
*(e) If the Bureau determines that audience composition data for advertising or marketing provided by a licensee does not comply with the requirements of subsection (a) of this section, or the licensee fails to provide audience composition data to the Bureau within the time specified by the Bureau upon request, the licensee shall remove the advertising or marketing placement in question.*
*(f) In construing and enforcing the advertising provisions of the Act and this division, any action, omission, or failure of an advertising agent, representative, or contractor retained by the licensee, shall in every case be deemed the act, omission, or failure of the licensee.*

**Comment:**
CCIA wholeheartedly supports the requirement that cannabis products be marketed and sold solely to adults and that restrictions on access to minors under 21 years of age not be only encouraged but strongly enforced. At the same time we believe that section 5040, as currently drafted, is overly restrictive on what constitutes appropriate business activities.

The previous draft regulations were clear that the sale of cannabis products to minors was strictly prohibited. However, under the draft permanent regulations, common business practices such as promotions to provide permitted non-cannabis marketing collateral would be prohibited. Further, requiring that signage be affixed to "a building or permanent structure" unnecessarily hinders pop-up venues otherwise in compliance with the Outdoor Advertising Act and restricts businesses already licensed by the BCC as temporary events. For these reasons, we believe that the proposed permanent regulations are overly restrictive and in need of further modifications.

**Recommendation:**
CCIA recommends that the BCC adopt the language contained in the re-adopted emergency regulations of June 6, 2018, which we believe adequately safeguards against exposing cannabis to underage minors, while allowing the responsible promotion of cannabis and cannabis products.

**2. Section 5407. "Sale of Non-Cannabis Goods on Premises"**
Section 5407 states the following:
*In addition to cannabis goods, a licensed retailer may sell only cannabis accessories and any licensee's branded merchandise or promotional materials.*

**Comment:**
The proposed language restricts retail business operations by removing products and services from sales that have traditionally been a part of retail storefronts, including the sale of books and educational materials as well as wellness services and classes. Licensed retail businesses must be able to provide related sales and services that strengthen consumer loyalty and provide

appropriate education. Permitting such activities will allow licensed retail operators to maintain existing services germane to the cannabis industry.

**Recommendation:**
CCIA supports maintaining the language contained in section 5407 as re-adopted in the emergency regulations on June 6, 2018.

### 3. Section 5413. "Exit Packaging"

Section 5413 states the following**:**
*Cannabis goods purchased by a customer shall not leave the licensed retailer's premises unless the goods are placed in a resealable child-resistant opaque exit package.*

**Comment:**
Further legitimizing the regulated market requires the industry to support best practices that promote public safety and comply with mandated regulations set forth by our licensing entities. In furtherance of these goals, the California cannabis industry responded to and conformed with multiple iterations of child resistant packaging regulations aimed at keeping cannabis and cannabis products out of the hands of underage minors.

CCIA remains strongly committed to adhering to strict CRP requirements and has been working with the licensing entities to meet the following objectives.

1. Ensure that strict child resistant packaging (CRP) requirements are maintained;
2. Encourage the use of environmentally sustainable CRP alternatives that support our state's environmental objectives, including the reduction of unnecessary landfill waste;
3. Promote consumer education programs on appropriate storage and use;
4. Minimize costly and burdensome requirements on the cannabis industry; and
5. Protect cannabis businesses from undue liability.

**Recommendation:**
CCIA supports section 5413, which requires the use of resealable child-resistant opaque exit packages at the retail level. We also support efforts that encourage 1) the use of recyclable and/or biodegradable exit bags by January 1, 2022; 2) the development of a robust consumer education program to promote responsible cannabis storage and use that deters underage access; and 3) efforts aimed at protecting cannabis businesses from strict liability in the event that consumers misuse or abuse purchased cannabis and cannabis products.

### 4. Section 5416(d). "Delivery to a Physical Address"

Section 5416(d) states the following:
*(d) A delivery employee may deliver to any jurisdiction within the State of California.*

**Comment:**
CCIA members believe that 5416(d) clarifies that a licensed retailer who performs delivery may deliver to any jurisdiction within the State of California and reduces uncertainty for businesses, consumers as well as law enforcement. This interpretation is pursuant to B&P Section 26090(e). Increasing accessibility to the regulated cannabis market will reduce demand for products from the unregulated market. We believe that proper regulations for all delivery services provides a level playing field.

**Recommendation:**
CCIA strongly supports the recommended changes to section 5416(d) and thanks the BCC for this important amendment, which will remove barriers to access to safe, quality cannabis and cannabis products in local jurisdictions that currently ban commercial cannabis activity.

**5. Section 5418(c). "Cannabis Goods Carried During Delivery"**
Section 5418(c) states the following**:**
*(c) A retailer's delivery employee shall not leave the licensed premises with cannabis goods without at least one delivery order that has already been received and processed by the licensed retailer.*

**Comment:**
CCIA supports the concept of technology platforms and dynamic delivery, but believes that public trust and safety must always be the number one priority. The lack of regulatory oversight of technology platforms operating in the dynamic delivery cannabis space has become a major concern for the majority of our members.

Since the roll-out of the state licensing framework in January 2018, retail delivery operators have faced significant challenges. Access to consumers has been undermined due to a strict interpretation of existing law by local governments that has precluded access to customers in banned jurisdictions. Such obstacles have been exacerbated by the use of dynamic delivery, which has been largely promoted by technology platforms. This model has encouraged unfair competition and created an un-level playing field for licensed delivery operators. Larger companies with more resources will have a distinct advantage if the current language persists.

While CCIA represents companies of all sizes, we are keenly aware of the challenges the dynamic delivery model has created for licensed operators and are concerned that the very companies that helped build a legal and regulated industry might have a very difficult time competing should this model be allowed to continue absent of being subject to the same state licensing and regulatory requirements.

**Recommendation:**
CCIA is supportive of dynamic delivery, but is concerned that the current regulations do not offer the appropriate oversight and safeguards to ensure public safety. CCIA recommends that the administration and regulatory authorities regulate all tech platforms that operate in the dynamic delivery cannabis space as all other operators complying with state regulations. Providing regulations to establish a level playing field for new as well as existing operators will promote commercial activities in an unbiased manner while safeguarding the public and quality of cannabis products overall.

**6. Section 5427(a). "Retailer Premises to Retailer Premises Transfer"**
Section 5427(a) states the following:
*(a) A licensee who holds multiple retail licenses may arrange for the transfer of cannabis goods from one licensed retail premises to another licensed retail premises if both retail licenses are held under the same ownership.*

**Comment:**
CCIA requests clarification with regard to subsection (a). Specifically, clarification of the phrase "may arrange." Given that the regulations are set up to require distributors to transport products to retailers, is this meant to require that a distributor arrange the transport?

**Recommendation:**
CCIA recommends that retailers have a distributor transport license in this limited instance, as any cannabis products that are moving between a retailer's licensed retail locations would have already been delivered by a distributor that has conducted the appropriate quality control requirements.

**7. Section 5050(d). "Loss of Access"**
Section 5050(d) states the following:
*(d) A licensee shall not transport, transfer, receive, or deliver any cannabis goods until such time as access is restored and all information recorded in the track and trace system.*

**Comment:**
Subsection (d) will unquestionably have unintended consequences resulting in shutting down the entire legal marketplace. METRC *will* inevitably experience technical difficulties resulting in a system wide shut down. In an industry of unknowns, one constant is that all technology providers experience technical difficulties. California is arguably the largest cannabis market in the world and its operators would be crippled and paralyzed should a shutdown of the METRC system occur. An example of a system shut down involving METRC occurred in Maryland with approximately 47,000 patients, a fraction of the consumers in California.

Here in California we are looking at an enormous amount of data being uploaded with 50+ data points required across five license categories, with various sub-licensing categories, coupled with significant amount of back stock inventory and a system that is continuing to generate data.

**Recommendation:**
CCIA recommends striking section 5050 (d) as technology will, at some point, fail and cause delays of an unknown amount of time.

**8. Section 5730(h). "Eliminate requirement for replicate re-tests of failed samples if laboratory quality control (LQC) samples meet acceptance criteria"**
Section 5730(h) states the following:
*(h) If any analyte is detected above any action level, as described in this chapter, the sample shall be re-prepped and reanalyzed in replicate within another analytical batch.*
*(1) For quantitative analyses, the re-prepped sample and its associated replicate must meet the acceptance criteria of RPD ≤30%.*
*(2) For qualitative analyses, the re-prepped sample and its associated replicate results must concur.*

**Comment:**
Additional testing on failed samples puts an undue burden on not only customers but also on testing laboratories. Samples that fail regulatory testing are not released for public consumption therefore re-testing is superfluous and does not enhance public safety. Further, if a sample fails regulatory testing it is highly unlikely that a customer will be willing to bear the cost of replicate testing. This cost therefore would unavoidably fall to testing labs. Testing labs in California are struggling to meet not only market demands but to encourage customers to actually test cannabis products in compliance with California mandated requirements. Cost for testing previously failed samples would put an extreme financial burden on already strained testing laboratories.

**Cost Impact:** Cost impact of repeat testing to testing labs is significant. Customers who fail compliance testing will be extremely unlikely to agree to pay for further testing thus the cost would be borne by the testing labs. For every failed sample the cost burden increases as the laboratory

must add two additional tests for every type of analyte that fails. The cost could be contained by eliminating the requirement to test failed samples.

**Market Impact:** Repeat testing would cause turn-around times for impacted samples to increase substantially as any sample that fails compliance testing on even a single analyte must now be re-prepped and re-analyzed twice in a new batch with its own set of laboratory quality control (LQC) samples. This increase in time will impact safe cannabis products entering the market as well as negatively impact the regular supply chain. Delays in bringing safe and compliant product to market may continue to support the illicit market while burdening testing labs and their customers.

**Recommendation:**
Failed regulatory samples will never be released for public consumption. Thus, requirements to retest failed regulatory samples is not only costly but unneeded to support public safety. If an LQC sample meets acceptance criteria but otherwise fails no additional re-testing should be needed. The QC Committee recommends that the Final Regulations and section 5730(h) reflect this.

**9. Section 5726(e)(5). "Eliminate the requirement for testing laboratories to substantiate label claims"**
Section 5726(e) states the following:
*(5) For representative samples obtained from a cannabis goods batch to which a content label is affixed at the time of sampling, the laboratory shall report the following on the COA: (A) The cannabinoid content and terpenoid content as printed or written on the label that is affixed to the cannabis goods batch; (B) The cannabinoid profile and the terpenoid profile of the representative sample as determined by the laboratory as required under section 5724 and section 5725 of this division, respectively; and (C) The difference, in percentage, between the cannabinoid content and terpenoid content as printed or written on the label and the cannabinoid profile and the terpenoid profile of the representative sample, if any, as determined by the laboratory.*

**Comment:**
Label claim verification should not be the responsibility of testing laboratories. The role of testing labs is to certify the content of products specifically relating to safety and quality. In other industries, including pharmaceuticals and agricultural products, there are very specific label claim regulations and the verification of these claims are certified by an accredited body or the entity issuing permits/licenses. The legal liability of performing label claim verifications and failing licensees based on label claims should not be the purview of testing labs. Testing labs should focus on ensuring the production of efficient and accurate test results without having to verify commercial claims made by manufacturers.

**Cost Impact:** If testing labs are legally responsible for label verification, the cost of testing will reflect such a responsibility. This will increase costs for laboratories to hire additional resources to address label verification issues as well as passed to the end customer thus increasing the overall costs on an already struggling new industry. These increase costs may ultimately lead to less testing as customers decide to flout testing regulations in order to conserve costs thus propagating the illicit market. Finally, products that pass compliance testing but fail label claims will result in a significant increase in cost and time delays for release to market since the product will have to be re-labelled and re-tested for compliance.

**Market Impact:** The verification of every label claim is a time-consuming process that is difficult to automate or perform high-throughput analysis since every product will have different types of labeled claims. Lack of automation makes the entire label verification process entirely manual.

Manual processing will significantly increase release time for products and slow the overall cannabis supply chain.

**Recommendation:**
Laboratories should focus on safe and efficient testing of cannabis products. The attention should be on the verification of cannabinoid and terpenoid content in mg/g as stated in regulations and testing for analytes that may impact the safety of the product. All other label claim verifications would add an unnecessary burden on the labs and slow the cannabis supply chain. To ensure accuracy and ensure consumer transparency, commercial product claims need to be verified but outside of the testing laboratories. We recommend revising the Final Regulations and section 5726(e) to remove label verification from testing laboratory duties.

**10. Section 5713(H). (2) "Revise acceptance criteria for percent recovery to 70%-130% for all LQC samples"**
Section 5713(H)(2) states the following:
*(2) The laboratory shall use certified reference materials, to validate the following chemical analyses. The test method used for analysis is valid if the percent recovery of the certified reference material is between 80% to 120% for all required analytes.*

**Comment:**
However, we note that Section 5730 (g), in contradiction to section 5713(H)(2) above, contains a table that states that acceptance criteria for percent recovery in laboratory control samples is 70%-130%.

We are in agreement with the table in section 5730(g) and that the acceptance criteria should be 70&-130%. It is of utmost importance to increase the overall variability requirements and widen the acceptance criteria. It is noted that other state programs have utilized a wider variance acceptance criteria without issue[1]. Thus, increasing the acceptance criteria to 70%-130% is supported. Further, acute toxicity studies have shown that it is highly unlikely if not "virtually impossible" to die from acute administration of marijuana or tetrahydrocannabinol (THC)[2]. With the current overly restrictive acceptance criteria, otherwise safe and quality products will be rejected and thus destroyed. The current requirements are unnecessarily narrow compared to other industries, for example agricultural products, and can be safely widened without impacting quality or safety. A more realistic acceptance criteria of 70%-130% is both supported in the industry and would ensure a robust supply chain of tested products.

**Market Impact:** Narrow acceptance criteria will lead to delays in samples passing compliance and QC checks and greatly increase the testing bottlenecks. Many samples that would be considered safe would not be failed leading to potential compliant product shortages and slow the overall testing process.

**Recommendation:**
The acceptance criteria for percent recovery should be 70%-130% for all LQC samples. No impact to product safety is anticipated with this change. We recommend the Final Regulations reflect this and that section 5713(H) be amended to reflect the range identified in section 5730(g).

[1] Oregon regs for a Control Study (Oregon Health Authority, Public Health Division - Chapter 333, Division 7, Marijuana Labeling, Concentration Limits and Testing, 333-007-0430, Standards for THC and CBD Compliance testing.
[2] See Animal data. Pain Res Manage. 2005;10(Suppl A):23A–6A.

**11. Section 5718(c). "Eliminate minimum limits of quantification (LOQ) and replace with specific action levels (pass/fail)"**

The regulations specify that there should be minimum LOQ requirements for category 1 residual solvents and pesticides.

Section 5718(c) states:

*(c) The laboratory shall establish a limit of quantification (LOQ) of 1.0 µg/g or lower for all Category I Residual Solvents or Processing Chemicals.*

Section 5719 (c) states:

*(c) The laboratory shall establish a limit of quantification (LOQ) of 0.10 µg/g or lower for all Category I Residual Pesticides.*

However, specific action levels or pass/fail criteria is stated as being based on LOD. Section 5719 (b) states:

*(b) The laboratory shall report whether any Category I Residual Pesticides are detected above the limit of detection (LOD)…*

Section 5718 (d) (1) states:

*(1) The presence of any residual solvent or processing chemical listed in the following tables in Category I is not detected, and*

Section 5719 (d) (1) states:

*(1) The presence of any residual pesticide listed in the following tables in Category I are not detected, and*

**Comment:**

**Cost Impact**: Samples are more likely to unnecessarily fail compliance testing using an LOQ method rather than minimum action levels. This can severely impact not only the cost of goods for consumers but also increases testing costs for customers and resource needs for testing labs. In addition, samples will have a greater chance of failing at labs with higher sensitivity limits causing customers to forum shop for labs with less sensitivity limits. This hurts not only the testing laboratories and encourages labs to offer less sensitive testing methods but hurts consumers and the quality of cannabis products overall.

**Market Impact:** Two issues are presented with the current regulation text. First, labs that have more sensitive LOQ detection than those required by regulations will be boycotted by customers since labs with more sensitive detection systems may be harder to pass. This will result in 'forum' shopping and labs with less sensitive equipment will receive more customers and inappropriately sway the industry. Establishing action levels (i.e. pass/fail criteria) rather than minimum LOQ will address this issue. Secondly, LOQ is statistically a better value than LOD to utilize in failing samples since the confidence level in detection and quantification in the presence of various matrix effects is higher. In the current testing environment, a variety of matrices are being submitted and not all the matrix effects/interferences have been defined. These effects significantly reduce the confidence level of detection at LOD.

**Recommendation:**

Specific action levels should be instituted rather than minimum LOQ requirements. Further, the pass-fail criteria should be based on the statistically more significant LOQ values rather than LOD values. We recommend revising the Final Regulations to reflect this and update sections 5718 and 5719 to reflect this.

**12. Section 5705. "Bulk batches of concentrate/distillate should be considered to be in final form prior to packaging to avoid issues with packaging breakdown"**

The Quality Control Committee and CCIA support the proposal that a product may be considered to be in its 'final form' prior to packaging (at the distributor) as long as the distributor agrees not to add to or tamper with the product aside from packaging it after it is tested. (see §5705 of the proposed permanent regulations) This is especially applicable to products in cartridges and other hard container materials.

Other industries, such as pharmaceuticals and agriculture, quality test product prior to packaging. This allows for clean sampling, reduction in waste and efficiency in sample preparation. Breaking, smashing or crushing glass and other materials to retrieve sample material places laboratory employees at risk and increases the chance of cannabis material being inappropriately displaced. Testing prior to final packaging eliminates these risks and provides for cleaner and more efficient sampling. To address the issue the BCC could require (i) an attestation by the distributor that no additions or changes have been made to the product after testing or (ii) scheduled spot-checks of packaged product.

**Cost Impact:** The cost of breaking down packaging is significant both in terms of the manufacturer cost of goods as well as the laboratory man-hours required. Eliminating breaking down packaging could have a positive impact on overall testing cost that could be passed to the distributor customer.

**Market Impact:** Testing turn-around time would decrease with the elimination of final package breakdown by the testing laboratory. Since package breakdown cannot be automated, additional manual resources are required to extract the needed sample material prior to testing. This is time consuming and expensive as well as increases the chance of potential injury to testing lab employees. Without product packaging, testing would occur on the bulk product without the need to breakdown packaging materials freeing up both labor and other resources. Moreover, using bulk product would result in better homogenized sampling and lead to more accurate testing results as there would be less chance for human error trying to homogenize multiple packaged products into an appropriate sample.

**Recommendation:** Bulk batches of concentrate/distillate should be considered in final form prior to packaging. This would allow sampling and testing to be conducted on bulk product, support more accurate testing and reduce the time and resources needed to breakdown and destroy packaging material. We recommend that the Final Regulations clearly reflect this.

**13. Section 5726(d)(10). "Eliminate product density requirements from testing labs"**

Section 5727(d)(10) states that the COA must contain:

*(10) Measured density of the cannabis goods;*

The density of a product has no bearing on the safety and quality of the product. Most analysis that are required in the regulation require reporting on a per gram basis. Density is a physical characteristic that must be established by manufacturers not the testing lab. With the large variety of matrices in cannabis, a testing lab would have to incorporate several instruments in order to accurately determine the density. While it may have merit to determine density for free-flowing liquids such as tinctures, it is very difficult for solids and concentrates and should not be the responsibility of testing laboratories.

**Cost Impact:** The density measurement now requires additional instrumentation which adds to the overall cost of testing. This additional cost is not supported by reducing safety concerns as density does not correlate to the overall safety of a product.

**Market Impact:** All the instruments utilized for determination of density are not made for high throughput analysis. Each sample would have to be individually tested to determine density and cannot be batched. This would add a significant amount of time for processing each sample, slowing product release.

**Recommendation**: Any tests that do not directly impact that safety or quality of a product should not be added as a regulatory requirement for testing laboratories. Laboratory testing in the emerging regulated cannabis industry is already challenging without the addition of unnecessary tests so we recommend that section 5727(d) (10) be amended to remove the density testing requirement.

**14. Section 5724(d)(1). "Increase variability requirements regarding acceptance criteria (20% for cannabinoids; 25% for terpenoids)"**

Section 5724(d)(1) states the following:

*For edible cannabis products with a cannabinoid serving size greater than 5.1 mg, and for all cannabis goods, the concentration of any one cannabinoid shall not exceed the labeled content of the cannabinoid, plus or minus 10%.*

Section 5725 (c) states:

*(c) The sample shall be deemed to have passed the terpenoid testing if the concentration of any one terpenoid, claimed to be present at 5% or greater of the total terpenoid profile, does not exceed the labeled content of the terpenoids, plus or minus 10%.*

Although the tiered acceptance criteria for cannabinoid content in edibles considers for variability at low levels, 10% is too narrow a criterion for all cannabis products. Errors and inter-lab variability alone can account for 10% variability which leaves manufacturers with no room for error, even when that error presents minimal safety risks. Terpenoids (and solvents) are quite volatile, and the concentration of these volatile analytes can change substantially with any atmospheric exposure. Therefore, it is extremely important to consider increasing the overall variability requirements and widening the acceptance criteria so that safe samples are not unnecessarily rejected by extraneous factors.

The FDA Guidance on bioanalytical methods validation suggests that the precision determined at each concentration level should not exceed 15% of the coefficient of variation (CV) except for the Lowest Limit of Quantitation (LLOQ), where it should not exceed 20% of the CV.

In the BCC's Initial Statement of Reason, the section pertaining to the tolerance level, the following is stated:

*A tolerance of plus or minus 10% variance protects consumers while allowing for variation in manufacturing processes. (115) Proper labeling is critical to ensuring that cannabis users are sufficiently informed of product potency and can make informed decisions when purchasing cannabis*

*goods. Requiring cannabis goods to be within plus or minus 10% of their labeled content is not an unreasonable variance.*[3]

Cannabis is a plant-based material thus comparing cannabis based products to pharmaceutical powder blends with manufactured active pharmaceutical ingredient (API) is inaccurate and does not consider the variability associated between batches of plant material, extraction process, distillation, etc. While there are some correlations between cannabis products and pharmaceuticals this is not an area where direct comparisons apply or are even appropriate.

**Cost Impact:** With lower variability requirements, samples would fail label claims more often which would result in re-labeling and possible re-testing. These measures are expensive and overly burdensome on the market

**Market Impact:** Samples that fail label claims but pass all compliance testing relating to safety would be delayed in getting to market. There would be delays in labeling as well as testing time that would substantially slow the regulated cannabis supply chain.

**Recommendation:** In order to pass cannabinoid and terpenoid testing, the acceptance criteria for label claims should be increased to at least 20% for cannabinoids and at least 25% for terpenoids. This would eliminate the need for tiered acceptance criteria for edibles and not present safety issues for consumers. As testing becomes more standardized and the manufacturing practices become more consistent, these criteria can continue to evolve. In the current atmosphere, however, the existing criteria would have a negative impact on the industry by increasing cost and delaying the smooth supply chain flow. We recommend that the Final Regulations reflect the proposed increase to testing criteria.

## 15. Provide basic guidelines for visual inspection testing.

Since foreign material testing is not a quantitative assay with any specific analytes or target compounds, there are concerns that requiring visual testing would be difficult to standardize since it would be extremely subjective and prone to biases of the tester. Concerns also arise with potential quantification of particulates without standard measures and consistent documentation for Individual results.

**Cost Impact:** If testing laboratories are legally responsible for visual testing verification, additional equipment would be needed as well as additional human resources and internally processes and documentation. These costs would be passed onto consumers increasing the overall testing costs without adding any uniform safety parameters.

**Market Impact:** Additional instrumentation would be needed to conduct these visual tests increasing set-up costs for the testing laboratories. Labs may not want to incur these costs leading to inaccurate and extremely subjective visual test results. Distributors would end up seeking out laboratories with less sophisticated equipment thus skewing the testing market and results.

[3] Center for Drug Evaluation and Research (CDER), U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry: Powder Blends and Finished Dosage Units — Stratified In-Process Dosage Unit Sampling and Assessment (Oct. 2003) Pharmaceutical Current Good Manufacturing Practices (CGMP) (as of Mar. 30, 2017).

**Recommendation**: Objective standards and uniform guidelines for visual inspection should be implemented prior any mandates to testing laboratories to perform visual testing. It is recommended that a general visual inspection at the distribution facility occur prior to release to the testing laboratory. The distributor is much better equipped to make the visual inspection and it would reduce cost and testing time for the testing laboratories. We recommend the removal of visual inspections from testing laboratory requirements.

**16. Section 5728(a). "Reduce sample storage time until it can be established that all analysis can be performed reproducibly on samples stored beyond this time frame"**

Section 5728 (a) states the following:

*(a) The laboratory shall retain the reserve sample, consisting of any portion of a sample that was not used in the testing process. The reserve sample shall be kept, at minimum, for 45 business days after the analyses, after which time it may be destroyed and denatured to the point the material is rendered unrecognizable and unusable.*

According to current Environmental Protection Agency (EPA) methods for solid samples, solvents must be analyzed within 14 days and pesticides must be extracted within 14 days[4][5].. If holding times are longer than EPA identified holding times, analytes cannot be guaranteed to stay within acceptance limits for repeatability.

In the BCC's Initial Statement of Reason, the following is stated with regards to the 45-day retention time:

*This is necessary to establish a timeframe that the testing laboratory must keep the reserve sample for that allows sufficient time for the Bureau to verify results and to ensure that questionable samples can be reanalyzed.*

If the purpose of the retention time is to ensure that analyte levels do not change, the 45-day period is too long. It is highly likely that analytes will degrade after the 14-day hold time and subsequent tests will not reflect the condition of the sample as originally tested. Unless stability data for all the analytes is obtained for that period of time, the 14-day hold time should be instituted.

**Cost Impact:** The storage and destruction of such massive amounts of cannabis goods will add considerably to the cost structure for testing laboratories and as a result will also burden distributors and consumers. Moreover, testing laboratories will likely fail audit inspections, if requested by the BCC, if samples are re-tested after 14 days which could have severe implications on operations and licensing. The current proposed requirement of 45-day storage requires a testing laboratory to maintain significant storage space for samples as well as presents a potential security risk of storing cannabis products for such a long time period. It further subjects the testing laboratory to potential liability if the original sample and the sample held for up to 45-days do not match testing outcomes caused by potential degradation of product or environmental conditions or other unknown factors out of the testing laboratory's control. Finally, there is currently no data to support a 45-day storage period which as presented here is simply too long and onerous to require

[4] Bellar, T.A. and Lichtenberg, J.J. "Determining Volatile Organics at Microgram-per-Litre Levels by Gas Chromatography," Journal American Water Works Association, 66, 739 (1974).

[5] 2. Bellar, T.A. and Lichtenberg, J.J. "Semi-Automated Headspace Analysis of Drinking Waters and Industrial Waters for Purgeable Volatile Organic Compounds," Measurement of Organic Pollutants in Water and Wastewater, C.E. Van Hall, editor, American Society for Testing and Materials, Philadelphia, PA. Special Technical Publication 686, (1978).

of a testing laboratory. Fourteen-day storage is supported by established EPA guidelines and should be considered by the BCC in this case.

**Market Impact:** The storage of unnecessarily large quantities of cannabis goods will create substantial security risks to the public, lab personnel, business associates and local communities. Additional security will need to be retained as well as create storage issues for testing laboratories. Further, storage conditions for individual products will need to be considered and special needs may require labs to turn away customers if storage conditions are too onerous.

**Recommendation**: Sample storage time should be reduced (14 days) until it can be established that all analysis can be performed reproducibly on samples stored beyond this time frame. We recommend that the Final Regulations amend the sample storage requirements for testing laboratories from 45-days to 14-days.

**17. Section 5705(a). "Remove constraints on testing laboratories to conduct all required testing in a single licensed facility"**

Section 5705 (a) states:

*The laboratory that obtains a representative sample from a licensed distributor or licensed microbusiness shall perform all the required testing at one licensed laboratory premises.*

As laboratory testing needs grow in California, several laboratories have expanded to multiple locations or buildings. As long as the entire laboratory has the same management and quality system in place and all the methods are validated and accredited, it is pragmatic to allow laboratories the flexibility of testing samples at any of its facilities.

**Cost Impact:** Requiring labs to use a single facility to test cannabis product needlessly adds to costs. It requires labs to use a single location with other locations may be better equipped to handle specific testing concerns and does not allow appropriate commercial flexibility for a lab to determine the optimal location for sample testing. This leads to increase costs for the lab and in turn increase costs for consumers.

**Market Impact:** If labs do not have the flexibility of testing at any of its licensed facilities, labs cannot effectively respond to instrument or building issues impacting analysis times. This could potentially impact turn-around times and slow the supply chain unreasonably.

**Recommendation**: Laboratories should be allowed to conduct testing at any of its licensed and accredited facilities as needed. This would allow samples to be processed in a timely manner and give labs to ability to optimize their testing capabilities. We recommend that section 5705(a) be amended to reflect that samples may be tested at any licensed facility of a testing laboratory.

**18. Additional Recommendations:**

**(a) Supply Chain Sampling**

Allowing distributors to provide samples to retailers is an important business activity. However, a strict interpretation of Section 26153 of the Business & Professions Code prohibits a licensee from giving away any amount of cannabis or cannabis products, or any cannabis accessories. In other consumed good industries such as wine and food products, distributors and others in the supply chain are able to provide limited samples of products to retailers for them to sample to determine if the product meets their consumer and sales needs. For example, a retailer may only want to carry products that complement existing inventory or address a specific flavor. Being able to provide a

sample allows retailers to make more informed choices about the products they carry and address business concerns. Similarly, cultivators may want to provide samples of plants to distributors, retailers and manufacturers to demonstrate quality or consistency of a plant line. This activity is performed in other agricultural industries and cannabis is being unfairly restricted as the current regulatory language would prohibit such activities. For clarity, CCIA is not recommending samples be made available to end consumers in any form. Rather CCIA understands the legitimate business needs of cultivators, distributors and retailers in purchasing new products, carrying product lines and understanding the plants themselves. Samples address this need. As this poses no public safety issues and continues to restrict sample to end consumers, we recommend that the BCC provide guidance that expressly permits licensed distributors to provide free products samples to retailers as part of its normal business activity.

**(b) Compassionate Care Programs**

Compassionate care programs are a foundational cornerstone of the regulated cannabis market. These programs provide necessary care for patients and are essential to maintain. As such, CCIA strongly urges the BCC to exempt compassionate care programs from paying state cannabis taxes when they are providing free medical cannabis to financially disadvantaged people living with serious health conditions. Not-for-profit donation programs have been serving medical cannabis patients for decades and are now being forced to pay taxes meant for commercial businesses. The current cannabis tax structure is placing compassionate care programs at risk and needlessly burdening seriously ill patients and their caregivers. Patients with life threatening conditions such as HIV/AIDS, cancer and epilepsy will be faced with considerable costs for medical cannabis and in many cases will no longer be able to access as programs close and financial burdens increase. Compassionate care programs should be exempt from paying state cannabis taxes so they can continue to use their resources to support financially disadvantaged patients.

**(c) Research & Development**

Little is known about which cannabis contaminants pose a health risk to humans, especially when the cannabis in question is combusted prior to consumption. CCIA recommends that the state fund research into the public safety threat posed by microbiological and/or pesticide contaminants present in cannabis products intended for consumption by combustion.

CCIA further recommends that future changes to increase testing standards are proposed only in response to demonstrated consumer safety threats. Furthermore, where perceived risks are shown to be unwarranted, CCIA recommends that testing standards are liberalized.

In addition, current regulations provide no allowance for any license type (other than nurseries) to conduct R&D internally for product development. While funding research is necessary and much needed, so is internal exploration for product development and the ability to do market research.