MICIL

MICHIGAN COALITION OF INDEPENDENT CANNABIS TESTING LABORATORIES

January 8, 2020

Marijuana Regulatory Agency - Legal Section
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SENT VIA EMAIL ONLY

Re: Response to MMFLA and MRTMA Draft Rules and Safety Compliance Facility Sampling and Testing Technical Guidance

Dear Sir or Madam,

The Michigan Coalition of Independent Cannabis Testing Laboratories (MICIL) – currently comprised of all six licensed Safety Compliance Facilities - has reviewed the MRTMA and MMFLA draft rules, as the most recently updated Technical Guidance Bulletins.

Our Coalition has a number of concerns outlined below, as well as suggestions to help amend issues that we have identified.

Thank you in advance for your consideration.

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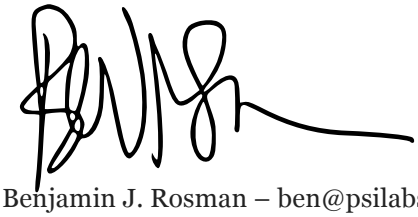

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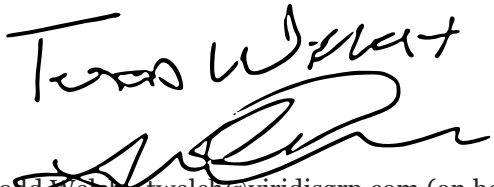

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Response to Draft Rules and Technical Bulletin

R 420.304(2)(b) Unlimited Batch Size:

- *"Except otherwise required by the agency, the laboratory shall collect a sample size that is sufficient to complete all required analyses, and not less than 0.5% of the weight of the harvest batch. At least 50% of the sample taken must be homogenized for testing. The agency may publish sample sizes for other marihuana products being tested."*

- The draft rules remove the 15 lb. maximum flower batch size, leaving an **unlimited batch size** in its place. It will be extremely difficult for SCFs to obtain a truly representative sample if there is an unlimited batch size. Sampling will take longer, be more labor intensive, create more of a bottleneck in a system that is already stressed.

- For example, imagine an outdoor grow with a 1,500 lb. total harvest:

    - Draft Rules: 1,500 lb. batch
        - = 7.5 lbs. of 1,500 lb. batch required (0.5% minimum of the batch)
        - Rule 4(2)(b): "At least 50% of the batch must be homogenized for testing":
            - In the example above, this would mean needing to homogenize nearly 4 lbs. of flower for testing.
    - Current Rules: 100, 15 lb. batches
        - =100, 0.075 lb. samples required

- Contamination can often spread out in a heterogeneous manner – especially for microbiological contamination. Splitting samples up across 15lb. batches helps samplers (and facilities) identify areas of the harvest batch that may be more problematic.

- **Recommendation: Michigan should not change the 15 lb. maximum batch size.**

R 420.301(g):"Final Package"

- *"'Final Package' means the form a marihuana product will be in after fully complying with these rules. This is the form marihuana product is in when it goes from a marihuana sales location to a consumer, registered qualifying patient, or a registered primary caregiver."*

- This definition requires more clarity - especially since SCFs can be given citations for providing retests of a product that is in its "final package".

- As an example, it is unclear if the following would be considered final packaging:
  - Products in boxes/packaging, but without affixed test result labels.
  - Products in packages but without any labels whatsoever.
  - Products in packages that have failed, but were taken out of the packages and submitted for a retest?
  - Products in packages, but would be further packaged (e.g., gummies in a bag, but will be placed in an additional container) or would be repackaged.

- There is no clear scientific reason to suggest that once a product has reached a final package state it cannot be safely repackaged without compromising safety or quality. If a processor is able to package a product once safely it seems likely they would be able to unpack and repack product as needed.

- **Recommendation: the definition of "Final Package" needs an explicit, clarifying definition to help alleviate industry confusion.**

R 420.304(2)(e)(iv): "laboratory confirms"

- *"If the product test sample is obtained for a retest, the laboratory confirms that it is not accepting a product test sample that is prohibited from being retested."*

- The state has placed the responsibility on SCFs to monitor their clients, ensuring they are in compliance with the rules. In effect - an SCF must act as both a laboratory and a branch of MRA-Enforcement. However, in failure of those Enforcement duties, the SCF (whose most important duty, and expertise, lies with the testing of samples for compliance) faces penalties, including citation or even suspension.

- Should the onus not be on the sample-submitting facility itself? And because MRA regulates and monitors all traffic via Metrc, could MRA not take this on as their responsibility?

- For example, if a sample has failed for chemical residue, it should automatically be placed on hold and *not* be able to be transferred to another facility.

- **Recommendation: MRA should handle all aspects of enforcement, tracking and monitoring, rather than relying upon (and penalizing) licensed facilities, who should spend their time perfecting their own processes.**

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R 420.305(1)(a): Scope of Accreditation

- A lab must be accredited within 1 year of licensing. However, there is no mention (and has never been mention in any previous rule set) that after 1 year a lab must have each specific assay (and analyte) in its scope of accreditation in order to perform that test.

- **Recommendation: The state should further clarify this verbiage to allow MRA to approve and validate a SCF's new method, and allow at least 6 months for a scope expansion (which should fall within the SCF's regular ISO surveillance period).**

R 420.305(12): COAs to MRA

- Sending COAs of all failing results to MRA is unreasonably burdensome - especially when all of the data is available to MRA in Metrc. However, upon request the SCF can send any and all COAs. The need to send *all* failing COAs will slow a SCF's turnaround time and, generally, negatively impact industry health.

- **Recommendation: MRA should rely upon Metrc-submitted lab data, and request COAs on an as-needed basis.**

R 420.304(2)(f): Three Day Rule:

- *"The laboratory shall enter into the statewide monitoring system the test results within 3 business days of test completion."*

- Mandating a testing facility to meet deadlines, imparts undue pressure on the analytical staff that will ultimately lead to quality assurance issues within the laboratory. The very standard that the MRA requires the Safety Compliance Facilities to meet for accreditation purposes (ISO 17025), specifically addresses these pressures that have a negative impact on the impartiality of the test results and the laboratory's quality management system governing those results.

- **Recommendation: MRA needs to narrowly define "test completion", given that technical and administrative reviews are a standard, necessary practice.**

R 420.305(4): GMP Certification to Replace Aspects of Safety Compliance Testing:

- *"All marihuana businesses may become certified to GMP by an ISO 17065 accreditation body. This accreditation may enable the licensee certain allowances with testing. The agency will publish those allowances and information on how to obtain approval for*

allowances."

- The ISO 17065 standard is what *certification bodies* become accredited to which brings higher credibility to their product certification operations. They are not an *accrediting body* and subsequently cannot offer accreditation, rather they certify the quality of a product being manufactured. Nowhere in the FDA's Code of Federal Regulations Title 21, where Good Manufacturing Practice is addressed, does it suggest allowances can be made from regulated testing requirements.

- **Good Manufacturing Practice (GMP) is internal to one's processes and should not be used as a measure to avoid testing requirements that ensure the health and safety of consumers.**

R 420.306(2): MRA-enforced lab shopping

- *"The laboratory that reported the initial failing results shall not perform the tests".*

- This is arbitrary and there is no scientific evidence to support the practice. The test should be performed the same way each time, if a failed product is remediated and sent for retesting, there is no reason why it could not be tested at the same SCF to confirm whether the remediation was successful.

- Lab shopping is already a known problem within the cannabis industry. This rule mandates that a facility *must* attempt to find another lab that will pass their product.

- Pursuant to Rule 5 (13), the state already mandates proficiency testing in an attempt to ensure standardization across labs. Further, in order to perform the assay, the lab's methods must have already been approved by both the state and an ISO 17025 accreditation body.

- **Recommendation: MRA should not promote doubt and a lack of confidence in its licensed SCFs. MRA must not force facilities to shop for a lab that will give them the most favorable results. Simply put, MRA should not mandate lab shopping.**

Vape Cartridges - required ATA tests, additives and copper test

- ATA Testing:

    - We want to ensure that moving forward (post-emergency rules), Vitamin E-acetate (ATA) will be a *required* test for *all* newly manufactured vape cartridges -

not merely something notated on a waiver/attestation form, signed off by processors. The recent outbreak of lung injury associated with vape cartridges (EVALI) is becoming a serious health crisis.

- **Recommendation: Michigan must enact a mandatory ATA test for all vape cartridges. Anything less would be irresponsible.**

- Additives:
  - It is currently unclear if botanical terpenes are allowed as an additive, though they are chemically indistinguishable from cannabis-derived terpenes. All vape cartridges (and other marihuana products) are tested for pesticides, metals, solvents (and hopefully ATA) under MRA.
  - **Recommendation: MRA should allow processors to use botanical terpenes as additives, since they are chemically indistinguishable from cannabis-derived terpenes, and they will ultimately undergo the same level of testing scrutiny as all other marihuana products.**

- Required copper test:
  - Copper is now a required test - for vape cartridges only. This was amended, where copper was first required for all marihuana products. Because copper-based fungicide is a safe (approved by MRA) and effective tool in eliminating fungal contamination, a vast majority of flowers we've tested are "contaminated" by copper at high levels. MRA's indifferent knowledge of the fact that patients and adults will be smoking plants "contaminated" with copper - but requiring a health and safety copper test, solely for vape carts, is unusual and illogical.
    - One exception could be if there is scientific data to support the idea that inhaling vaporized copper is more harmful than inhaling copper during combustion of plant material.
  - **Recommendation: Copper should either be a mandatory test for all inhaled products, or be removed entirely as a required test.**

Potency Test

- Reported variance:

- Scientific measurements are reported as ranges or with the ± sign rather than as single values because ***every measurement*** has some degree of variance, which must be reported

- e.g., a cannabis lab may report the variance at 10% relative - an industry standard.

- Statistically speaking, an infused marihuana product reported at 200 mg is equivalent to 180 - 220mg.

- The potency action limit for certain infused marihuana products is 200mg. If a processor yields a "fail" with a test result of 205mg ± 20.5mg (which is statistically equal to 184.5mg), it should not result in a "fail".

- Conflicting information currently exists for this guideline.

    - There is no mention of variances or error tolerances in a recent bulletin on infused product limits, however, a separate webpage for "Rule 34" says that all limits have a variance of +/-10%

- **Recommendation: MRA should account for a lab's reported variance – possibly rewriting the "error" section of the testing guide in ISO terms.**

Homogeneity and Potency Test:

- The Homogeneity Test was recently described to our lab by MRA as an optional test for processors, though the technical bulletins read as it being mandatory for the first batch and every 6 months thereafter.

    - **Recommendation: A Homogeneity Test should be mandatory, and MRA should clarify same to SCFs and Processors.**

- A related issue has to do with the difference between **Precision** and **Accuracy –** in this case, the difference between the homogeneity of a batch of infused products (**precision**) and the variance from the target dose (i.e., **accuracy**).

    - **Precision** is the variability from unit to unit within the batch which is covered by the +/-15% variance allowed in Homogeneity Tests.

- e.g**.,** if each individual increment tested was within +/-15% of each other (e.g., 10 mg, 11 mg., 10.5 mg, 12 mg.) - the product would **pass homogeneity**. If the doses were significantly different (e.g., 10mg, 50mg and 100 mg), the product would **fail homogeneity.**

- **Accuracy** is how close the actual measured potency is to the target dose.

- While it is very important to establish that tested products are homogenous (to ensure the end user gets the same expected dose each time, that only addresses the **precision** of the edible dosing. **Accuracy** is *not* being addressed with the current iteration of Homogeneity Testing, and has thus far been ignored for Potency Testing, possibly as an oversight.

  - Example: Target dose of 200mg, and actual potency of:

    - 201mg - **fails** Potency Test.

    - 6 mg - **passes** Potency Test.

      - Increments tested w/in +/- 15% of each other – 6 mg, 6.4 mg, 6.1 mg, 6.3 mg – **passes** Homogeneity Test.

- **Recommendation: MRA should mandate the Homogeneity Test (Precision), and also flag products as Potency Test failures if the tested potency is not +/- 15% of the target dose (Accuracy). Remediation can include repackaging with a different label to reflect the lower/higher dose.**

- **Measuring both Precision and Accuracy is crucial for establishing the consistency of the products from package to package and dose to dose, and will also help ensure that the dose is within +/- 15% of the target dose (often permanently printed on packages as part of branding).**