CALIFORNIA CANNABIS INDUSTRY ASSOCIATION

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VARIABILITY IN CANNABIS TESTING DATA

Produced by the CCIA Quality Control Committee

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CALIFORNIA CANNABIS INDUSTRY ASSOCIATION EST. 2013

CCIA QUALITY CONTROL COMMITTEE

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OVERVIEW

Variability in measurement is a natural and unavoidable reality. Regardless of what is being measured, we cannot assume any "absolute" values. An analytical measurement is an estimate, and the more data points collected, the better the estimate. In Cannabis analysis, there are several key factors that will influence the variability of these estimates.

FACTORS AFFECTING VARIABILITY

1) **Natural Variability** - Cannabis is a plant, and no plant is completely homogenous. On an apple tree, you will find varying levels of sugar and vitamin C in each apple. On a Cannabis plant you will find varying levels of THC and other Cannabinoids in different buds, as well as in stem and leaf material. Fungal contaminants will attack a plant in some places and not others, and applied pesticides will inevitably be more concentrated in some areas than others.

2) **Process Variability** - Any time Cannabis undergoes processing, whether this be trimming a bud, extracting leaf material into concentrates, or mixing oil into an edible recipe, more variability is introduced. The new matrix of the product will influence the distribution of cannabinoids with varying levels of homogeneity (some products are more homogenous e.g. chocolate, versus a product like granola - not homogenous).

3) **Sampling Variability** - when dealing with inherently non-homogenous products, sampling can provide an opportunity to decrease or greatly increase variability. If sampling is conducted in a representative fashion, and a proper sample size is obtained, analytical variability can be mitigated. If sampling is conducted in a non-representative way (i.e. samples are only drawn from a small part of the batch, too small of a sample is drawn) the data generated from this sample will not be applicable to the entire batch, and can negatively affect subsequent formulations, labeling, or even the ability to bring a product to market.

4) **Analytical Variability** - Recognized sources of analytical variation include the day/time, scientist, equipment, reference standards, and preparation of the sample. ISO certified labs understand variation and can work with tight guidelines. Analytical variation is inversely related to concentration. The lower the concentration of a target, the higher the variability.

HOW TO MITIGATE SOURCES OF VARIABILITY

1) **Natural Variability** - this is the hardest to control, but plants should be treated as identically as possible (i.e. same amount of nutrients, same soil, same application of pest control). Any differences that are intentional should be documented.

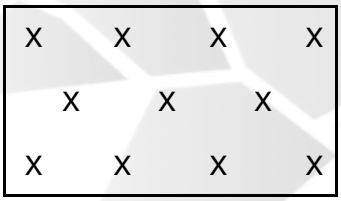
2) **Process Variability**
   a) Concentrate manufacturers should be aware that different fractions of an extraction machine will likely have different Cannabinoid concentrations and potentially pesticide concentrations (if present).

During an extraction or distillation process, certain contaminants may be reduced, but others may be concentrated.

b) Edible manufacturers should engage in GMP's (Good manufacturing processes) and ensure that all products are properly mixed to increase homogeneity. All infused-product manufacturers (whether making a solid or liquid product) should measure ingredients using masses rather than volumetric units (i.e. measure cannabis oil in grams rather than cups or ounces)

3) Sampling Variability

a) Geometric Sampling: One method to help obtain a more representative sample could be using the geometric approach i.e. pulling from various locations throughout the batch, mixing the selected material thoroughly and then obtaining your sample from the composite. This geometric approach should be applied to every container holding the batch and should be utilized in a 3-D fashion.



b) Random Sampling: Another method for representative sampling involves visualizing the container as a 3-D grid and assigning location numbers to each part of the grid. A random number generator is utilized to determine which location is sampled and then all the sample increments from those locations are pooled to form the final representative sample. This protocol can be applied towards both cannabis plant material as well as manufactured units.

c) It's also recommended to submit multiple samples for testing. Any piece of data collected will fall somewhere on a bell curve, which means that only one data point could be an outlier (i.e. on the low end of the bell curve, or the high end). Taking several samples, and then averaging the data will result in a more accurate number for making formulations going forward.

4) Analytical Variability - To reduce analytical variation, labs must follow SOPs, and maintain a robust Quality System. The BCC has implemented the strictest laboratory quality control (LQC) standards in the country. At least 20% of a Cannabis testing laboratory's capacity is taken up by laboratory quality control samples. This includes: a reference standard, an initial calibration verification, subsequent continuing calibration verifications, blanks, matrix spike samples, and a replicate from each analytical batch. Every analytical batch is only 20 unique samples, followed by at least 5 LQCs.

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 relative percent difference ≤30%. These practices collectively reduce the impact of analytical variability on the compliance samples results.

CONTRIBUTORS

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