Legislative Report Draft Outline

Sara Sekerak
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CANNABIS SCIENCE TASK FORCE RECOMMENDATIONS
Cannabis Laboratory Quality Standards and Proficiency Testing
Executive Summary
• Recommendations overview

Introduction
  Background
  • 2019 - House Bill 2052
  • 2020 First report; recommendations to strengthen testing protocols for pesticides and creation of the ICT

Cannabis Science Task Force
• Roles, structure, deliverables, timeline

Work Continuation
• Continued workgroups and focus areas
• Delivery of memo

<table>
<thead>
<tr>
<th>Workgroup/Focus Area</th>
<th>Term</th>
<th>Status</th>
<th>Location of Final Recommendations</th>
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<tr>
<td>ANALYTICAL (PESTICIDES)</td>
<td>August 2019 – February 2020</td>
<td>Completed</td>
<td>Report #1</td>
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<td>PROFICIENCY TESTING</td>
<td>August 2019 – March 2020</td>
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<td>HEAVY METALS</td>
<td>June 2020 – February 2021</td>
<td>Completed</td>
<td>Report #2</td>
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<tr>
<td>POTENCY</td>
<td>June 2020 – June 2021</td>
<td>Completed</td>
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<td>RESIDUAL SOLVENTS</td>
<td>March 2021 – June 2021</td>
<td>Completed</td>
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<td>MICROBIOLOGICAL</td>
<td>April 2021 – 2022</td>
<td>Continuing</td>
<td>Report #2; memo to WSLCB/ICT</td>
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<td>MYCOTOXINS ^</td>
<td>June 2021 – 2022</td>
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<td>Memo to WSLCB/ICT</td>
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<tr>
<td>MOISTURE CONTENT AND WATER ACTIVITY ^</td>
<td>June 2021 – 2022</td>
<td>Continuing</td>
<td>Memo to WSLCB/ICT</td>
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Laboratory Quality Standards support Product Standards and Accreditation Standards

- **Product Standards**
  - Defines acceptable product content

- **Laboratory Quality Standards**
  - Defines test methods, method validation, and performance measures
  - Used by labs to test products to product standards
  - Used for accreditation to verify laboratory competence

- **Accreditation Standards**
  - Defines procedural accreditation practices

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**Defining Standardized Methods and Performance-Based Methods**
- Descriptions of each premise

**Importance of In-Matrix Proficiency Testing**
- Integral role in regulatory testing; tool for accreditation
- What it means to be “in-matrix”
- How in-matrix PTs work

**Barriers to Cannabis (In-Matrix) Proficiency Testing**
- Federal and state barriers
Interagency Cooperative Team

Genesis of the Interagency Cooperative Team
• As identified in first report
• Critical roles and responsibilities for pesticides

Additional ICT Roles and Responsibilities
• Roles to fill overarching gaps and challenges

  **Initial Integration of Laboratory Quality Standards**
  Scientific support to put Laboratory Quality Standards into practice

  **On-going Method Maintenance**
  • As identified in method recommendation motions

**Potency**
• Method modification pathway development
Heavy Metals and Residual Solvents
- EPA method updates and expectations

Microbiology, Mycotoxins, Moisture, Water Activity and Foreign Matter
- Identifying need for finalizing remaining fields – research methods (if not completed), author guidance

Advancing the Science
- Anticipating technology development
- New cannabis products
- Outlined Pathway

Cannabis Proficiency Testing Program Facilitation
- Filling the in-matrix PT gap
- Removing barriers
- Action items

ICT Formation Framework
- Identifying progress completed and anticipated ahead
Laboratory Quality Standard Recommendations
• RCW 43.21A.735 mandated items
• Method, validation and performance measures, sampling and homogenization, PT, necessary regulatory updates

Potency Recommendations
The Task Force recommendations for potency are as follows:
1. Appropriate approved testing methods: New York State (NYS) Department of Health (DOH)
   Medical Marijuana (MML)-301, revision 6 - Medical Marijuana Sample Preparation
   Protocols for Potency Analysis and NYS DOH MML-301, revision 6 - measurement of
   Phytocannabinoids in Medical Marijuana using HPLC-PDA (Appendix XX-xx).
   a. When newer revisions of the approved test methods are published by the NYS
      DOH, the ICT shall review the newest version(s) prior to implementation.
      Document control and ultimate revision decisions shall be under the ICT
      authority. When new versions are authorized the laboratories would be required
      to update their methodology accordingly.
2. Method validation protocols: Method validation protocols are as established within each
   approved method.
   a. A future validation pathway for laboratory-initiated modifications to increase
      method scope, beginning with minor matrices/products not included in the NYS
      DOH MML methods, shall be further developed by the ICT. The ICT pathway
      development shall incorporate the key attributes (Appendix XX-xx), and further
      develop the process using outlined process guidelines (Appendix XX-xx).
      Guidelines include method validation and review using steps necessitate the use
      of U.S. Food and Drug Administration document “Guidelines for the Validation
      of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products”, Level 4
      (Appendix XX) and AOAC Appendix D: Guidelines for Collaborative Study
      Procedures to Validate Characteristics of a Method of Analysis (Appendix xx).
3. Method performance criteria: Performance criteria are as established within each
   approved method. The following additional performance measures and adaptations shall
   supersede, or be used in conjunction with the minimum method requirements, as
   appropriate.
   a. The Task Force Potency Adaptations to the NYS DOH MML – 301 Revision 6 and
      NYSDOH MML – 300 Revision 6 methods shall be implemented to facilitate
      appropriate use of NYS methods (Appendix xx).
   b. Potency determinations shall be performed on samples "as is" or as received by
      the lab.

Heavy Metals Recommendations
Residual Solvent Recommendations
Microbiological Recommendations
Proficiency Testing Recommendations
• Addressing comprehensive programmatic approach
• Covers critical matrices and identified matrix categories
• Recommendations to remove barriers for in-matrix PTs to be used in Washington

Reoccurring Challenges and Topics of Concern
  Sampling Cannabis and Cannabis Products
  Cannabis Reference and Blank Materials

Conclusion

Definitions
References
Appendices
  Motions
  Recommended Methods
  Task Force Members
  Cannabis Matrix Proficiency Testing Trial
  • Proof-of-concept trial scoped by workgroup
Timeline and Next Steps
Task Force Report Timeline

- **April 2021**: Report Writing Begins
- **5/24**: All Task Force Final Report Recommendations Complete
- **6/1/2021**: Report Review & Publications
- **7/1/2021**: 8/5 Outline Presentation
- **8/1/2021**: 8/11 - 8/27 Task Force Review
- **9/1/2021**: Draft to Ecology’s Publications
- **10/1/2021**: Briefing with tribes
- **10/13**: Report to Ecology’s Government Relations
- **11/1/2021**: Report to Governor’s office
- **11/3**: Report to Legislature
- **12/1/2021**: Report to Legislature

**Timeline Dates:**
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