



January 31, 2019

Department of Licensing and Regulatory Affairs
Bureau of Medical Marihuana Regulation
Medical Marihuana Facility Licensing

SENT VIA EMAIL ONLY

Re: Suggested Temporary Rules for Licensees and Temporary Operators

Director Brisbo,

As you know, there is a shortage of supply of licensed, lab-tested cannabis products in Michigan's marketplace.

The vast majority of caregiver samples submitted to licensed provisioning centers and processors have failed compliance testing. This is in part due to the small handful of licensed facilities, as well as the state's rigorous testing guidelines.

In an effort to assist LARA-BMMR, we have prepared the attached suggested temporary rules for the transitional period (ending 3/31/2019).

The suggested rules ease the rigors of testing to help allow more caregivers and licensees to pass compliance, while preserving patient safety and product quality control.

We believe these rules present a suitable compromise, and we hope you'll agree. As always, please contact us with any questions or comments.

Warm regards,

Ben Rosman

SUGGESTED TEMPORARY RULES – TRANSITION PERIOD

WATER ACTIVITY:

Products cannot fail for Water Activity

MOISTURE:

Products cannot fail for Moisture

FOREIGN MATTER:

Products cannot fail for *Foreign Organic Matter* (e.g., insect exoskeletons, insect excrement, mold hyphae)

Products may not contain more than 2% *Foreign Inorganic Matter* (e.g., plastic fibers, metal fragments)

HOMOGENEITY TEST (Ingested Cannabis Products):

Expand Allowable Variation to +/- 20%

“Low Dose” Ingested Cannabis Products (> 1 mg) should be +/- 50%

CHEMICAL RESIDUE:

Inhaled Cannabis Products

Up to 2 ppm action limit for each analyte *

Ingested Cannabis Products

Up to 10 ppm action limit for each analyte*

Topicals, Salves, Patches and other products not intended for consumption

No limit

HEAVY METALS:

Inhaled and Ingested Cannabis Products

Refer to previous action limits in Table 4: "*Heavy Metals Concentration Limits in Parts Per Million (PPM)*", Safety Compliance Facility Sampling and Testing Information, Final Testing Guide, August 29, 2018

Topicals, Salves, Patches and other products not intended for consumption

No limit

* *Piperonyl Butoxide should have no limit if other pesticides are absent because it is a synergist and not a pesticide on its own. It is thought to be relatively benign according to the National Pesticide Information Center.*

- <http://npic.orst.edu/factsheets/pbogen.pdf>

Pyrethrins are a natural pesticide that should also have no action limit or a higher action limit. Both pyrethrins and piperonyl butoxide are approved for use on cannabis in Oregon and Washington.

- <https://www.oregon.gov/ODA/shared/Documents/Publications/PesticidesPARC/GuidelistPesticideCannabis.pdf>
- <https://agr.wa.gov/pestfert/pesticides/docs/PesticidesAllowedUseOnMarijuana.pdf>

RESIDUAL SOLVENTS:Cannabis Concentrates and Ingested Cannabis Products

Refer to the "Action Limit for All Other Products" in Table 4: "*Action Limits for Residual Solvents in Parts Per Million (PPM)*" in Safety Compliance Facility Sampling and Testing Information, Final Testing Guide, December 18, 2018.

Topicals, Salves, Patches and other products not intended for consumption

No limit

MICROBIAL SCREENING:Topicals, Salves, Patches and other products not intended for consumption

No limit

Total Viable Aerobic BacteriaInhaled & Ingested Cannabis Products

CFU/g 100,000

Total Yeast and Mold CFU/gInhaled & Ingested Cannabis Products

CFU/g 100,000

Total Coliforms CFU/gInhaled & Ingested Cannabis Products

CFU/g 10,000

E. coli (pathogenic strains) and Salmonella spp.Inhaled & Ingested Cannabis Products

Not detected in 2 grams

Bile-tolerant gram-negative bacteria CFU/gInhaled & Ingested Cannabis Products

CFU/g 10,000

Aspergillus flavus, Aspergillus fumigatus and Aspergillus niger**Add *Aspergillus Terreus***

Aspergillus terreus should be added to this list for consistency with other states that require an *Aspergillus* test.

There are also implications for consumable PCR lab supplies, resulting in additional unnecessary costs for labs performing these tests with PCR, which is the most feasible method to use.

Inhaled Cannabis Products

This is a pass/fail test. If the *Aspergillus* spp. are detected, the sample fails.