CALIFORNIA CANNABIS INDUSTRY ASSOCIATION

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CATEGORY 1 PESTICIDE TESTING: WHY FAILING BASED ON LIMIT OF DETECTION INSTEAD OF ACTION LEVELS IS AN INFERIOR STANDARD

Produced by the CCIA Quality Control Committee

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CCIA QUALITY CONTROL COMMITTEE

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OVERVIEW

The testing of cannabis products as they move from manufacturing through distribution towards the retail marketplace is one of the key steps in providing consumers with added levels of public safety. The State of California and its regulators researched the actions of other states in development of the testing policies and in the opinion of many involved in the cannabis industry, have made decisions that are continuing to slow the success of the emerging regulated cannabis industry in California. The purpose of this white paper is to discuss scientifically viable methods and reasoning to the analysis of pesticide levels in California and its enforcement in the regulated cannabis industry.

Under the BCC Emergency regulations, a sample failed compliance testing if Category I residual solvents or Category I pesticides were detected above the limit of detection (LOD). The LOD can be explained as the lowest detectable concentration of a specific substance that can be distinguished from noise using contemporary testing methods and machinery. Although the regulations did not specify the requirements for LOD, there were specifications for the required Limit of Quantification (LOQ) for both Category I residual solvents and Category I pesticides. The LOQ is the lowest concentration that can be quantified reliably. The LOD is typically three times signal to noise while LOQ is typically ten times signal to noise (See Figure 1).

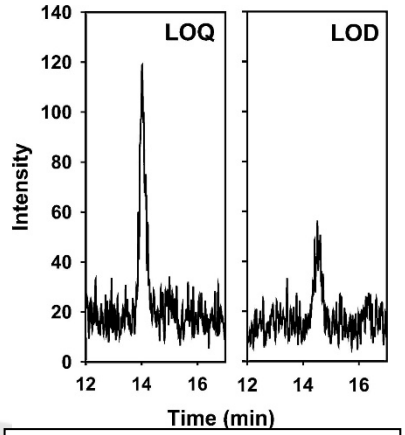

Figure 1. Typical Signal-to-Noise Ratios for LOQ and LOD

When the final regulations were released, there was a change made to how solvents were to be tested. The Category I residual solvent testing now had **Action Levels** (see

BCC code§ 5718) as opposed to LOQ requirements and failing based on LOD. The BCC's Final Statement of Reason states:

"*The proposed language would have required testing laboratories to establish a limit of quantification (LOQ) of 1.0 µg/g or lower. The Bureau received numerous comments that the proposed language is arbitrary and that it increases the variability in testing results from one laboratory to the next. Numerous commenters specifically requested that the Bureau establish specific action levels for Category I solvents, rather than allowing laboratories to establish a LOQ on their own.*

Thus, the Bureau determined that specific action levels are necessary to ensure standardization across the licensed laboratories."

The change to using Action Levels **only** applied to Category I residual solvents and did **NOT** apply to Category I pesticides. It is the strong feeling of the authors of this paper, which include testing laboratories and manufacturers, that the same justification for using Action Levels for solvents is equally applicable to Category 1 pesticides and using Action Levels is a more appropriate method for the control of pesticides in cannabis products. Additionally, there is confusion as to why this change was only made for solvents and not Category 1 pesticides. We strongly urge the State and the appropriate regulatory bodies to review our recommendation to apply the same reasoning used for solvents to be used for pesticide analysis.

ISSUES WITH CURRENT PROTOCOL

Under the final/current regulations, there is no Action Level for Category I pesticides. The methodology for passing or failing compliance samples continues to be based on the LOD, and in essence the LOD as determined by each laboratory, functions as the Action Level. A laboratory determines the LOD/LOQ on every instrument as part of the protocol for validating an analytical method. The LOD and LOQ are also reported on the Certificate on Analysis (COA).

A laboratory is required to only report numerical values for analytes that are detected at concentrations higher than the LOQ. The reported result for an analyte that is not detected at all or detected at levels below the LOD is a non-detect (ND). The reported result for an analyte that is present at levels above the LOD but below the LOQ is below LOQ (<LOQ). By this protocol, a sample would fail Category I pesticide testing when the result for any of those pesticides is <LOQ and cannot be reliably quantified. In contrast, the DoD Quality Systems Manual for Environmental Laboratories (DoD QSM), Version 5.1, for instance, requires all data results reported between the LOD and the LOQ be flagged with as an "estimated result" because the "estimated result" cannot be accurately quantified at that level.

The LOD is an inherently unreliable value and can vary significantly between laboratories and also between instruments. The LOD is **not** a value that can be accurately or reliably quantified. Additionally, the protocol by which a laboratory may determine LOD can vary as well. If a laboratory determines LOD in solvent, which is typical, the determined value may not be valid in real cannabis samples because of background interferences.

An additional issue with basing compliance pass/fail testing on either LOD or LOQ is that laboratories with more sensitive instrumentation would have lower LOD and LOQ values resulting in a higher failure rate for compliance samples This bias towards laboratories with less sensitive equipment escalates the perception of inter-laboratory variability, leading to more laboratory shopping, a perception of the unreliability, and an overall negative impact on the industry.

A common example of how the LOD/LOQ methodology is choke-holding the industry:

A cultivator, manufacturer or distributor attempts due diligence through R&D sample testing for pesticides and sends units to their chosen laboratory for R&D sample testing. The laboratory passes the samples a Category I pesticide that was detected a value right under LOD which is reported as a ND on the R&D testing COA. The cultivator, manufacturer, or distributor uses these results as a positive sign and sends more products from the same batch, or a later batch using the same materials in for compliance testing but now fails for the same pesticide because the level detected was right above the LOD and is now reported as <LOQ on the COA resulting in a failure. This creates a negative impact on all parties involved and a product that is safe for consumption may be destroyed.

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The regulations also require laboratories to re-prep and re-test samples that fail compliance in replicate. The re-prepped sample and its associated replicate must meet the acceptance criteria of RPD ≤30%. For samples that fail Category I pesticide testing below the LOQ, this is a difficult standard to achieve since the quantification is not reliable or accurate at these levels.

The BCC recognized all of these issues with regards to the residual solvent testing and amended the associated section by establishing action levels. This change must be made to rules related to Category 1 pesticides also.

RECOMMENDATIONS

As an industry, we are working diligently to meet all State mandated laws and regulations. The testing of all cannabis products for pesticides is vital to public health and safety so it is prudent to base regulations on scientifically proven methodology.

The issues and reasoning outlined in this paper can be used to modify the regulations regarding Category 1 pesticides by incorporating Action Level detection and enforcement, which would facilitate a level playing field for all laboratories. Action Levels should be established for Category I pesticides, similar to the changes made on Category I residual solvents testing. The LOQ requirement for Category I pesticides of 0.1 µg/g could be amended and used as the action level. A specific action level would go a long way in ensuring standardization and reducing variability in results.

CONTRIBUTORS

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