Washington State
Liquor and Cannabis Board

Washington State Liquor and Cannabis Board Cannabinoid Science Work Group Meeting

Thursday, August 3, 2023, 10:00 a.m. to 11:30 p.m.
The meeting was convened via Teams

Meeting Minutes

AGENDA ITEM 1: CALL TO ORDER AND ROLL CALL – 10:05AM

Kathy Hoffman opened the discussion.

Present:	Richard Sams*	Absent:	Ryan McLaughlin
	Ryan McLaughlin		Holly Moody
	Jessica Tonani		Tracy Klein
	Taylor Carter		David Gang
	Chris Beecher		Brad Douglass
	Justin Nordhorn, WSLCB		Jim Vollendroff, WSLCB Board Member
	Kathy Hoffman, WSLCB		
	Angie Peck, WSLCB		Nick Poolman, WSDA

AGENDA ITEM 2: JUNE 1, 2023 MINUTES AND ACTIVITY REVIEW

Kathy Hoffman asked group members to offer changes/concerns regarding the June 1, 2023, meeting minutes. There were no revisions offered by email before the meeting or during the meeting, and the group accepted meeting minutes as drafted. Kathy briefly discussed workgroup activity between the June 1 and August 3, 2023, meetings.

AGENDA ITEM 3: Subgroup Report outs

Detectable Levels of THC and Future Standards

Kathy Hoffman: This morning we wanted to report on our first two subgroups that met in July to talk about two things: detectable levels of THC and future standards. And then the second subgroup was discussing cannabis product safety. I am going to give a brief overview of what we accomplished or the things that we talked about first, with respect to detectable levels of THC and future standards. We met on July 12th and members in attendance in that particular subgroup were Jessica, Brad, Richard, Holly, Chris, and Taylor and Sara were alternates. I don't believe they attended those meetings, but we discussed a couple of things.

First was a survey of the private labs to talk about instrumentation, and we believe that results of that survey could help us separate theory from what is reliably possible in Washington, in terms of determining detectable limits. It may also help us better understand the limits of technology and help us work more towards safety standards. We also wanted to begin to create buckets to create a matrix of product types that may help us begin to unpack units of detection by product type. And I will stop right there and let the group members chime in and maybe have some additional discussion.

Jessica Tonani: Kathy, I think that summarizes it pretty well. I mean, I think that different technology has different limits, and we have a strong indication that most labs here in the state will probably be HPLC-UV. We went over some of the paperwork that ASTM and others have put out on what they think should be theoretical standards. And I think the goal was let's confirm our theory of what technology people are using and then begin to divide out based upon matrix and volume what we actually believe may be detectable levels. So, for example, a larger volume of beverage may have a different detectable level than a smaller, edible, just based upon the limitations of technology. And to really kind of begin to define what we believe labs should be able to detect is I think what we discussed.

Chris Beecher: I agree. The minutes basically do that, they are correct. I do have a feeling that we really need to define what the need is before we define the equipment. I think it would be a mistake to limit what you can see by limiting technology. I really think we need to just figure out what we want to see, what you need to see, and how you need to see it. And I believe that there may be two levels of that. I think that in chemistry and industrial levels, most of the pure materials that come in are tested and are

characterized, and then the final products are characterized. And I think that maybe the simplest way around it would be to suggest that you really need to test the material that is used in making the products separately than the products in a more complex matrix. And it may be that the product is in a more complex matrix. They really don't need the same level of scrutiny that the raw material does.

But I think there are too many industrial accidents where the material that is used in a product is contaminated or is -- I mean, along these lines we test for pesticides, and I think the correct place to test for many of these things would be a more detailed test that probably occurred before the material was inserted into a product before it was used, some sort of a certification. And, again, as a chemist, I think virtually every product I buy has a cheat sheet on it that tells me what it is and what it has been tested for. And so I think that we really need to figure out what we need to see, and when we need to see it. And that may not be a one-time look that sees and does everything.

Jessica Tonani: I think there is a little bit of the backdrop on that. There was a fair amount of discussion that went on around this in the Hemp and Food Safety Task Force, and I would have to go and pull my notes. I think that concern with testing potentially upstream, which is an idea that I personally like, but the concern with that, I think, was spot-checking downstream, and so how you correlate those and the thought that maybe not all products would be manufactured in Washington. And so just really trying to figure out how a GMP-type process would flow through that. I think that there were some concerns with other groups, and we can go back and look at the notes on whether or not just testing midstream would be feasible.

Chris Beecher: I understand that, but it may be that one of the restrictions to sell in the state would be that the material would have to be certified to some level in order to simplify the products made within the state. And on some level, it favors local producers, so I would think that the state would find that somewhat attractive.

Kathy Hoffman: Chris and I were talking about this before we started the meeting this morning, that the testing standards in Washington state for cannabis originally had a two-gated system, where we did test the plant matter before it was turned into or inserted into an edible or became a concentrate or something like that. In this last set of rule changes that were made to the cannabis product testing standards, we removed that first level. So really, what we were concerned in testing or making sure it was fully tested was the product that hit the shelves for the consumer. That approach gave a little more flexibility to producers and processors and also helped to sort of mitigate costs that became part of product testing in Washington when we made pesticide testing mandatory. Just something else to consider in the conversation, and that would be the impact to the industry when additional testing is required.

Chris Beecher: It would seem to me that the actual -- it would be faster, cheaper, and easier to do a batch certification of the year's produce upfront and certify that batch and then distribute it, and then you know that it is -- you don't have to find the low abundance materials in the final product because finding them in something, Jessica, as you say, a dilute solution is going to be far more difficult. I mean, sure, you can analyze 10 mL concentrated onto 0.5 mL. But the reality is if you were to do a certification of the material, then the certification on the product becomes much faster and easier, and you don't need to have as much rigor on the certification of the product because the material is already certified. You are just verifying the concentrations are what you expect and that they are meeting the profile. But the safety of the material that is used, the pesticides, the concentrations of the cannabinoids, the appropriateness of the cannabinoid distributions can all be done as part of the certification.

Jessica Tonani: And I think one of the concerns that -- and when I am thinking back to the other work group that came up -- was just essentially mixing in formulations. So essentially, how do we? I don't know if we can get away from that end-level testing. I mean, we may be able to, but the reality is mixing these products is one of the concerns, like, adequately getting cannabinoids mixed into a solution, let's say, for example, a large beverage batch or something. You may have certain cans. If you are not end-testing, people might not be as efficient with emulsions or things like that. And so that was one of the concerns that came up. I think it's definitely worth re-evaluating. But it was something that was debated pretty heavily in the last workgroup on whether --

Chris Beecher: I think what I am hearing from you is that there is a larger number of batches in the product lines currently as opposed to -- and so there would be more small batches that would need to be tested. And I think in -- I am coming from a more industrial background, where I would think that what you would want to do is to sort of pull stuff together so that the testing was done in fairly large batches, where you could have consistency and more reproducibility as a function of time.

Jessica Tonani: I think that the discussion before was, let's say, for example, somebody gets some crude oil or something like that or distillate, whatever it is, that distillate could end up in a number of products downstream. And so let's say, for example, that distillate was tested, and it passed. I think that there were a lot of people that said, hey, that would be a good enough standard. But then there was a lot of discussion on if that distillate was used to make chocolates in a bar and soda or whatever it was, also it's really making sure that there is the right amount in the product that the consumer purchases.

Chris Beecher: Absolutely.

Jessica Tonani: And so there was some concern that essentially what we would be doing is setting up a two-tiered testing system versus single-tiered testing system because there was not necessarily -- and maybe things have changed. It is definitely worth bringing up and having the discussion on whether or not we believe the manufacturing is as consistent as it may be in manufacturing Tree Top apple juice or something where you test the upstream, and then it is diluted out downstream. Where this may be a slightly different situation, there was a lot of desire to do, essentially, the ingredient testing. But there was a lot of pushback, and I think we need to go back and look through the notes on where that pushback came from about not doing finished product testing.

Chris Beecher: I am not saying not to do finished product testing. I actually think finished product testing is critically important. But I am saying that finished product testing may require that you only verify that the THC levels are as expected are within predefined limits in the final product, whereas, right now, you may be obligated to test for a much larger number of things if you only have a single level. If in the final product, if the material is certified and you know the levels of the various cannabinoids that are relevant, then you can test the final product to make sure that one or more of them because the material is certified they are all going to act in concert are at the levels that you expect. And it becomes a rather straightforward test and is, in fact, of great benefit to the public. The product is always going to be reproducible. But I don't think that you want the raw materials to be tested at a fairly cursory level.

I think you want a reasonably deep analysis of the pesticides, of the metal, possible contaminants, and I think at this point because the semi-synthetics are creeping in at such a level. I mean, in their minor modifications of natural plants, I really think it serves the public, and I think it serves the LCB to analyze the material that is used as starting material and certify it for quality that it can be used as a starting material. Otherwise, you have mom and pop shops that are basically going out into the field and grabbing their own plants and popping them into a brownie and selling it in the farmer's market.

Jessica Tonani: Well, and I think that the discussion before was separating out like the pesticide and heavy metal and allowing that to be preferentially done at an ingredient level as a single test but the cannabinoid level actually having to be done in at the finished goods is I think how things ended up.

Chris Beecher: I can see -- I think that is the reality as it sits now. But I think that the cannabinoids really could and should be done up at the top just because the products that are coming down now. I am in North Carolina, where it is not yet legal, and yet there are stores that are selling completely hallucinogenic products that are within the law, and I find that to be somewhat horrifying. And I think there are so many things coming in these days. You know, these are -- you shift to double-bond, and you have got a compound that is not regulated. The reality is that it would not be a bad idea to control the product so that the starting materials were verified safe and of a good quality level. And it may be

the technology has just changed. This chemistry, I don't know, I don't think it existed 10 years ago on the commercial scale that it is now.

Jessica Tonani: And I think the concern was in the broad definition of like manufacturing with an ingredient that our concern was the final product does not contain the cannabinoids of concern and that bringing in the ingredient do not necessarily mean that people could not manufacture and have a finished product with a cannabinoid of concern. And that is why heavy metals and pesticides and things could be done at a more concentrated level but downstream potentially doing the cannabinoid analysis that needed to be done in the product that ended up in the consumers' hands.

Kathy Hoffman: So I kind of like to steer the conversation back to some of the things that we were talking about with respect to serving labs if I could. Although, I want to just pause for a minute and reach out to anyone else on the workgroup or anyone from LCB who has a question or a comment that they would like to offer at this point in the conversation. I do know we have some technical difficulties. Richard, if you want to send me an email with anything that you are thinking, I am happy to read it to the group, or a text message. But Justin, Angie, anything to offer? Anyone from the group?

Justin Nordhorn: Not right now. Thanks.

Kathy Hoffman: Okay. If we could do something for the folks listening in, Jessica, you were talking about HPLC-UV, those kinds of things. Can you give a brief description for folks who may not know what those acronyms stand for?

Jessica Tonani: There is different technology people can use to detect cannabinoids, and probably the most common and probably the only platform. It may not be, but definitely, I would think the overwhelming platform in this state that is used is high-pressure liquid chromatography with a UV light detection on the backend. And it's kind of been the gold standard that we have built our cannabinoid safety levels around in the state, and, I mean, it's worth surveying. And I think we have the eight labs what they use, but the labs that I know are using it, and so the thought is we really should when we think about our discussions around this, I think it's fair to say that the testing will be done, most likely, in those labs, and we should facilitate based upon the gold standard technology that they are utilizing.

Kathy Hoffman: Right. And I think that, too. I go back to the conversation and think about what we are trying to do is determined by product type what the limit of detection might be. Right?

Chris Beecher: In North Carolina, the State lab uses mass spec, and it does have greater sensitivity and greater specificity. However, it is a much more expensive piece of equipment. There is no question about it. The LC-UV is a great piece of equipment, but I would guess that most of the UV bands for

most of the cannabinoids are pretty similar. They will all have absorption in the same range. And so if your chromatography is off -- and I think the reason the state here has required the mass spec is actually to get that higher level of detail. I actually think that you are correct. LC-UV would be fine if you are really verifying that a product does not contain twice as much as you think. But I don't know that it -- I don't know if it -- I am a mass spectroscopist myself, so I love mass spec. What can I say? And it is a much higher level of detail and a much more sensitive piece of equipment and modern techniques.

And this is where I say it seems to me that looking at the ingredients in a higher level and then verifying that the product as it goes out is what you expect it to be is sort of in the interest. But I don't know that all labs need to run a mass spec, but I think at some point you are going to. The pesticides are done on a mass spec, but you don't have that much sensitivity in UV for the pesticides. That is why they were split out earlier.

Kathy Hoffman: If I could for a minute turn back to the question about levels of limits of detection. The other thing I think the group didn't really touch on, and maybe we should think about that, is other labs that will be testing. Are going to have the Washington State Patrol Lab that will also be testing, likely, and WSDA, as well. I think we can create a survey that will go to our independent labs, our certified labs. And bear in mind that there are two other entities that will likely be performing limits of detection testing as well when we think about standards.

Jessica Tonani: But I do believe that it is extremely important that we enable a system that commercial companies can get an answer that they can rely on. And if we look back at the bill, if I remember right, the mass specs got actually cut from our patrol lab. So I think it is really important for us to understand how our commercial labs compare and how do we enable a system that commercial companies can have security in their testing results?

Chris Beecher: Right. You know why the mass specs were cut?

Jessica Tonani: Pricing. Budget, I believe. Kathy?

Chris Beecher: I am sure it is budget, but it is the sensitivity, and the specificity are orders of magnitude higher.

Kathy Hoffman: Justin has his hand raised. Please, Justin, go ahead.

Justin Nordhorn: I think as the discussion unfolds and exploration occurs, I think we were looking at two things. One from Washington state, of course, we have the issue that was left in the bill on us not

requiring the liquid chromatography equipment. And so we need to figure out how the standard is going to work within Washington for the private labs and the state labs. But I think overall, it is really important as we are looking at this from a broader scale, we also consider what is the best practice, and so kind of what has been discussed here on this is the best equipment, this is the best way to evaluate these particular levels, and I think we need to recognize what is the best practice and then what are we doing within our state to work around what the current statutory language says. And so I think it is a little bit twofold for us, and so I don't want to deter the conversation around what would be the best practice because we may be limited based on current statutory language. But I think it would be really wise to recognize that best practice. So I just wanted to throw that out and not discourage any conversation towards that end.

Kathy Hoffman: Thank you for that, Justin.

Taylor Carter: Is there some sort of central agency for checking almost like a spike sample across all these labs across the state and the commercial, basically like a central agency to have one person with the set level of spike sample to test all of them or not really?

Jessica Tonani: Taylor, in Washington we are in the process of kind of migrating that situation, and I think that there will be a little bit more ring testing type protocols in the future. But we are in the process of doing a multi-year kind of transition on that.

Chris Beecher: You know, the FDA does. It sends out a sample on a regular basis. I think they are now up to the fourth or fifth sample they send out. And it is a sample that they have certified, and they send it to any lab that requests it. It would seem that it might not be a bad idea to participate in the FDA Program and make it even sort of a qualification that you participate in if you want to prove that you are, in fact, doing the job. And I think everybody is doing the job. But that is a standard sample that they will push out. At this point, they have been doing it at least once or twice a year for the last few years.

Jessica Tonani: I think that there is a lab subgroup that has had a lot of discussions around this. And I think there has been a lot of debate about whether you use ASTM standards, the FDA standard, different standards, and different matrixes. My understanding is that is part of a separate subgroup that is being rolled out here. I think there was a meeting yesterday on it that I didn't make but on as part of the certification here.

Cannabis Product Safety Guidance

Kathy Hoffman: The next subgroup was the Cannabis Product Safety subgroup. We met on July 20th, and present there was Brad Douglass, Jessica Tonani, Taylor, David Gang was there as well. We discussed different product types. We talked about different product standards, and then we talked about production standards, like extraction, types of extraction, and what that meant. We discussed consumption concerns versus environmental concerns as they relate to production. We also discussed remediation and food safety.

One thing that Brad Douglass really underscored -- and I know he is not able to join us right now because I believe he is traveling -- he underscored and really wanted the group to increase our understanding related to total exposure, to carefully translate what this might mean in our recommendations or options that we offer in the future. He talked about orders of magnitude in the difference that occurs back to the concentration of the contaminant that is in the product. We had a really robust discussion and really great debate. I think Jessica alluded to that, and I'd like to open the floor for members of that group to share additional thinking or add additional thoughts that I didn't cover in that synopsis. Taylor, if you want to jump in, that would be great.

Taylor Carter: Sure. I feel like you covered a lot of it very well. It is unfortunate he is not here to go over some of the stuff that he has covered. But I think the progress that was kind of started in that group was very efficient. I mean, again, I think there is still some stuff to go on it. But I do feel like a lot of good progress was made during that meeting.

Kathy Hoffman: And Jessica.

Jessica Tonani: I agree. And I think that there was a lot of discussion about that all extraction is not the same extraction. And there may be standards within the state that we allow certain forms of remediation and that potentially, we need to really look at exposure very differently from like an inhaled product perspective versus a 10 mg consumption and that those may be different scenarios, and we just need to break out the product classes and figure out what may be possible or what is definitely not possible.

Kathy Hoffman: The other thing I wanted to offer for folks who may not have joined us in previous meetings is that the larger group identified four or five different areas of interest that they wanted to explore this year, and those areas of interest aligned with what the Board was interested in, as well. We were able to sort of rate those interest areas in terms of how much interest there was, and the things that we are talking about here within the subgroups are the two top areas of interest, so that is why they are a little bit different. But there are some similarities, and we are creating sort of these

buckets, if you will, to sort our thinking out and help inform our recommendations and the options that we offer moving forward.

For this particular group, I did start creating the buckets, and one thing that was sort of interesting to me as I started to unpack the discussion and creating a product standard bucket and a production standard bucket, is I think that group needs to spend some time defining what a product standard means and what a production standard means because those aren't necessarily clear and they sort of cross over into each other. So if we are going to make those distinct, I think we might want to spend some time unpacking that a little more, as well.

Then, looking at existing rule and the document that I shared with that group, I think it was just earlier this week, I was trying to align what is in existing rule and statute with what our thinking is around product standards and production standards, and where we might need to make some revisions or where we can align our thinking with what is already in rule and statute.

Jessica Tonani: I think you did a good job of summarizing it. And I think that our goal is really to start working on that table that you sent out and having more active discussion around it and filling it out.

Kathy Hoffman: Right. And Taylor, I think you are the only other person from that workgroup here. Anything else to add? I think you made really great contributions to that debate.

Taylor Carter: I agree that I think with more discussion we can kind of narrow it down. I am always in literature about cannabinoids and just kind of more recently in some of the liver byproducts, like what it is kind of breaking down into and just a lot of the stuff with the body. So, I think any of those discussions, I think there is more to definitely be had with the consumption route and just kind of maybe where some of the standard levels need to be based on like a toxicology level of some routes may have potentially more harm down the line than others, so you may need to be more precise in your measurement of some of these potential byproducts. But again, I think the discussion in that group is moving in a very good direction.

AGENDA ITEM 4: WRAP UP AND NEXT STEPS

Kathy Hoffman: Ending a little early. I do hope that during our October meeting, we will use the entire hour and a half because I do believe that we will have documents that we can share broadly with the group and with the public that contain some recommendations that have built out some of these buckets that we have been discussing today. Those documents will be in draft form, but I think as we are coming to the close of the estimated lifespan of this workgroup, I think we are making great

progress in providing some deliverables. So with that said, we can close the meeting about 45 minutes early, but I do want to offer a couple of things in closing.

With respect to the subgroups, we are going to have at least three more subgroup meetings. Those will occur later this month throughout September so that we can have some robust content to offer in October for the CSWG. And ultimately, that is the goal of this workgroup, to provide some guidance, at least some recommendations to decision makers moving forward, and we do want to be able to support the work in determining detectable levels that several agencies are working on. I would like to hand it over to Justin if there is anything else he would like to offer before we close.

Justin Nordhorn: Just thank you, everybody, for your continued participation. I think this is really important for us to get our minds around. So we can be productive moving forward and looking at the standards, particularly when we are looking at some of the national interest right now with the Farm Bill, and what is that going to look like. The FDA is looking for feedback right now, and so I think this is really a group that can inform some of those conversations as well to make sure that multiple states are moving in the right direction. Thank you all for your continued participation in this, and we really appreciate your input.

Kathy Hoffman: Thanks, Justin. All right. With that, I'm happy to give you 45 minutes back in your day. Thanks very much for joining us today, and we will see you in October. Take care, everyone.

ADJOURN

SPECIAL NOTE:

Richard Sams was in attendance but experiencing technical difficulties that limited his ability to participate. Following the meeting, he offered the following comments by email for the group's consideration:

I was on the call until the end and found the discussion relevant and useful.

I would make the following comments/recommendations regarding the topics that are under discussion.

1. The lower limit of detection LOD can be determined by a variety of methods. Some of those methods are subjective whereas others are objective.
2. The LOQ is calculated from the LOD so uncertainty in the determination of the LOD is reflected in the LOQ.
3. Some laboratories claim that their methods are better than those of other laboratories by claiming lower LODs.
4. Sample preparation affects the estimate of LOD. For example, if laboratory A dilutes the initial plant sample in 10 mL of solvent whereas laboratory B dilutes the same sample in 50 mL of solvent, laboratory

A will legitimately have LOD values that are 5-fold lower than those of Laboratory B. This difference is real.

5. For this reason, I like to determine the minimum amount of a substance that my instrument can detect. This is easily determined by injecting smaller and smaller amounts into the instrument and then identifying the lowest amount that produces a detectable signal. Once I know this value, then sample amounts, dilution volumes, and injection volumes are all easily determined.
6. Since laboratories are using reversed-phase high-performance liquid chromatography with photodiode array (RP-HPLC-PDA) or similar detection (not MS), the minimum amounts of substances detected by RP-HPLC-PDA are going to be very similar unless someone is using a much older instrument because these detectors are all based on the same principle and perform similarly.
7. When this is the case, the reported differences in LOD values between laboratories are due to differences in the mass of material sampled, the dilution volume, and the volume of the sample injected into the RP-HPLC=PDA instrument.
8. In other words, near uniformity of the LOD for target analytes can be achieved (nearly) by standardizing the sample size, dilution volume, and injection volume.
9. When these factors are all taken into consideration, a claim by a laboratory that their RP=HPLC-PDA method has a substantially lower LOD should be considered suspicious and would need documentation. The required data to document the LOD were acquired during the method validation study that the laboratory performed some time ago.

RP-HPLC-PDA is widely used and is appropriate for determining neutral and acidic cannabinoids in flowers and other substances in Cannabis. This method is fit-for-purpose and is widely used. H

We frequently encounter consumer products in which the cannabinoid concentrations in the finished products are different from the target values. In almost all cases, we have learned that the manufacturer/formulator relied on the claims of the seller regarding the identity and purity of the material to be used and the manufacturer did not obtain the results of independent analysis before formulating the product. This scenario has the potential to put three or more interested parties in conflict. If sellers were required to provide certificates of analysis from independent laboratories manufacturers would more likely prepare products that meet their targets. It is our experience that most manufacturers can properly prepare consumer products that meet target concentrations if they have reliable information about their ingredients.

We encounter samples every day that contain hemp-derived cannabinoid products. These are substances that have been prepared by altering a hemp component such as CBD to produce a hallucinogenic substance that may (or may not) have been reported from a rare strain of Cannabis in Tibet at a concentration of a few micrograms per kg but which is now being synthesized from CBD in kg quantities to make vape carts. Since these substances are synthetic substances, they contain synthetic impurities that, in most cases, are new chemical entities for which no toxicologic data exist. Reference standards don't exist for many of them so regulatory standards cannot be established because laboratories cannot measure them without a reference standard.

A sample matric containing the products of one of these reactions to synthesize a new hemp-derived cannabinoid product to spray on a hemp flower but to increase its psychoactivity is not the matrix that in which the RP-HPLC-PDA method was validated. It is totally different and, in our experience, one that requires test methods that possess greater selectivity and specificity than those of RP-HPLC-PDA. Many commercial laboratories have been slow to accept this reality and, consequently, consumer products containing new chemical entities are being sold without any knowledge of their potential human toxicity. They may all be inert substances at the exposure rates possible with consumer products but it wouldn't take much effort to subject these materials to some in vitro toxicological screening tests that are widely available for new pharmaceutical compounds and cosmetics.

I find it useful to identify early in the discussion that a consumer product or ingredient contains "hemp-derived consumer products". If it does not, then I probably will use RP-HPLC-PDA to determine the cannabinoid content. On the other hand, if it does, then I know that I need to use a GC-MS procedure (with derivatization) to separate the synthetic impurities from the target substances and permit their determination without interference from the synthetic impurities that are present.