Labs Technical Advisory Committee

July 21, 2015 Meeting Summary and Recommendations

Committee Attendees: Ric Cuchetto, Rowshan Reordan, Jeremy Sackett Bethany Sherman, and Bear Kyle

Other Attendees: Chris Lyons (RAC Chairperson), Shannon Swantek (ORELAP)

OLCC Staff Representatives: Danica Hibpshman, Amanda Borup

The Labs Technical Advisory Committee met on July 21, 2015 to discuss revisions to the last set of rule recommendations, THC reporting and variances, residual solvent testing, and general ORELAP accreditation processes. The following is a summary of that meeting and the committee's rule recommendations on those topics. For purposes of this and future summaries and recommendations, these phrases are defined as follows:

- **"*Believes,*" or "*agrees*":** no member of the committee voiced a conflicting opinion or approach.
- **"*Generally agrees*"**: some members of the committee voiced a differing sentiment than this prevailing opinion or approach.

1. THC Values and Acceptable Variances

The committee agrees that it is incredibly important to define "Total THC." Because delta-9 THC is the main psychotropic compound of interest, the committee recommends that "Total THC" should be reported as the total potential of all delta-9 THC in any given sample. Because delta-9 THC is a derivative of THC-A, the committee believes the total potential of delta-9 can be calculated with a simple mass differential equation:

(THC-A*0.877) + delta-9 THC = TOTAL THC

The committee recommends that until or unless further research provides a valid basis to do so, the rules should prohibit the addition of delta-8, THC-V, CBN, and any other form of THC or THC derivative within the reported "Total THC" calculation.

The committee discussed acceptable variance rates and margins of error, and ORELAP's role in defining how variances are calculated and reported. Typically ORELAP will require that labs report their actual experimental variances as determined through their accreditation process, and that standard then sets the measure of acceptable variance for that particular lab; resulting in different acceptable variances from lab to lab, depending on methods used, instrumentation, and other factors. In overseeing the cannabis testing industry, the committee recommends that ORELAP set acceptable methods for calculating variances, as well as set an acceptable margin of uncertainty for all labs. ORELAP representative Shannon Swantek will take the group's recommendations back to ORELAP and bring back some additional comments and thoughts for discussion at a future meeting.

2. Samples and Batches

A. Size and characteristics (supplementing the 7.2.15 recommendations)

The committee continued their discussion on appropriate testing batch and sample sizes, and discussed the recent recommendations made by the growers technical subcommittee.[1] The committee agrees that if larger batch sizes are desired by the industry, then larger testing samples are necessary to ensure an adequate amount of homogenized material is obtained. The committee discussed the possibility of individual producers having distinct and individualized sampling plans using NEFAP's sampling methodology, which could be tailored to each site and grow operation. The committee agrees that this may be a long-range goal, and could provide some desired flexibility for individual growers while not compromising the labs' need for sufficiently sized, statistically random samples of cannabis material. The committee recognizes, however, that NEFAP accreditation of labs and development of personalized quality assurance plans for growers will take time, and that in the interim there will need to be established maximum batch and sample sizing.

Therefore, the committee recommends requiring the following batch and sample sizes, as well as a method for mandatory microbiological and pesticide testing of flower and/or leaf material: a batch of material should not exceed ten (10) pounds. Ten pound batches should be separated into one (1) pound containers, and a sample should consist of nine (9) one-half (1/2) gram samples per one pound container. This will generate a forty-five (45) gram sample per ten pound batch. For producers with smaller harvests, the committee recommends requiring a minimum of 1% of the total batch, utilizing the same per pound containerized sorting method (i.e. taking nine ½ gram samples per pound).

The committee believes that setting mandatory sample amounts at this level may result in the labs taking more material than is needed for mandatory testing, and consequently will require labs to be responsible for proper disposal of the excess. The committee recommends requiring these amounts, however, because the committee believes it is imperative that samples be sufficient to perform all mandatory testing, as well as account for any possible need to retest or reanalyze the same sample material. The committee also believes that these sample sizes will allow producers to have larger batches, thereby reducing overall testing costs, while still ensuring that the quality and accuracy of test results are not compromised.

Several committee members have concerns about testing costs being more than the market can bear, and raised the question of whether the recommended batch and sample sizes may present an uncomfortably high operational expense to producers. Particularly because the committee believes that pesticide evaluations will ultimately be the largest testing expense by far, the committee recommends that the economic impacts of testing costs on the entire industry be considered when setting any required testing standards. Those members do not necessarily disagree with the sizes recommended above, but believe the

[1] The growers subcommittee believes that a batch size for obtaining a sample to test for pesticide and microbiological contamination should be equivalent to the size of the harvest, as determined by the producer. In other words, that subcommittee recommends that there should be no batch size limit other than the amount of product that can be produced in a single area at a time. For example, the subcommittee recommends that the batch size for an indoor grow operation should be the harvested amounts of material from each flowering room, while for an outdoor grow the subcommittee recommends that the batch size be the entire harvest. The subcommittee believes that entire harvest batches works well in testing for microbiological and pesticide usage, but that potency testing will require that each strain be batched separately.

appropriate regulating entity should continually look for creative solutions that keep overall testing costs down without compromising safety and accuracy.

B. Storage of Sample Material

The committee is divided on what constitutes an appropriate storage period of leftover sample materials in order to allow customers to have any retesting or reanalysis performed of the original sample. Generally the committee agrees that labs should be required to retain samples in appropriately refrigerated storage containers for no more than 2-3 weeks, as after that time period the material will have changed sufficiently to no longer be representative of the original product.

C. Mandatory Testing: Residual Solvents

The committee recommends that cannabis processors be required to report the materials used in their extraction processes, and to do so in the state tracking system so that testing labs can have access to that information when performing their work. The committee generally agrees that, ultimately, once more is known and understood about certain extraction methods, it may not be necessary to require residual solvent testing in all extraction processes. At this time, however, the committee believes it is prudent to require residual solvent testing on marijuana items that fit these categories:[2]

> (3) "Cannabinoid concentrate" means a substance obtained by separating cannabinoids from marijuana by:
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> (b) A chemical extraction process using a nonhydrocarbon-based or other solvent, such as water, vegetable glycerin, vegetable oils, animal fats, isopropyl alcohol or ethanol;
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> (c) A chemical extraction process using the hydrocarbon-based solvent carbon dioxide, provided that the process does not involve the use of high heat or pressure;
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> * * *
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> (5) "Cannabinoid extract" means a substance obtained by separating cannabinoids from marijuana by:
>
> (a) A chemical extraction process using a hydrocarbon-based solvent, such as butane, hexane or propane;
>
> (b) A chemical extraction process using the hydrocarbon-based solvent carbon dioxide, if the process uses high heat or pressure.

In particular, the committee agrees that those materials created using the process defined under (5)(a) need mandatory residual solvent testing the most. The committee agrees to discuss identifying a list of compounds that processors will be required to test for at a later meeting.

[2] This follows the definitions in HB 3400, Sect. 1 (3)(b) and (c), and (5)(a) and (b).

D. General ORELAP Accreditation

The committee spent a great deal of time discussing various aspects of ORELAP's accreditation standards and anticipated requirements for the cannabis testing lab industry. In general, ORELAP is encouraging all businesses which desire to obtain accreditation to contact ORELAP as soon as possible; the accreditation process can take many months, and assessments are already being scheduled into the fall of 2015. ORELAP representative Shannon Swantek provided some insight into the process and required steps, and estimates that labs desiring ORELAP accreditation by late spring/early summer 2016 should be submitting completed applications and proposed SOPs (standard operating procedures) no later than October 2015 – and emphasizes this is just an estimated timeframe, and assumes no obstacles or delays occur.

The committee also spent time discussing HB 3400's mandate that OLCC not license labs without accreditation as determined by OHA. ORELAP may look into whether some form of provisional accreditation, or temporary accreditation, could be allowed while the formal accreditation process is proceeding, but ORELAP representative Shannon Swantek notes that this is unlikely to occur given ORELAP's standard accreditation procedures.