Proficiency Testing Workgroup 4/28 and 5/12 Meetings Report

Presented at 5/18/2020 CSTF Steering Committee Meeting

Attendance

Ryan Zboralski, Ecology
Sara Sekerak, Ecology
Alyssa Peter, Ecology
Qingfen Gu, WSDA
Steve LaCroix, DOH
Nick Poolman, WSLCB
Bonnie Luntzel, Praxis
Jay Burns, Treeline Analytics
Steve Loague, Integrity Labs
Kyle Shelton, Medicine Creek Analytics

4/28 Meeting

Survey Discussion

At the April 16th Steering Committee meeting a couple of concerns were raised by the committee in regards to two of our questions. The first was the question regarding if labs are staggering or batching their required PTs. It was mentioned that we would should re-word the questions to include what the definitions of batching and staggering. The group agreed that this was a good thought and obliged this request. Another comment was that the second question was confusing. The intent of the question was to ask if labs are analyzing multiple tests from a single PT. For example are they participating in a single PT study, analyzing, and reporting both pesticides and potency. The group changed the question to read, "Are you analyzing multiple methods within the same PT study?" the group wants to know if this is a possibility in the permanent model for us to try to reduce the cost per study. The group made a couple minor clarifications to other questions but decided it was ready to move to Ecology's Communications team for insight and final tweaks. The group moved on to the next item on the agenda.

Outlining Trial study needs

The goal of the rest of the meeting was to outline, to the best of our group's ability, the specific needs of the laboratory and PT provider for both the trial run and permanent model. This would be a key piece to getting the trial run going and keeping the state from having to enter into a contract with any specific PT provider. The group acknowledged that there is only 1 PT provider currently providing this in-matrix PT, but others could enter into the marketplace down the road. We want our recommendations to be flexible enough for new entities to enter into this space if they want to.

First, Ryan asked the group what the host lab needed to be capable of for production of the study material. In theory, the commercial labs should be currently capable of doing this. However, Ryan added that the host lab also should be independent of the industrial market, or at least that specific study. Jay felt that the use of a commercial lab for the trial would be okay there was no other option, but Jay was adamant the permanent model be at an independent lab. Most of the lab representatives agreed, although Steve Loague mentioned he believed that we should do whatever is easiest for the POT provider in either case. Naturally, the option of the use of the WSDA lab in Yakima came up. Nick

mentioned that the host lab must be legally able to hold the required amount of Marijuana to generate the PT material, and there is a possibility that the WSDA lab cannot have marijuana on-site for this purpose. This is a question that the members of the workgroup do not have the authority or expertise to answer. The group will look for guidance from the agencies on this.

Qing mentioned it was critical that the host lab have the proper equipment and instrumentation to produce and test the PT material for homogeneity. Sara started listing the equipment she believed were critical. Kyle mentioned that it was unlikely that production of the PT material would occur in a single day. Therefore, proper cold storage was also a requirement. Kyle also mentioned the need for fresh standards. Sara mentioned that this brings up the question of how much of the standards (if any) the host lab is required to provide. Ryan said he would see if he could reach out to Ty and ask for clarification on what standards (if any he uses when on-site). Here is the complete list the group came up with as requirements for the host lab.

1. Validated methods and all the necessary materials to perform said methods.
    a. For the trial run in Potency that includes but not limited to...
        i. Grinder
        ii. Sieve
        iii. HPLC/ UV vis
        iv. Orbital Shaker
        v. Solvents
        vi. Top-loader Balance
        vii. Oven
        viii. Cold Storage
    b. List may change for other methods in permanent model
2. Can the lab legally hold the required amount of Marijuana to generate the material
3. Independent to the participating labs
    a. Not necessary for the trial run

The next item on the group's agenda was to outline what requirements the PT provider would need to be able to fill. We used our earlier recommendations regarding logistics and ISO requirements as starting points. The next topic to address was the licensing issue. Technically, this person has to be able to legally sell marijuana in the state of Washington. Nick mentioned that since a transaction involving marijuana occurs, the PT provider must have some license or LCB approved exception. Here is the complete list of the PT provider and related logistics recommendations.

Requirements of PT distribution

1. The PT provider, or their liaison (as designated by the Client), shall notify the labs 30 days in advance of the study. 48 hours prior to the availability of the study, labs will receive notification to schedule pick-up and distribution.
2. The courier of the PT material must be capable of transporting said PT material to the labs under manifest within 24 hours.
    a. Examples of a courier: A lab's individual courier, licensed 3rdparty courier, or state/client representative.

Requirements of PT provider

1. Needs to be able to technically sell marijuana in the state
2. ISO 17034 and 17043 Accredited
3. The PT provider, or their liaison (as designated by the Client), must be able to facilitate the delivery of PT material at conditions appropriate to preserve study integrity.

5/12 Meeting

Survey, and ORELAP communications update

The first item up for discussion was a recap of where the progression of the survey. Ryan mentioned to the group that the survey published Monday (5/11) afternoon and that the deadline for replies was in two weeks (end of the day 5/25). Ryan mentioned to the group that the survey had already received three responses. We will discuss the responses to the survey at our next meeting.

Ryan also mentioned that he has had a couple conversations with some of his counterparts at ORELAP in regards to Cannabis Accreditation. Ryan mentioned that the labs in Oregon are required to participate in the Phenova in-matrix studies but only offer pesticides and potency in flower. Another highlight is that custody of the PT material is transferred to ORELAP upon completion of the production. At that point, ORELAP only functions as a storage location for the material and labs arrange with ORELAP pick-up when they/Ty have worked out the timing of the study (it may or may not be immediately after production). ORELAP does have a formal contract with Ty and Phenova, however it is no cost to the state and ORELAP did go through a formal bidding process. Ryan mentioned that the ORELAP representatives believe Ty does not have a license of any type but were not sure.

Matrix Recommendation discussion

The remainder of the meeting was dedicated to going through all the required tests on flower lots and deciding what our recommendation is to their in-matrix requirement. The scope of this exercise was the required tests for flower lots in LCB's WAC 314-55-102. Another important qualification Ryan made was that we were going to include pesticides and metals since they are very likely going to be required tests in the future. Finally, Ryan made it clear what the group was to consider the term, "in-matrix" to mean. For this exercise in matrix is defined as, cannabinoid dominant flower.

The Group then went through each of the required tests for flower lots and discussed if we believed that the PTs needed to be in-matrix or if hemp was serviceable. The general thought being if a hemp-flower PT is treated significantly different from a cannabinoid dominant flower, it was not acceptable unless in extreme circumstances. The group was in consensus throughout the exercise, and here is what the group agreed on per each of the required tests.

- Potency: Should be in-matrix, would be acceptable only in extreme cases
- Pesticides: Should be in-matrix, would be acceptable only in extreme cases
- Metals: Hemp is fine
- Water Activity: Hemp is fine
- Foreign Matter: Hemp is fine
- Microbial: In matrix if possible, however hemp is serviceable
- Mycotioxins: In matrix if possible, however hemp is serviceable

After we finalized the required tests, Ryan asked about Terpenes. Kyle and Jay brought up the issue of the levels of Terpenes in PTs is not in-line with what is actually present in standard samples. He mentioned that Phenova assigns values for any Terpene over 50ppm, but Kyle said his lab does not report anything under 120ppm; therefore they are reporting values as non-detect because they are not sensitive enough to detect the analyte. Steve Loague mentioned the non-required cannabinoids produce a similar situation. Since there is no standardized reporting limit for terpenes or the other cannabinoids, this currently is not a problem but definitely could be for accreditation down the line. Ryan believed that as far as accreditation was concerned that, if a lab is producing data used in label claims, PTs should be required whenever available. Sara mentioned that this is a problem for the client to decide down the road.

Lastly, Jay asked about how to handle the differences between High-CBD and High-THC flower. This was a hotly debated topic in the pesticide analytical workgroup and Jay believes we consider having PTs in both of those flower matrices. Bonnie presented the idea of rotating through the two types of flower. Steve Loague countered by stating that high-CBD flower made up less than 2% of the market, why should we require an extra PT for that little of the market? Kyle mentioned that this difference should come out in method development. That way there is only one method for all cannabinoid dominant flower utilized by a lab. Ryan mentioned that he believed the best way to overcome this was to allow the PT provider the flexibility to occasionally produce a PT in a high CBD flower. However, noticing the time Ryan mentioned we would table this

Action Items

1. Work with the Communications team to finalize and distribute the survey.
2. Seek guidance from the agencies on the Steering Committee on how to overcome the remaining challenges to the trial run.
3. Ryan asked the group to consider 2 topics for next meeting:
    a. Are we going to require a PT for high CBD flower separate from high THC flower, or allow the PT provider the leniency to make the PT in a CBD dominant flower at their discretion?
    b. What will the group recommend for Terpenes and non-required cannabinoids in flower?
4. Next meeting will be Thursday 5/28.