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CSTF Steering Committee Meeting

3/23/2021

9am

Agenda:

9:00 Greeting
9:15 Develop Guidance Motion for Flexibility & Motion for Modifications
10:15 Potency Workgroup Update
10:30 Heavy Metals Workgroup Update
10:45 Residual Solvents Workgroup Update
11:00 Microbial Workgroup Update
11:10 Implementation Presentation
11:30 Public Feedback
11:45 Adjourned

Guidance Discussion:

Consistency between labs. Cannabinoid testing as commodity. Prescriptive method. Guidance from LCB or rule change that would allow labs to pursue other testing end points. Regulatory and mandatory pathway and non-regulatory and non-mandatory pathway.

Creating specific and narrow performance criteria. Good Laboratory Checklist as a starting place and focus on QA. Define parameters to create a more prescriptive document. Labs could use NY Method and be compliant or use a different method that follows our performance criteria. Clearly state the 4 cannabinoids.

Agree with Amber. We need consistency between the labs and prescriptive methods would get us there. I don't believe NY Method is the best method we could have chosen. If a lab can demonstrate their preferred method is better, this should be an option. What validation steps would I need to share with the ICT to demonstrate my labs ability? Taking the Good Lab Checklist and applying values to it would allow more flexibility within the labs.

If labs are making small changes but still pass the QC criteria and can validate. Potency workgroup and task force can come up with items that cannot be changed and areas that would be acceptable. Small changes would gradient change. Big change would be column, ESI source APCI source.

We are looking for consistency within labs to get more accurate data. We need to choose a pathway for one or the other.

One standard consistent method for product matrices that make up the bulk of market (flower, concentrates). Adaptation for potency would have to be set for the unusual product matrices and performance parameters that are set. Mandatory and non-mandatory testing. WAC and RCWs- Labs have the ability to have marijuana to do specific testing. Guiding principles around scope of CSTF and required testing for regulatory purposes.

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Should every lab run the same method?

- One standard consistent method for the bulk of the market matrices.
- 2 separate methods within NY Method. Analysis and sample prep. Analysis should be the same between every lab. Who is validating? Extraction side of this method is where the concern lies.
- Prescriptive methods will need adaptations over time. How would we make these changes down the road?
- How adaptations get made in the future and having a procedure laid out.
- Prescriptive/Standardized methods are typically used in the regulatory world to protect public health, ie. drinking water. It sounds like we need a pathway for a very small list of end products. ICT will play a large roll in bridging this gap.

Maybe rather than try and set criteria for lab changes to the NY Method, we need to provide guidelines for ICT to process these requests from labs.

If there isn't a way to have a lab test these adaptations while we are making these decisions, I believe setting clear performance criteria is the best pathway.

Majority of the market can be testing using the NY Method. Changes to this method would need to be based on a validation/performance criterion. We will need to figure out what adaptation qualify.

We will need to make changes to the NY Method for other cannabinoids. This method does not cover end products like hard candies.

Minor cannabinoids. Is the scope of the workgroup just to find the 4 main cannabinoids? Qualification and quantitative rules are needed for minor cannabinoids.

We need to test for the minor cannabinoids in order to find whether they influence the outcome of the analysis. Any method we use will have to be evaluated for Delta 8.

Labs can test for minor cannabinoids but they do not have to report it.

Minor cannabinoids are an interference that needs to be identified. Separation but not measured.

Minor cannabinoids as interference that need to be separated, does the NY Method address this?

Workgroup members are asking how they can add minor cannabinoids for measurement.

Our scope is about focusing on getting accurate data for regulated or mandatory components. If a lab wants to go beyond that it may be a list of other specific needs but not a topic that should bog down the workgroup meeting their objectives.

Fundamentally we need to ask- are we ok with small changed to the analysis method.

Drinking water method allows change to method but can take years- EPA or Federal. What small changes can be allowed and what is the process? Application? Quality objective are met then change can be made.

Potency is the main reason this task force was put together because of concerns regarding consistency. The pathway FDA or an agency run lab there is more of an agency approach. ICT allows changes would

be applicable among other labs. We describe the route through prep methods and on validation criteria the ICT can use. Boundaries the ICT can use to process future modifications. Workgroup needs to develop and adopt this criterion.

Validation criteria pathway can be set up by the task force. What would we recommend as a platform or starting point to address modifications? Until rule making changes occur.

Modifications get approved we need to determine how public these changes are. Is this a public portfolio of approved methods or is a lab able to keep these changes as proprietary? Would these method adaptations be made available for all laboratories?

Every record we keep is accessible to the public. Auditors are part of the government and their record is open to public inspection. Will it be easily accessible? We do want the labs to be doing the same thing. Consistency is a good step towards sound data and making Washington a leader in this industry. Proprietary conversation has come up before, we want things to be more open and transparent. Consumer confidence depends on that.

All the records and SOPs are disclosed now and it would stay that way going into the future. Framework analysis.

Are we going to allow small changes for the bulk of the market? Could I use one internal standard differing from what the other labs are using?

Internal standard meaning QC?

Internal standards. Surrogate standards

What is being said “better” is faster and cheaper. NY Method works better in quality. If labs are wanting adjustments for economic reasons, what would be acceptable? Modifications would make this method not prescriptive.

Small changes are pretty arbitrary but are we comfortable calling them small changes?

There needs to be an oversite group deciding what changes would be allowed.

The discussion is not only sample prep but all samples.

Analysis or prep changes, who has the authority to approve those changes. Auditor when doing accreditation or the ICT?

Downside of the auditor making this decision is less consistency and longer time to accredit. There is a cost involved with the time and manpower. The cost would go down if all labs are doing the same method with small or no adaptations.

Next steps:

- Proprietary changes
- Pathway for changes
- Who validates

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- Parameter for adaptations
- Who has authority
- What are the validation criteria