

Proficiency Testing Workgroup 5/28 and 6/9 Meetings Report

Presented at 6/24/2020 CSTF Steering Committee Meeting

Attendance

Ryan Zboralski, Ecology

Sara Sekerak, Ecology

Alyssa Peter, Ecology (Last meeting with the team was 5/28)

Anastacia Green, Ecology (Replaced Alyssa, first meeting with the team was 6/9)

Qingfen Gu, WSDA (Absent 6/9)

Steve LaCroix, DOH (Absent 6/9)

Nick Poolman, WSLCB

Bonnie Luntzel, Praxis

Jay Burns, Treeline Analytics

Steve Loague, Integrity Labs

Kyle Shelton, Medicine Creek Analytics (Absent 5/28 and 6/9)

5/28 Meeting

Follow up from last meeting

The meeting opened with Ryan recapping some highlights from his conversations with Ty Garber of Phenova. Ty's schedule makes him available to come into the state for the trial study in July/August. Since the trial study has eight participating labs and is a small analytical scope, Ty will not need more than the legal carry-limit to produce this study. This will greatly reduce the cost of the study for the agencies/Taskforce. Essentially, the only cost for this trial study will be for the ounce of marijuana needed to produce the study.

At the end of the last meeting, the group started a contentious discussion regarding high CBD vs. high THC flower material for PTs. The Pesticide workgroup initially wished to have three commodity groups: High THC, High CBD, and Hybrid (catches anything not in the other two groups) due to significant analytical differences that are present. The hope is that laboratories would be able to catch all these commodities within their method development so that they would not need, but they do present different challenges when analyzed. When presented to the steering committee, the committee decided only commodity group for flower was necessary.

When our workgroup distributed our data mining exercise, we wanted to reflect the difference that the pesticide workgroup identified. We did assume that high CBD and hybrid would likely make up a very small segment of the flower market (likely why the steering committee decided have one commodity). Our exercise backed those suspicions, with high CBD flower samples making up less than 2% of the flower seen in the surveyed market. Taking everything mentioned above into consideration, Ryan proposed three options to account for the difference between these different types of flower identified by the Pesticide Workgroup:

1. Allow the PT providers to send out a PT that fits into the high CBD category with the possibility that they may never. (Affectively do nothing)
2. Negotiate a rotation with the PT provider. We would need to figure out that rotation and it might become predictable.
3. Only provide high THC. Downside is it is not representative of high CBD.

Although most of the group acknowledged there is some analytical difference, most of them also mentioned that due to both the market rarity and industry's young age, there is not sufficient data available to take a hard stance on this topic. Therefore the group agreed to the first option; the "Do nothing" approach and leave further refinement of this to the Client down the road.

Another carryover topic from the last meeting was the issue of how to handle Terpenes. Although Terpenes are not a required test for certification by RJ Lee/LCB, they are required for a producer processor to make label claims. Most of the group noted that there was not a set list, or reporting limits, for Terpenes and this created a lot of discussion in regards to the labs feeling a set state list (similar to the state of Nevada). Although there is a lot of valid discussion to have on this topic, Ryan reminded the group that this not within the scope of this specific discussion. He asked simply what we believe their matrix-match requirement should be in PTs. The group made a consensus that for Terpenes, in-matrix is best, but Hemp would be serviceable. The crux of this issue being that available Hemp PTs can be significantly below labs' reporting limits, leading to the possibility of false negatives in the PT reports.

Survey results

Since our last meeting, the Survey we distributed regarding PTs have come back. Six labs participated in the survey, and all expressed interest in the Trial Study. Ryan mentioned he would be reaching out to those participating labs with pertinent information. Thankfully, there was a geographic split among the participants. The labs range east to Spokane, and along the I-5 Corridor from Bellingham to Centralia. This will provide us a comprehensive feedback in regards to the logistic concerns we have for the permanent model. Another take-away that the group found re-assuring was that the answers to questions five and six fall in-line with our matrix-matching recommendations. Here is a brief breakdown of the results:

- Q1: 2 labs reported spending \$3501-\$5000 and 4 labs reported more than \$5000.
- Q2: all labs reported that they do not analyze multiple methods within the same study.
- Q3: Range from 10-20 with the average being 15 total PTs analyzed in 2019.
- Q4: Batching vs staggering had an even split (3 to 3).
- Q5: First marijuana flower, then hydrocarbon/CO2 extracts, then edibles, isolates and distillates, a tie between food grade solvents and infused oils, last is non-solvent products.
- Q6: Potency and pesticides first, then mycotoxins, microbial, terpenes, residual solvents, metals, water activity, moisture, and lastly foreign matter.

Edibles/End Products

Although Edibles/End Products only require potency analysis, this is a very difficult matrix to try and match for PTs. Due to the extremely diverse nature of available Edibles/End Products, the team had to rely on the market data we have and some commercially available products to guide our matrix-matching recommendation regarding Edibles/End Products. According to our data, Edibles/End Products make up around 6% of the total cannabis samples. Within that, there are about four types that each make up around 20% of that group. Those are, Baked Goods, Candies, Beverages, and Tinctures.

Ryan asked the labs what Edible/End Product PTs are commercially available. The consensus answers were that Emerald has provided gummies, hard candies, and cookies in the past. Jay mentioned that this could be a really slippery slope if we try to get too into the weeds on specifying what matrices need to be done for PTs. Ryan agreed and asked the group if they would prefer to leave this a little more vague for now hoping that the Client could address this in the future if needed. Thus the group agreed that PTs need to be in matrix, but are not specifying what type of matrix for now.

All of the laboratories agreed that the Potency PTs they have for Edibles/End Products are far-off from the concentrations seen in the market. They all strongly agree that a PT needs to be available that is more in-line with the concentrations seen in the market. Thus, the group made a caveat to our matrix-match recommendation for Edibles/End Products: We strongly believe that a PT needs to be produced in the state that is more in line with concentrations seen in the market.

Another issue with Edibles/End Products is that sometimes labs receive types of Edibles/End Products that they have never seen before. Typically, the lab works with the customer on how to adapt their method to accommodate this new product, but this is a very time consuming process and often costs more to develop the method than the lab can recover in their pricing. Ryan mentioned that the Pesticide workgroup recommended that intermediate products coming from a producer/processor must include an ingredient list, so they can save time on re-analyzing samples that are not what the lab expected. Jay and Steve Loague mentioned that might be a more difficult sell for Edibles/End Products because the likelihood of significant investment by the producer/processor in this Edible/End Product is high. Sara mentioned that this would have to come in the form of a formal recommendation from a workgroup. Sara mentioned that this is something that falls more in to the purview of the potency workgroup and this recommendation should come from them.

Intermediate Products

Due to the time remaining in our meeting, we decided to focus our efforts on just Potency analysis for Intermediate products today. Ryan noted that of all the available intermediate products, what the analytical workgroup designated as Hydrocarbon Products made up almost half of all intermediate products and nearly a quarter of all products in the market. Due to this, the group will focus on this as the representative for this group. The group agreed that for Potency, Hemp and THC containing oils are affectively the same. However, all agreed that residual solvents and terpenes are a different story. At this point, the group was out of time and adjourned to pick this up at the next meeting on June 9th.

6/9 Meeting

Intermediate Products Continued

After a brief update from Ryan on the Trial study, the group began wrapping up their recommendations for Intermediate Products. Microbial analysis was the first field of testing addressed by the group. Similar to flower lots, the group was in consensus that microbial analysis is more reliant on proper sterile procedure than the tested matrix. The group all agreed that hemp is serviceable for Microbial PTs. The next field of testing was Mycotoxins. The group was again in a consensus that, similar to flower lots, Mycotoxins should be in-matrix, however hemp would be acceptable in some cases.

The group mentioned that residual solvents would be the field of testing that is most critical to matrix-match, due to the instrumentation used for residual solvent analysis. Hemp oil used in PTs is typically produced from Hemp seeds, which have organic compounds that could be co-eluted with the residual solvents of interests if a non-Mass Spectroscopy analysis method is utilized. Marijuana oil does not have these interferences, as it is usually an oil derived from the cannabis flower. All the represented laboratories are utilizing head-space analyzers which cannot separate some of the organic solvents the lab is looking for from other chemicals in the matrix of Hemp Oil.

The last item the group had to tackle was terpenes. As we discussed in the prior meeting, since Terpenes are not a required test (in the same way potency is) there is not a list of required terpenes, leading to a wide disparity of what terpenes each lab is analyzing. Most of the labs either have the ability to analyze for terpenes, or do analyze for terpenes so some standardization would help bring some clarity to how PTs will be scored down the road, especially for the minor terpenes that might not be present in a PT. Although this is a valid concern, it is not within the scope of this workgroup. Similar to the recommendation for Terpenes in Flower lots, the group believed that Terpenes should fall in the middle category, should be in-matrix, however hemp would be acceptable in some cases.

This concluded the testing outlined in WAC 134-55-102. Here are the recommendations the workgroup came up with:

	Flower Lot	Intermediate Products (Not including flower lots)	Edibles (end products)
Potency	X	X	X
Pesticides	X		
Metals	X		
Moisture	X		
Foreign Matter	X		
Microbial	X	X	
Mycotoxin	X	X	
Residual Solvents		X	
Terpenes	*	*	
X=required by WAC		*=required if used for labeling	
		needs to be in-matrix but the specific matrix is limited to market availability, we would really strongly recommend a PT to be made available that is more in-line with the concentrations seen in the market	
needs to be in matrix, unless only other options exist			
should be in matrix but hemp is sevicable			
hemp is a servicable replacement			

Ryan will present these recommendations to the Steering Committee for review. The workgroup assumes that The Client will have the ability to edit these as the industry evolves over time. However, the accreditation body should be involved in that process. The group is confident that these recommendations are appropriate for use in the permanent model; however, the group believes that Steering Committee and the specialized workgroups should have the ability to provide feedback on this. Therefore, we do not believe that it is appropriate to bring this to a motion at this time. Once the other workgroups and steering committee have had a chance to provide input, that will be the right time to set these recommendations in place.

Discussion on Accreditation by Ecology

The next item for discussion was the frequency laboratories would be required to perform PTs. Currently, LCB required two per year, per field of testing, with one of the required two of each field of testing to be within six months of their yearly audit date. At surface level, this is not too much different from the Ecology model. Ecology requires one per year per parameter for micro tests, and two per year per parameter for chemical tests (the remaining test in the cannabis industry would fall into this category). Chemical test have the caveat that if a lab has an accreditation year where they analyze two or more PTs for a parameter and have no failures, they are only required to perform one PT per year per parameter until they have a failure.

Sara shared Ecology's Lab Accreditation Unit's (LAU) Procedural Manual for the group to read. This manual outlines the accreditation requirements and process the LAU follows. At this time, the LAU has not agreed if they are going to edit this procedural manual to include cannabis, or if they are going to create a separate manual for Cannabis labs. Ryan did mention that if a separate manual is drafted, it will be largely similar to the current manual.

Ryan mentioned there are a few terms that the group needs to clarify, particularly Matrix. The term Matrix is defined by the LAU as, “The substance from which a sample is collected, such as groundwater, ambient water, wastewater, air, solid, semisolid (such as tissue), or chemical compounds (such as oil).” Since the Pesticide workgroup established the USDA’s PDP model as the framework the terms commodity and commodity group have been used quite often in a somewhat synonymous manner. However, it has never been explicitly mentioned which of those two terms (commodity and commodity group) matrix is most synonymous with. For the purpose of this exercise, we have defining the matrix down to the difference between hemp flower and cannabinoid-dominant flower. Definition or clarification as to if it’s more synonymous with commodity or commodity group will bring clarity to the discussion going forward.

One of the goals of the LAU is to allow labs flexibility to seek accreditation in whatever Field of Testing they want to be. Allowing labs the flexibility to be accredited in the parameters that is in the best business interest of that laboratory. The laboratories also raised the question of how the transfer will happen from their perspective. The labs want to know if they will they have to apply as new labs seeking initial accreditation, or will it be a modified form of renewal? This is a good question that Ryan mentioned he will circle-back to his LAU colleagues and start working on how the non-PT aspects of accreditation will be handled.

Action Items

1. Present the “ingredient list” idea to the Potency workgroup for their consideration.
2. Present our recommendations for PT matrix-matching to the Steering Committee.
3. Ryan will consult with his colleagues at the LAU on how they want to handle cannabis accreditation. This will unlikely be complete anytime soon. This will require a significant amount of time for the group to develop.