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February 17, 2020

Marijuana Regulatory Agency
Legal Section
P.O. Box 30205
Lansing, MI 48909

Re: Comments to Proposed Combined Topic-Based Rule Sets

To Whom it May Concern:

As the chair of the Cannabis Law Practice at Dykema, I am writing to offer comments on the Michigan Marijuana Regulatory Agency's (the "MRA") proposed combined topic-based rule sets: Marijuana Licenses; Marijuana Licensees; Marijuana Operations; Marijuana Sampling and Testing; Marijuana Infused Products and Edible Marijuana Products; Marijuana Sale or Transfer; Marijuana Employees; Marijuana Hearings; Marijuana Disciplinary Proceedings; Industrial Hemp for Marijuana Businesses; and Medical Marijuana Facilities (Rescinded) (collectively referred to as the "Proposed Rules") being promulgated pursuant to the Medical Marihuana Facilities Licensing Act ("MMFLA") and the Michigan Regulation and Taxation of Marihuana Act ("MRTMA").

As you know, our attorneys and government policy advisors represent clients in all facets of the medical and adult use cannabis industry. Our comments are based on our collective experience and the experience and views of many of our clients. Pursuant to the rulemaking process and the request for public comments, please find below Dykema's comments and recommendations on the proposed rules.

1. General Global Comments

Although most of our comments are targeted to isolated provisions within the Proposed Rules, and are set forth below on a rule by rule basis, two of our comments implicate issues that are reflected by multiple proposed rules.

First, as a general matter, all provisions related to Labor Peace Agreements should be eliminated. A mandate to enter into Labor Peace Agreements as a condition of licensure violates the National Labor Relations Act ("NLRA") and exceeds the statutory authority given to the

Department. Additionally, Labor Peace Agreements effectively place the terms and conditions of employment in the hands of an arbitrator. In an industry that is just beginning to find its way, and where income and expenses already fluctuate wildly, requiring critical economic decisions to be made by a third party does nothing to protect the interests of the industry, patients, consumers, and the state. Therefore, all provisions related to Labor Peace Agreements should be removed in entirety from all rule sets.

Second, we believe that there should be significant rewrites of the testing provisions. We have already seen instances where MRA has imposed new standards and ordered hundreds of thousands of dollars of product to be destroyed, only to then realize that the standards were flawed or should be implemented differently, and reverse course. Producers who were ordered to destroy product that MRA later determined was not harmful have suffered significant economic harm with no recompense. We believe these concerns are best addressed by allowing greater flexibility when it comes to remediation and by broadening the concept of administrative holds beyond simply cases of rules violations, to also encompass product that has initially failed testing. This would provide producers the ability to contest the appropriateness or sufficiency of testing standards without having to destroy viable product.

Third, we believe that the MRA should exercise its authority to establish new license types to establish a license for receiver businesses. As we have learned from other states, we should expect significant business failures in this industry. Yet, cannabis businesses cannot avail themselves of federal bankruptcy protection. Additionally, MRA's rules provide for the suspension and revocation of licenses. In an industry where licensees may have product midstream in growth or production, or significant inventories, suspending operations can lead to significant loss, and jeopardize the interests of creditors. This can also incentivize product diversion. Having licensed receivers able to step in to operate or liquidate facilities serves numerous public interests.

2. Marijuana Licenses 2019-67 LR

<u>R 420.1(1)(c)—Definition of "Applicant"</u>

The term "indirect ownership interest," used in 420.1(1)(c)(i), comes directly from the MMFLA but was not defined by the Legislature, leading to confusion and inconsistent practice and advice from attorneys in the industry. The Proposed Rules should either define the term or state that MRA will provide guidance as to the MRA's interpretation. We often see what may be considered indirect interests arise through the provision of equity in only one license of an entity that possesses multiple licenses, or with respect to one product line. Today, it is not clear if an indirect interest of 10% should be calculated based on total equity, total revenues, or some other metric. MRA guidance would be useful.

Also, we appreciate the express permission for both financing arrangements and licensing agreements. Under 420.1(1)(c)(ii)(A) and (D), however, we recommend defining the terms "reasonable interest rate" and "reasonable payment," respectively. At a minimum, the rules should state that MRA will provide guidance to the industry with respect to these terms.

R 420.1(1)(l)—Definition of "Employee"

Under 420.1(1)(l), the definition of "Employee" excludes "individuals providing trade services who are not normally engaged in the operation of a marihuana business." Dykema suggests that the language read "Employee" does not include "individuals providing trade ***or professional*** services who are not normally engaged in the operation of a marihuana business.

R 420.3—Application procedure; requirements

Under 420.3(2), Dykema suggests allowing prequalification status for grow facilities currently under construction to extend beyond 1 year to avoid having to re-qualify grow facilities whose municipal approval process and construction schedule often extends far beyond that timeframe. This is especially problematic when a municipality requires prequalification status as a condition to local approval, and prequalification status could be temporarily lost. Dykema suggests providing that the MRA may request updated information from an applicant within 90 days prior to the expiration of prequalification status, and allow applicants with their facility under construction to maintain uninterrupted prequalification status so long as circumstances have not changed in a manner that affects suitability.

R 420.4—Application requirements; financial and criminal background

Under 420.4(2)(a)(i)(C), Dykema suggests amending the language "all loans" to read "all loan types specified by the Department," thus providing explicit authority for the MRA to exclude auto loans, credit cards, student loans or other loans that the MRA may find to be unnecessary to examine.

Under 420.4(13), while we understand the need to have adult-use licensees pass a facility inspection on a timely basis, we also believe that this requirement provides municipalities the ability to sidestep important MRTMA protections, at least insofar as MRA requires local certificates of occupancy as a condition for passing inspection. As you know, MRTMA provides municipalities the ability to opt out of allowing adult use businesses in their communities, but MRTMA also explicitly states that ineligibility of an applicant to receive a license on this basis must be tested as of the time the applicant files its application. MRTMA also expressly provides that a municipal ordinance may not prevent an applicant from operating certain types of adult-use establishments where the applicant already has an operating MMFLA facility. Despite the fact that MMFLA and MRTMA operations and impacts are identical in nature (indeed, for many

license types the only observable difference is the color of the Metrc tag), we have seen municipalities refusing to issue certificates of occupancy for adult-use purposes to existing medical facilities. A licensee should have the ability to demonstrate to MRA that a municipality is improperly withholding documentation, without being forced to suffer a license denial and then sue either the MRA or the municipality.

R 420.5—Application requirements; complete application

Under 420.5(4)-(5), Dykema suggests allowing more than 5 days for applicants to supply missing information or proof of corrected deficiencies to the agency, at least in the case of MMFLA applicants for whom there is no 90-day deadline for MRA decision making.

R 420.10—Proof of financial responsibility; insurance

Dykema suggests adding language to sections (1) and (4) that would require licensees to maintain $100,000 in liability insurance ***per location*** as opposed to per license.

R 420.11—Capitalization requirements; medical marihuana facilities licensing act

Dykema suggests amending section (1) to read "On its initial application for licensure under the medical marihuana facilities licensing act, an applicant shall disclose the sources and total amount of capitalization to operate and maintain a proposed marihuana facility." In other words, the capitalization requirements should not be applicable to the expansion of existing facilities.

R 420.12—Denial of a marihuana license; additional reasons

Dykema suggests that 420.12(2)(e) and (n) apply to adult-use applicants only, as they again stem from the MRA's need to more quickly process adult-use applications.

R 420.13—Renewal of state license

Under section (1)(a) and (2) the MRA is requiring spouses on renewal applications to be fingerprinted, and apparently treating a disqualified spouse as a basis to disqualify an entity on renewal. This applies new "applicant" language from 2018 statutory amendments to both initial applicants ***and*** renewals. We believe this is entirely contrary to legislative intent and to the language of the MMFLA.

The original set of amendments proposed by LARA/BMMR in 2018 made the definitional change equally applicable to those in the application process and those who had yet to file. This caused a particular concern by essentially retroactively changing the standard for

those who had already filed applications. More specifically, this caused specific concerns for applicants who worked with Rep. Kesto to ensure the changes would not be retroactively applied; this was the genesis of the language limiting the effectiveness of the change to only applications submitted "on or after January 1, 2019." To now include and enforce these standards on renewal to entities that applied before January 1, 2019, would completely subvert and undermine the Legislature's intent in adding the January 1, 2019, language.

Additionally, to add these requirements on renewal is inconsistent with the statutory language itself. The MMFLA, as amended, makes an express distinction between "Applicant" and "Licensee" under the MMFLA, as amended, along with a possible argument about MRA not properly exercising its deference when carrying out the MMFLA depending on its ultimate position. The MMFLA has specifically defined both "Applicant" and "Licensee" and references the various definitions based on whether the license is being applied for or whether it is being renewed. Thus, an "Applicant" is not a "Licensee" and a "Licensee" is not an "Applicant." Michigan courts have continuously held that "[w]hen interpreting a statute, our primary obligation is to ascertain and effectuate the intent of the Legislature. To do so, we begin with the language of the statute, ascertaining the intent that may be reasonably inferred from its language." *Lash v Traverse City*, 479 Mich 180, 187 (2007). "When the language of a statute is unambiguous, the Legislature's intent is clear and judicial construction is neither necessary nor permitted." *Id*. The Michigan Supreme Court has further held that "ambiguity is a finding of last resort." *Stone v Williamson*, 482 Mich 144, FN 21 (2008).

The MMFLA defines "applicant" as "a person who applies for a state operating license." MCL 333. 27102(c). The statute further clarifies that applicant includes, "with respect to disclosures in an application, for purposes of ineligibility for a license under section 402, or for purposes of prior board approval of a transfer of interest under section 406, and only for applications submitted on or after January 1, 2019, a managerial employee of the applicant, a person holding a direct or indirect ownership interest of more than 10% in the applicant." *Id.* The MMFLA defines "Licensee" as "a person holding a state operating license." MCL 333.27102(j).

MCL 333.27402 provides that "[t]he board shall issue a license to an applicant who submits a complete application and pays both the nonrefundable application fee required under section 401(5) and the regulatory assessment established by the board for the first year of operation, if the board determines that the applicant is qualified to receive a license under this act." MCL 333.27402(1). Section 27402 further provides that "[a] license shall be issued for a 1-year period and is renewable annually. Except as otherwise provided in this act, the board shall renew a license if all of the following requirements are met: (a) The licensee applies to the board on a renewal form provided by the board that requires information prescribed in the rules; (b) The application is received by the board on or before the expiration date of the current license; (c) The licensee pays the regulatory assessment under section 603; and (d) The licensee meets the

requirements of this act and any other renewal requirements set forth in the rules." MCL 333.27402(9).

From the statutory language it is apparent that the Legislature intended to distinguish applicants (persons applying for a state license) and licensees (persons holding a state license). Section 27402 outlines the requirements for applicants to obtain a license, throughout the entire section pre licensure requirements are referred to by "applicant." However, provisions outlining the requirements for licensure renewal specifically reference the "licensee." Thus, the Legislature intended that the definition of applicant apply to only those seeking licensure, while the definition of licensee refer to holders of licenses.

Dykema suggests adding qualifying language to section (1)(a) and (2) carving out an exception for spouses of applicants and licensees whose original application was filed prior to January 1, 2019.

R 420.21—Designated consumption establishment license

Dykema suggests adding "***program or manual***" to section (2)(k) to read: "A documented employee training ***program or manual*** that addresses all components of the responsible operations plan."

R 420.27—Marihuana delivery business

Dykema recommends removing rule 420.27 in its entirety. Licensees who make significant investments in facility construction, inventory, and operating costs have a meaningful financial incentive to fully comply with statutory and regulatory obligations. A licensee who makes no such investment and has a role simply limited to delivering retail product does not have such incentives. This new license type simply presents too much risk.

3. Marijuana Licensees 2019-68 LR

R 420.108—Grower license

Under section (6), Dykema suggests defining "investor."

R 420.109—Processor license; exception for industrial hemp

Under section (1), Dykema suggests re-wording the section to read "A processor license authorizes purchase of marihuana only from a grower or another processor." Currently, the section allows the sale of marihuana from another processor but not the purchase. If the sale is authorized to another processor, it is inherent that the purchase would also be allowed. (We note

also that the title of this rule includes "exception for industrial hemp," yet the rule does not mention hemp.)

4. Marijuana Operations 2019-69 LR

R 420.201—Definitions

Under 420.201(1)(c), Dykema suggests extending the definition of Administrative Hold to include the failure to meet testing standards, and allow facilities having product that fails testing standards to hold the product during an investigation into alleged violations or sufficiency of testing standards.

Under 420.201(1)(e)(ii)(D), the MRA should define what is a "reasonable payment" under a licensing agreement.

R 420.203—Marihuana licenses; licensees; operations; general

420.203(2)(a) provides that "a marihuana business shall be partitioned from any other marihuana business or activity, any other business, or any other dwelling." While section (2)(a) provides an exception for operation of separate licenses at the same location and for operation of equivalent licenses at the same location, we believe that the current language does not fully contemplate the processing of industrial hemp. Section 7(1) of the Industrial Hemp Research and Development Act (the "Hemp Act") states that a processor licensed under the MMFLA may process industrial hemp. Therefore, we believe that language should be added at the end of section (2)(a) of proposed rule 420.203 to read "a marihuana business shall be partitioned from any other marihuana business or activity, any other business, or any other dwelling, ***other than activities in which marihuana businesses are entitled to participate, and provided further that growers and processors operated at the same location under R 420.204 shall not be required to partition.***" (This latter provision would eliminate the need for costly "mantraps" in co-located and integrated grower and processor facilities.)

Although the language of 420.203(2)(c) appears in the current rules, we believe that the MRA should remove the requirement that marihuana businesses must be contiguous. To date, MRA has allowed licensed activities to be in out-buildings on the same parcel as primary buildings (e.g., for grinding of waste). At a minimum, the MRA should at least define contiguous to mean structures located on one parcel.

Dykema suggests removing the prohibition against drive through operations in 420.203(2)(g).

R 420.204—Operation at same location

Dykema suggests amending 420.204(2)(d)(iii) to read "Have separate entrances, exits, inventory, record keeping, and point of sale operations ***other than for growers and processors at the same location***."

As noted above, in 420.204(2)(d)(ii) MRA should remove the requirement that marihuana businesses must be contiguous.

Dykema suggests adding a subsection (4)(d) under 420.204 that makes clear that a laboratory co-located with an existing non-marijuana testing laboratory must comply with all building security, design, and other MRA operational rules.

R 420.205—Equivalent licenses; operation at same location

Under 420.205(2)(c) to operate equivalent licenses at the same location, the operation cannot "circumvent a municipal ordinance or zoning regulation that limits the marihuana business under the acts." MCL 333.27956, however, provides that "[a] municipality may not adopt an ordinance that . . . prohibits a marihuana grower, a marihuana processor, and a marihuana retailer from operating within a single facility or from operating at a location shared with a marihuana facility operating pursuant to the medical marihuana facilities licensing act." Dykema suggest that this exact language be added to the end of (2)(c) after a "provided, however," in order to comply with the statutory requirements and prevent municipalities from sidestepping them.

R 420.206—Marihuana business; general requirements

Under 420.206(1)(b)(ii), cultivation may occur outdoors if "all drying, trimming, curing, or packaging of marihuana occurs inside the building meeting all the requirements under these rules." Dykema suggests adding "Provided, however, that marihuana may be transported to a grower or processor without drying, trimming, curing, or packaging of marihuana."

Under 420.206(8)(b), Dykema suggests defining the term "supervisory analyst."

Under 420.206(11), the term 'inactive ingredients' is a pharmaceutical product term. While the term and this requirement is sensible with respect to distillate blended with other products and intended for inhalation through vaping, to the extent that edibles or other supplements have ingredients that may be on the FDA inactive ingredient list, they are not intended to "facilitate the transport of marihuana in the body" and therefore the regulation makes no sense as applied to edible or ingestible marihuana products. As non-pharma products or supplements, such products should simply be required to list the ingredients pursuant to FDA labeling regulations (for food products).

420.206(14) requires marihuana businesses to comply with updated standards issued by the agency within 60 days of their adoption. However, for growers, 60 days does not provide enough time for a grow cycle to occur and product to be tested to comply with any changes. Therefore, Dykema suggests adding "Except in cases of public health emergencies, a lab must validate new tests within 60 days of adoption by the agency and growers and processors must meet the standards adopted by the agency within 150 days of adoption."

420.206(16)(a)-(b) quite simply amounts to a regulatory taking and must be removed. The agency has no statutory authority to force a sale of product to a third party "to ensure that all marihuana businesses are properly serviced." Such a regulation amounts to a regulatory taking and forces marihuana businesses to eliminate their competitive business advantage. By ***mandating*** sales in certain circumstances, it also puts the MRA itself in direct violation of the federal Controlled Substances Act, eliminating the defense to pre-emption challenges to the MMFLA (and, by extension, to MRTMA) relied upon by the Michigan Supreme Court in *Ter Beek v City of Wyoming*, 495 Mich 1 (2014). This step would thus threaten to undermine Michigan's entire statutory framework for the industry.

R 420.207—Marihuana delivery; limited circumstances

Under 420.207(3), Dykema suggests changing "shall establish procedures" to "***may*** establish procedures." (Otherwise, this could be read as mandating delivery for businesses that may choose not to engage in this practice.)

Under 420.207(4)(c), Dykema suggests amending the language to read: "All marihuana delivery employees meet the requirements in R 420.602 and are employees, ***as defined in R 420.601(1)(d)***, of the marihuana sales location.

R 420.208—Building and fire safety

Under 420.208(5), we believe that the MRA and Bureau of Fire Services needs to re-assess whether growers should be treated as an industrial use. This unique Michigan treatment has led to numerous requirements that are not present in any other state, including such absurdities as mandating sprinklers and specific paths and distances for marijuana planted outdoors under plastic high tunnels.

R 420.209—Security measures; required plan; video surveillance system

Under 420.209(3) Dykema suggests adding "***or other electronic or keypad access***" after "door locks." (The current mandate for commercial grade locks has been interpreted by some in MRA Enforcement to require low-tech deadbolt style locks, when electronic access controlled doors are more secure.)

5. Marijuana Sampling and Testing 2019-70 LR

R 420.301—Definitions

Under 420.301(1)(h) "Final Package" is defined as "the form a marihuana product is in when it is available for sale by a marihuana sales location." We believe the definition is ambiguous because it references the "form" of the product itself. The definition should reference the packaging, not the form of the product. Therefore, we suggest the definition be amended to read: "Final Package means the outermost container or box the marihuana product is house in when it is available for sale by a marihuana sales location."

R 420.303—Batch; identification and testing.

Dykema suggests that MRA clarify in 420.303(1) that each immature plant counts as one plant toward the grower plant count. As the MRA and others have determined, this is the count methodology required by the wording of the MMFLA. However, this provision for batch tagging in Metrc, while correct, continues to be misinterpreted, especially by new market entrants.

420.303(5) currently allows marihuana product that fails testing and is remediated to be sold or transferred once approved by the agency. We believe that agency approval should not be required for marihuana product that passes (under R 420.306) two subsequent re-tests following remediation.

Under 420.303(9), the MRA should change the language "anytime the marihuana product changes form" to read "anytime the marihuana product changes ***state***."

R 420.304—Sampling; testing

Under 420.304(2)(b)-(c), the MRA should amend section (2)(b) to read "The agency may publish sample sizes for other marihuana products being tested, ***and may provide for a maximum harvest batch size***." Additionally, the MRA should move the language at the end of section (2)(c) to the end of (2)(b) to now read "The laboratory must have access to the entire batch for the purpose of sampling and ***shall ensure that the sample increments are taken from throughout the batch***." (Sampling methodology should remain under the full control of the laboratory, not growers, and growers should not be held responsible for a laboratory's failure to take appropriate samples.)

In 420.304(2)(h), laboratories should be the parties responsible for uploading accurate data from the certificate of analysis into the statewide monitoring system. Certificates of analysis are not standardized, vary from lab to lab, and are commonly misunderstood.

Dykema suggests amending 420.304(2)(i) to read "This provision does not apply to a laboratory who engages another laboratory to perform certain safety tests on a subcontracted basis, ***or to a laboratory under common ownership***."

R 420.305—Testing; laboratory requirements

420.305(3) should be clarified so as to not interpret the section to mean a marihuana product needs to be tested every time it changes form (or state). Testing should be required before sale or transfer, but not when form changes due to processing.

420.305(10) currently sets a zero tolerance for chemical residue (pesticides). However, extremely low levels of pesticide residue is possible. We believe that chemical residue should have an action limit instead of a limit of quantification. Having an LOQ with a fail for even the slightest amount of chemical residue creates excess costs or production because potentially large batches must then be destroyed. At the very minimum we believe that R 420.306(3) should be amended to allow product that tests positive for chemical residue to be remediated to fall below the action limit allowable.

We believe that the accuracy thresholds for all licensed labs should be published by the department. This would allow other licensees to monitor and be aware of labs that are the most accurate.

The MRA should add a 420.305(2) stating that, "A marihuana business may have a failed batch R&D tested by a different laboratory to determine whether or not the laboratory that performed the initial test may have made an error. If an R&D test contradicts the failed result, the department will investigate the failed result and may have the item selected for random sampling by another licensed lab."

Finally, Dykema suggests adding a provision to Rule 420.305 that allows laboratories prelicensure possession of marihuana for the purpose of validating testing equipment. (With the passage of MRTMA, owners and operators of prelicensed laboratories have the legal authority to possess marijuana.)

R 420.306—Testing marihuana product after failed initial safety testing and remediation

Dykema suggests amending 420.306(2) to add a provision that prevents immediate destruction of product if the marihuana business is challenging the validity of testing. In this case, product would be required to be placed under an administrative hold as defined in R 420.501.

As discussed above, 420.306(3) is not ideal in practice. Currently, the rules propose a zero tolerance for chemical residue. However, ultra-low levels of chemical residue can be

attributable to accidental contamination rather than the use of a banned pesticide. Section (3) should be amended to allow processors to remediate the material to remove chemical residue. The implementation of the current section, as written, will result in exponential loses to licensees and a shortage of product for customers and patients. Growers are vulnerable to large losses as a result of accidental environmental contamination, while processors are vulnerable to large losses due to an accumulation of contamination during processing, even where no banned pesticide was utilized.

420.306(4) should be amended to specify that processors will be allowed to remediate any material that can be remediated. Additionally, this rule should allow processors to transfer material to another processor for remediation.

Finally, Dykema suggests amending section (4) to read "The agency ***shall*** publish a remediation protocol."

R 420.307—Research and Development

We believe that R&D testing should be allowed before or after final compliance testing.

6. Marijuana Infused Products and Edible Marijuana Product 2019-71 LR

R 420.403—Requirements and restrictions on marihuana-infused products; edible marihuana product

420.403(6) should be amended in accordance with our comment to R 420.206(11): The term 'inactive ingredients' is a pharmaceutical product term. To the extent non-medical marihuana products have ingredients which may be on the FDA inactive ingredient list, they are not intended to "facilitate the transport of marihuana in the body" and therefore the regulation makes no sense as applied to edible or ingestible marihuana products. As food or supplements, such products would be required to list the ingredients pursuant to FDA labeling regulations.

R 420.404—Maximum THC concentration for marihuana-infused products

420.404 should be amended to read "A marihuana sales location shall not sell or transfer marihuana infused products that exceed, ***by more than 15%***, the maximum THC concentrations established by the agency."

7. Marijuana Sale or Transfer 2019-72 LR

R 420.504—Marihuana product sale or transfer; labeling and packaging requirements

Under 420.504(1)(i), listing the name of the laboratory that performed ***any*** test, ***any*** associated batch number, and ***any*** test analysis date is very cumbersome and should be limited to certain laboratories, batch numbers, and analysis dates.

Under 420.504(1)(k)(iii), Dykema suggests amending the language to read: "For products being sold by a licensee under the medical marihuana facilities licensing act ***that exceed maximum THC levels allowed for products sold under MRTMA***, "For use by individuals 21 years of age or older only. Keep out of reach of children."

Additionally, under section (1)(k)(iv), Dykema suggests amending the language to read: "For ***all other*** products being sold by a licensee, "For use by individuals 21 years of age or older or registered qualifying patients only. Keep out of reach of children."

Together, the above changes would enable licensees to use the same labels for products that are allowed for both medical and adult-use customers, thereby reducing the costs incurred by growers and processors.

R 420.505—Sale or transfer; marihuana sales location

Dykema suggests amending section (1)(e) to read "A licensee ***selling marihuana product pursuant to*** the medical marihuana facilities licensing act."

R 420.507—Marketing and advertising restrictions

Under 420.507(6), Dykema suggests moving "under the medical marihuana facilities licensing act" to after "marihuana product" so that section (6) would read: "A marihuana product ***under the medical marihuana facilities licensing act*** must be marketed or advertised as 'medical marihuana' for use only by registered qualifying patients or registered primary caregivers."

Under 420.507(7), Dykema suggests moving "under the medical marihuana facilities licensing act" to after "marihuana product" so that section (7) would read: "A marihuana product ***under the medical marihuana facilities licensing act*** must not be marketed or advertised to minors aged 17 years or younger."

8. Marijuana Employees 2019-73 LR

R 420.602—Employees; requirements

Dykema suggests amending sections (6) and (7) to insert "***or professional***" after the word "trade".

9. Marijuana Hearings 2019-74 LR

R 420.706—Complaint by licensee

Dykema suggests adding a section that allows licensees to contest the standards set for testing.

10. Marijuana Disciplinary Proceedings 2019-75 LR

R 420.808—Citation

Dykema suggests amending section (7) to allow a licensee to provide "***a written response***" instead of limiting the response to one single page.

11. Industrial Hemp Rule for Marihuana Businesses 2019-88 LR

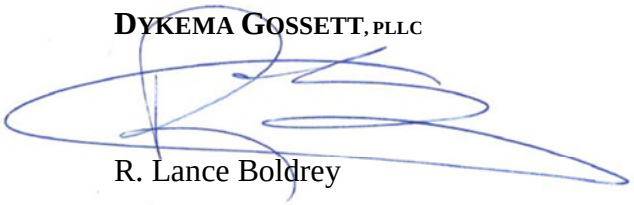
R 420.1003—Processing industrial hemp.

Sections (1), (2) and (5) of 420.1003 expressly require a medical or adult-use marijuana processor to comply with the Hemp Act and associated rules promulgated by the Michigan Department of Agriculture and Rural Development if the processor handles, processes, markets, or brokers industrial hemp. This would pose a serious compliance issue for marijuana processors that choose to process industrial hemp for several reasons. First and foremost, industrial hemp and marijuana are both defined as the plant Cannabis sativa L., with the only distinction between the two being the delta-9-tetrahydrocannabinol (THC) concentration of the plant. Under the Hemp Act, any cannabis in the processor's possession that exceeds .3% THC concentration would be considered non-compliant industrial hemp and would need to be destroyed. Thus, a marijuana processor that processes both industrial hemp and marijuana would not be in compliance with the Hemp Act because it would be processing and in the possession of cannabis with a THC concentration that exceeds the allowable limit under the Hemp Act. Similarly, a marijuana processor would be unable to use any industrial hemp-derived CBD or other ingredients in its finished marijuana products.

Therefore, the rule should be clarified to exempt marijuana processors from complying with the Hemp Act if and when the marijuana processor handles, processes, markets, or brokers cannabis with a delta-9-THC content greater than 0.3% on a dry weight basis.

Regards,

DYKEMA GOSSETT, PLLC



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MICIA COMMENTS ON DRAFT MARIHUANA RULES

(Rule sets # 2019-67 LR, 2019-68 LR, 2019-69 LR, 2019-70 LR, 2019-71 LR, 2019-72 LR, 2019-73 LR, 2019-74 LR, & 2019-75 LR.)

INTRODUCTION

The Michigan Cannabis Industry Association (MICIA) is the leading voice for Michigan's legal cannabis businesses. The association advocates for a responsible and successful medical and adult-use cannabis industry by promoting sensible laws and regulations and industry best practices among members. MICIA seeks to create a thriving industry for cannabis businesses in Michigan by developing opportunities for industry collaboration and partnerships and sharing industry knowledge and best practices among its membership.

MICIA supports many elements of the proposed rules. But MICIA offers the following constructive comments with the hopes of developing policies that promote both the growth of the industry and the establishment of good business practices. Moreover, MICIA seeks to ensure that the Marijuana Regulatory Agency (MRA) receives adequate stakeholder input prior to the adoption of its generally applicable policies, standards, and enforcement procedures consistent with the rule of law and the Michigan Administrative Procedures Act, MCL 24.201 *et seq*. Lastly, MICIA notes that, though it has not exhaustively commented on all of the rules, its silence on some rules should not be understood as either approval or disapproval of those particular provisions.

COMMENTS

1. Licensing Rules (R 420.1 *et seq.* and R 420.101 *et seq.*)

Licensing Prequalification Application Procedures

Proposed Rule 420.3(2) provides, in part, that prequalification status for a pending application is valid for 1 year after the agency issues a notice of prequalification status unless otherwise determined by the MRA. After 1 year has expired, the proposed Rule authorizes the MRA to require the applicant to submit a new application and pay a new nonrefundable application fee. While the permissive language of the proposed Rule provides that MRA with a great deal of flexibility, MICIA suggests that the MRA extend the period under which an incomplete, pending application may be held in prequalification status from a one-year or a two-year period. Oftentimes prequalified applicants who are actively under construction require more than one year to complete the final application due to circumstances beyond their control such as delay or inaction by contractors and/or local or county governments. To require those applicants to redo their

application and pay a new nonrefundable application fee under those circumstances can be unduly burdensome during the startup phase of a new business.

Licensing Application Procedures – Control

Proposed Rule 420.4(2)(*iv*)(B) requires applicants to disclose "any other person who . . . [i]s controlled, directly or indirectly, by the applicant or by a person who controls, directly or indirectly, the applicant." This cumbersome requirement has been difficult to understand and could theoretically require disclosure of a string of persons far removed from the applicant. MICIA suggests that this language be removed, limited, or further clarified.

Application Deficiencies – Opportunity to Cure

Proposed Rule 420.5(4) and (5) provides an applicant 5 days to correct any deficiency in the application. Failure of an applicant to correct a deficiency within 5 days of notification by the agency may result in the denial of the application. MICIA suggests that this timeframe be extended to ten days or, at least, be revised to provide five "business days" excluding holidays to cure application deficiencies.

Mandated Labor Peace Agreements

MICIA is opposed to the rules' mandate that licensees enter into and abide by labor peace agreements. R 420.5(6), R 420.13(1)(e), R 420.14(3)(h), & R 420.21(2)(m), R 420.801(1)(e), & R 420.802(3)(h). A legal mandate forcing a unionized workforce on applicants is both wholly unnecessary and unrelated to an applicants' qualifications to operate a marijuana establishment. The mandate also raises a number of significant legal concerns, including but not limited to whether it conflicts with federal law governing private-sector labor relations and state law preventing forced unionization. MICIA further believes such requirements are beyond the agency's delegated rulemaking authority under MCL 333.27206, MCL 333.27957, & MCL 333.27958. Additionally, the MRA has failed to engage in any cost-benefit analysis related to this requirement and its impact on the industry. See generally MCL 24.245(3).

Civil Lawsuit Reporting Requirement

Proposed Rule 420.14(5) requires applicants to notify the agency within 10 days of the initiation or conclusion of any new civil lawsuits or legal proceedings that involve the applicant. To the extent such actions are unrelated to any criminal or regulatory actions, this requirement is unnecessary and should be removed. The reporting requirement provides an incentive for third parties to target and seek to obtain leverage over licensees by threatening non-meritorious litigation. MICIA, however, continues to support reporting for civil judgments entered against licensees.

Excess Marihuana Grower Licenses

MICIA supports the MRA's inclusion of excess marihuana grower licenses. R 420.20(1)(b); & R 420.22. MICIA views this license as a significant means of addressing a market shortage of available product by permitting larger scale cultivation.

Marihuana Event Organizer Licenses and Temporary Event Licenses

MICIA supports the MRA's inclusion of marihuana event organizer licenses and temporary event licenses. R 420.20(1)(c), (1)(d), & (3); R 420.23; & R 420.24. MICIA sees both as a positive means of facilitating industry development and social consumption.

Marihuana Delivery Business License

MICIA opposes the MRA's development of rules allowing the licensure of standalone delivery businesses permitted to operate without a secured transporter license and without obtaining local approval. See R 420.20(1)(e) & R 420.27. MICIA believes that these services are more effectively regulated and tracked at licensed marihuana retail locations or when directly consummated by licensed marihuana retailers.

Research and Development License

MICIA proposes that the MRA develop and adopt rules to promote the growth of facilities specializing in genetic advancement of marihuana plant strains, seeds, and clones for sale via secured transporters to licensed growers.

Marihuana Plant Count – Female Flowering

MICIA supports the clarification in proposed Rule 420.102 that only female marihuana plants that flower may be included in the plant count referenced in subrule (1) of this rule. This treatment more accurately reflects marihuana growth and harvest cycles and should help alleviate the current supply shortage. MICIA further suggests replacing the phrase "female marihuana plants that flower" with the phrase "flowering marihuana plant" and defining that term as "a marihuana plant that has visible calices, stigma, or preflowers located at the node or a stem or branch."

Marihuana Transfers

MICIA supports the more flexible marihuana transfer provisions for licensed growers, processors, and retails in proposed Rule 420.102, 420.103, and 420.104.

2. Operations Rules (R 420.201 *et seq.*)

Orders Limiting Sales from Cultivators and Producers to Retailers Under Common Ownership

Proposed Rules 420.206(16)(a) & (16)(b) authorize the MRA to set orders limiting the sales from cultivators and producers to producers and marihuana sales locations under common ownership and establish sanctions and fines for violations of those orders. MICIA supports the concept of encouraging supply to licensed retailers who are not part of a vertically integrated operation and thus maintaining the value of separate license types. But MICIA believes that this issue can have a substantial impact on the industry and requires further study. Accordingly,

proposed rules should be withdrawn and a stakeholder workgroup should be established to provide more industry input on this issue before adoption of regulation on this topic.

Further, MICIA believes that, as part of that study, the MRA should identify either quantitative thresholds or qualitative standards for when the agency would exercise this authority. Although MICIA understands the MRA's position that these rules discourage stockpiling and promote adequate supply and distribution, MICIA requests that, to avoid inconsistent or arbitrary application of its authority, the MRA set standards to clarify the quantitative thresholds at which the agency may impose such an order or the limitations the agency intends to place on the amount of product that may be sold to entities under common ownership.

Prohibition on Sale of Fresh Food and Beverages

Proposed Rules 420.203(2)(b)(i) & (2)(b)(ii) prohibit marihuana businesses from allowing the onsite sale, consumption, or serving of food or alcohol unless designated as a consumption establishment and also prohibit the consumption, use, or inhalation of marihuana product without such license. See also R 420.201(1)(k) (defining "designated consumption lounge"). MICIA notes that MRA enforcement has interpreted this as prohibiting the sale or consumption of all kinds of beverages such as coffee, tea, or juice. MICIA recommends changing this rule to permit the sale of fresh food and non-alcoholic beverages at retail locations without additional approvals or licenses.

Access to Licensee Records

Proposed Rule 420.203(f) provides that "[l]icensee records must be maintained and made available to the agency upon request." MRA has taken the position that this language requires "immediate" access upon request. Many vertically integrated marihuana businesses maintain their records at a corporate headquarters and/or have security protocols that prevent immediate access to such records which presumably has a broad definition. MICIA recommends clarifying this language to provide access to records within 24 hours after a request.

Waste Removal Requirements

Proposed Rule 420.211(6) restricts a licensee's options for the disposal of marihuana product waste and marijuana plant waste to landfilling, composting, anaerobic digestion, and incinerator at a permitted, in-state municipal solid waste or hazardous waste incinerator. MICIA views these options for disposal as too restrictive. MICIA instead recommends that the MRA consider other innovative, sustainable, and/or environmentally responsible options for on-site disposal that may be more beneficial to the environment. MRA may thus amend the proposed rule to add the following language "or alternative method not listed with approval from the department." Along these same lines, MICIA further supports proposed Rule 420.211(13) which provides that "[n]othing in these rules prohibits a grower, with agency approval, from disposing of marihuana plant waste as compost feedstock or in another organic waste method at their marihuana business in compliance with part 111 of the natural resources and environmental protection act, 1994 PA 451, MCL 324.11101 to 324.11153."

Generic Adoption of the NREPA and Failure to Promulgate Rules Regarding its Application

Proposed Rule 420.203(3)(a) adopts entirely the application of the NREPA, MCL 324.101 to MCL 324.90106 to marihuana businesses without explaining which provision the MRA views as applying to particular circumstances and stating that "[t]he agency may publish guidance" to that effect at a later date.

MICIA and its members support good stewardship of the environment but oppose the imposition of new marihuana-specific environmental laws without the benefit of industry participation and other stakeholder's feedback through rulemaking. To the extent the MRA intends to set generally applicable policy on the environmental obligations of marihuana businesses that either the MRA or EGLE intends to enforce, such "guidance" must be promulgated. MCL 24.207; MCL 24.226.

Alternatively, MICIA requests that this new requirement not go into effect until one year after promulgation.

Broad Assertion of Agency Authority Unrelated to any Express Statutory Grant

Proposed Rule 420.203(3)(b) subtly assumes expansive authority to the MRA to require broad operational changes to marihuana businesses. The proposed rule states that "[a] marihuana business shall comply with . . . (b) *Any other operational measures requested by the agency that are not inconsistent with the acts and these rules*." (Emphasis added.)

MICIA opposes this assumption of broad and undelegated authority by the MRA. The agency's assertion of such broad power over marihuana businesses as to demand any operational changes "not inconsistent with" the law inverts the axiom that, as creatures of statute, administrative agencies can only assert the power expressly granted to them by law. See *York v City of Detroit*, 438 Mich 744, 767 (1991) ("While an administrative agency may make such rules and regulations as are necessary for the efficient exercise of its powers expressly granted, ''an administrative agency may not, under the guise of its rule making power, abridge or enlarge its authority or exceed the powers given to it by the statute, the source of its power.'")

Equivalent Licenses Operating at Same Location

MICIA supports the common-sense and efficient approach contained in proposed Rule 420.205 allowing equivalent licenses with common ownership to be operated at the same location.

3. Sampling and Testing Rules (R 420.301 *et seq.*)

Homogenizing of Samples

Proposed Rule 420.304(2)(b) requires the collection of samples of "not less than 0.5% of the weight of the harvest batch" and requires samples to be "homogenized for testing." This language seems to allow for unlimited batch sizes and marks a drastic departure from existing standard of 15-lb batches. MICIA suggests that, because contamination can spread out in a heterogeneous manner, it would be more appropriate to split samples up across batches with some

form of weight-based limitation in order to obtain a more representative sample of harvests. For example, under the proposed language, a 1,500 lb. summer "harvest batch" would require 7.5 lbs. to be tested and 50% of that homogenized. But sorting that harvest batch into smaller batches would provide better data on the quality of the product.

Scope of Laboratory Accreditation

Proposed Rule 420.305(1)(a) requires laboratories to be accredited within 1 year of licensing but do not clarify whether specific assays or analytes must be included within its accreditation. MICIA recommends that the MRA modify this rule to allow the MRA to approve and validate a Safety Compliance Facility's new method and to allow at least 6 months for a scope expansion within the Safety Compliance Facility's regular ISO surveillance period.

Good Manufacturing Practices Certification and Adoption

MICIA strongly supports the provision of the rules allowing for good manufacturing practices certification and adoption as applied to marihuana businesses. R 420.301(1)(i); R 420.305(4); R 420.602(2)(h).

Filing of Certificates of Analysis with the MRA for Failed Samples

Proposed Rule 420.305(12) requires laboratories to "enter the results into the statewide system and file with the agency within 3 business days of test completion" each laboratory test result "for any batch that does not pass the required tests." MICIA reads this requirement to unnecessarily mandate a duplicative "fil[ing]" of certificates of analysis with the agency after the results have already been entered into the statewide system. Because the laboratories will enter this information into the statewide system electronically, MRA should modify this requirement to clarify that it will not require a separate filing from laboratories. MICIA further seeks clarification regarding whether the language "test completion" refers to the completion of each individual test or when the full panel of tests per sample are completed.

Encouragement of "Laboratory Shopping"

Proposed Rule 420.306(2) prohibits laboratories that conduct an initial failed test of a sample from performing any retesting. The proposed rule has the perverse effect of encouraging laboratory shopping and discouraging the reporting of failed test results by laboratories. Rather than discourage accurate test reporting for failed samples, MICIA suggests that this language should be removed.

Retesting and Remediation

The MRA's proposed limitations on retesting and remediation, R 420.306(2) & (3), are unduly restrictive. The agency should broaden these provisions to allow for more extensive retesting and remediation. MICIA, however, supports R 420.306(4) which appears to allow quarantined product to be transferred between licensed processors for purposes of remediation as not all processors own applicable remediation equipment.

Failure to Promulgate Action Limits and LOQs

The rules require the agency to establish both action limits setting standards for "the permissible level of a contaminant in marihuana product" such as foreign matter, microbial screening, heavy metals, and residual solvents, R 420.301(1)(1)(a) and R 420.305(3)(b)–(3)(f), (6), & (9), and limits of quantification (LOQs) for chemical residue and target analytes. R 420.301(1)(n) and R 420.305(3)(i) & (10). Those action limits and LOQs are attended by significant consequences. Product failing to meet the standards "must be destroyed as provided in these rules or remediated" as permitted by the agency. R 420.306(2)–(4). The proposed action limits and LOQs thus set "agency regulation[s], . . . standard[s], . . . [and] polic[ies] . . . of general applicability that implement[t] or appl[y] law enforced or administered by the agency." MCL 24.207. As such, the action limits and LOQs are "rules" requiring promulgation in order to be enforceable by the agency. MCL 24.207; see also MCL 24.226; & MCL 24.232(5).

MRA's failure to include the proposed action limits and LOQs in the rules improperly circumvents the APA's rulemaking requirements. *Delta Co v Dep't of Natural Resources*, 118 Mich App 458, 468 (1982). Further, the failure to vet these standards through the rulemaking process and to allow the industry and other groups to have input into their development and their propriety for the purpose of establishing health-based standards will result in less technically accurate action limits and render them legally unenforceable.

Failure to Promulgate Remediation Protocol

Similarly, the rules delay to a later time the publication of a "remediation protocol." R 420.306(4). Like the action limits, this protocol sets "generally applicab[le]" agency policy "that implements or applies the law enforced or administered by the agency." MCL 24.207. Consequently, the remediation protocol is also a rule that needs to be promulgated.

Failure to Promulgate Safety Test Requirements

Additionally, the MRA has elsewhere circumvented the rulemaking process for safety test requirements, indicating that "the agency may publish a guide indicating which of the following tests are required based on product type when marihuana product has changed form." R 420.305(3). As noted above, such a decision sets an agency policy of general applicability concerning the law it enforces. MCL 24.207. Deciding which tests will be required for sampling and analyses must be vetted through rulemaking and included in this set of rules rather than via a later "guide" or bulletin. MCL 24.226; *Detroit Base Coalition*, 431 Mich at 183–84.

Vape Cartridge Testing

MICIA suggests the adoption of a rule to require vape cartridges to be tested for Vitamin E-acetate (ATA). Because of the recent outbreak of injuries associated with vape cartridges containing ATA, such a rule would promote the public health.

4. Sales and Transfers (R 420.501 *et seq.*)

Internal Product Sampling by Employees

Proposed Rule 420.509(5) permits cultivators to provide internal product samples to their employees but limits those samples to 2.5 ounces in a 30-day period. MICIA supports the rules' encouragement of employees' product sampling. Employee product sampling can foster familiarity with and develop their expertise concerning the product, which facilitates better operations and encourages sales. But the MRA's proposed limitation is too stringent and improperly sets a limitation that does not take into account the size of or number of employees at an operation. MICIA instead proposes that the MRA extend this provision to allow cultivators to provide internal product samples of up to 1 ounce per employee per month. MICIA further seeks clarification of what level of documentation will satisfy the requirement that "[t]he results of internal product sampling must be documented . . . ."

5. Non-compliance with APA Procedures (all sets)

MICIA also notes that the MRA has improperly failed to comply with APA procedural requirements for this set of rules in several respects. Per MCL 24.245(3)(*l*), (3)(*m*), & (3)(*n*) the MRA was required to include in its Regulatory Impact Statement and Cost Benefit Analysis (RIS-CBA) "an estimate of the actual statewide compliance costs of the propose rules on individuals" and "an estimate of the actual statewide compliance costs of the proposed rules on business and other groups" as well as "a demonstration that the proposed rule is necessary and suitable to achieve its purpose in proportion to the burdens it places on individuals." The RIS-CBAs in support of the rules do not engage in any significant substantive analysis of the economic impacts of the proposed rules on individuals and businesses nor include any numerical estimates of these impacts.

Additionally, MCL 24.245(3)(*o*)–(3)(*s*) require detailed analysis of and estimates of the financial impacts of the rules on small businesses. The RIS-CBAs do not provide any such estimates nor any substantive analysis and simply state that "[i]t is uncertain how many small businesses may be affected by the proposed rules" but that "the belief is that these proposed rules will make it easier for small businesses to enter the regulated market." The RIS-CBAs make such a statement without analyzing the barriers to entry imposed on small businesses as a result of the licensing and operational costs associated with the rules.

The rules also fail to estimate the impacts to state and local revenues as a result of the rules. MCL 24.245(3)(*z*) & (3)(*dd*). In response to question # 13 posed by the RIS-CBA requiring an "[e]stimate [of] any increase or decrease in revenues to other state or local governmental units . . . as a result of the rule," the agency merely states that "[t]here are no anticipated increases or decreases in revenues or costs to other state or local government units as a result of the proposed rules." This suggestion is not credible. Given the various direct compliance costs and other regulatory burdens imposed by the rules, the agency's failure to estimate the impacts of these burdens on marihuana businesses' sales and the resultant impact on state and local revenues through the State's corporate income tax, MCL 206.601 *et seq*, local income tax paid by both the businesses and their employees, MCL 141.501 *et seq*, sales tax, MCL 205.51 *et seq*, use tax, MCL

205.91 *et seq*, the General Property Tax Act, MCL 211.1 *et seq*, and of course, the Michigan Regulation and Taxation of Marihuana Act, MCL 333.27951 *et seq*., is unsupportable.

As one example, the testing and sampling rules' requirement to test "not less than 0.5% of the weight of the harvest batch," R 420.304(2)(b), means that at least 0.5% of such a harvest is not being sold. That cost has not been calculated and weighed against the alleged benefit of the sufficiency of that sample size to conduct required tests, the impact of sample size on sampling accuracy, and whether a smaller sample size would achieve the same goals. Nor has the agency calculated the impact of its proposal limiting the ability to remediate and retest (and ultimately requiring the destruction of) marihuana that does not meet action limits. See generally R 420.306. Recent market values of marihuana have averaged over $500 per ounce through licensed operations. See https://www.mlive.com/public-interest/2020/02/major-marijuana-website-bans-advertisements-from-black-market-companies-in-michigan.html. Consequently, small alterations to the scope of such requirements can impose a substantial cost on large volumes of sales as well as attendant costs state and local revenues of a minimum of 16% in sales and marihuana excise taxes. MCL 205.52(1); MCL 333.27963(1).

These procedural defects deprive stakeholders, the Legislature, and the agency of a more substantive debate regarding the costs and benefits of individual proposed rules. Additionally, the defects can render the rules invalid through an APA procedural challenge. MRA should therefore resubmit the rules with these legislatively required analyses.

CONCLUSION

MICIA appreciates the opportunity to comment on the MRA's proposed rules and the MRA's efforts to develop a sound regulatory structure for the cannabis industry. MICIA believes that, with the changes suggested above and with greater industry feedback and more thorough vetting of the costs and benefits of proposed regulations, Michigan can be a leader both economically and in its promotion of good business practices for the industry.

Respectfully submitted,

Robin Schneider, Executive Director
Michigan Cannabis Industry Association
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February 17, 2020

Marijuana Regulatory Agency
Legal Section
P.O. Box 30205
Lansing, MI 48909
Re: Comments on the Proposed Combined Topic-Based Rule Sets

To Whom it May Concern:

R 420.201 (a) defines “active ingredient” as marihuana, as defined in section 7106 of the public health code, 1978 PA 368, MCL 333.7106.”

The proposed definition of “active ingredient” excludes industrial hemp. If this definition is adopted, we will find ourselves in a situation where the same chemical compounds—from the same genus and species of plant—are considered either “active ingredients” or “inactive ingredients” depending on the percentage of THC in the plant.

For example, CBD from a Cannabis Sativa L plant with more than .3% THC would be considered “active ingredient”. This CBD could be added to products under the proposed definition. On the other hand, Chemically identical CBD from a Cannabis Sativa L plant with less than .3% THC would be considered “inactive ingredient”. This CBD could not be added to products under the proposed definition because “inactive ingredients” must be approved by the FDA under 420.206 (11).

As a second example, a terpene from a Cannabis Sativa L plant with more than .3% THC would be considered “active ingredient”. This terpene could be added to products under the proposed definition. On the other hand, a chemically identical terpene from a Cannabis Sativa L plant with less than .3% THC would be considered “inactive ingredient”. This terpene could not be added to products because inactive ingredients must be approved by the FDA under 420.206 (11).

Dual treatment of the same ingredient from the same genus and species of plant would be confusing and misleading to patients and customers. The cannabinoids and terpenes in marijuana products have the same medicinal properties regardless of the THC content in the Cannabis Sativa L plant from which they were extracted. The common usage definition of “active ingredient” carries the connotation of medicinal effect. A product label that listed a biologically active ingredient as an “inactive ingredient” would be misleading.

This is important because listing “inactive ingredients” is a labeling requirement in 420.206 (11). “All non-marihuana inactive ingredients must be clearly listed on the product label.” Listing the same cannabinoid or terpene ingredient as an “active ingredient” on one package and an “inactive ingredient” on another package would confuse customers, and it has the potential to cause customers to take the wrong dose of the ingredients they are seeking. It’s easy to imagine a patient or customer taking too large a dose or serving of a marijuana product because he or she was over-compensating for an ingredient that was listed on the product label as “inactive”.

We ask that MRA solve the problems described above by updating the definition of “active ingredient” to include industrial hemp.

R420.305 (1) (h) defines “final package” as “the form a marihuana product is in when it is available for sale by a marihuana sales location.”

It appears this definition of final package is attempting to conflate two independent and important concepts, “final package” and “final form”.

We believe “final form” should be defined in the rules in addition to “final package”.

“Final form” should be defined as the “final set of ingredients, after all processing, mixing, curing, filling, quality control, and other preparatory processes have been completed, such that the product is in the same state it will be in when sold by a retailer”.

“Final package” should be defined as “the final retail-ready protective packaging that houses and protects a product that is in final form, so it can be sold by a retailer”.

We worry that conflating the concepts of “final package” and “final form” could lead us to a situation in which processors are not allowed to produce marijuana-infused products in a way that allows for remediation and/or retesting because any product produced would be considered a product in “final package” as soon as it was in “final form”.

We hope to be able to produce an item and have it tested in “final form” before we place it into a “final package”. We hope to have the opportunity to remediate an item like a cartridge or edible after a failed test, before it is placed into retail-ready packaging. Remediation is technically possible and completely safe in situations like a potency fail in an edible or a residual solvent fail in a cartridge. We ask that remediation and retesting be allowed in all situations where full compliance testing can be performed after remediation, to ensure patient safety is in no way put at risk.

R. 420.303 (10) says, “After a package is created by a producer of the marihuana product **in its final package**, the producer shall have the sample tested pursuant to R 420.304 and R 420.305.

We believe this rule should be changed to say, “After a package is created by a producer of the marihuana product **in its final form**, the producer shall have the sample tested pursuant to R 420.304 and R 420.305.

This change requires the addition of a definition of “final form”, which we believe will remove the ambiguity from the definition of “final package”.

R. 420.304 (h) says, “a marihuana business that receives a certificate of analysis stating that the sample meets specifications required by the agency shall ensure that the test results entered into the statewide monitoring system matches the information provided on the certificate of analysis received from the laboratory prior to transportation, sale, or transfer of the marihuana product.”

We believe safety compliance facilities should be responsible for uploading accurate data to the statewide monitoring system. We are unclear why the responsibility of uploading accurate test data to the statewide monitoring system should extend to a grower, processor, or retailer. If an audit step or additional redundancy is needed because a laboratory doesn’t have an automated, error-free way of uploading results from their internal system to Metrc, this redundancy should be provided by a second laboratory employee doing an audit of the certificate of analysis to make sure accurate results have been uploaded to Metrc.

Growers and processors should not be responsible for laboratory mistakes. The statewide monitoring system provides test results in a standardized format. On the other hand, each certificate of analysis is formatted differently, and it’s often difficult to tell whether a product passed or failed testing when looking at a certificate of analysis.

The statewide monitoring system should continue to be the system of record for test results. Growers, processors, and retailers should be able to rely on the test results in Metrc. Growers, processors, and retailers should not have to check a COA to verify the data in Metrc is accurate.

R420.305 (10) says, "For the purposes of chemical residue testing and target analyte testing, the agency shall publish a list of quantification levels. Any result that exceeds the LOQ is a failed sample."

We understand and support the requirement in the MMFLA that marijuana be **reasonably free** of chemical residues. MMFLA Sec. 505. (4) says: "A safety compliance facility shall… ...Perform tests to certify that marihuana is **reasonably free** of chemical residues such as fungicides and insecticides."

The concern we have is that the proposed rule goes beyond the "reasonably free" standard. Under the proposed rule, a marijuana product must be absolutely free of chemical residues in order to pass testing. Any amount of chemical residue detected would result in a fail, and—if remediation and retesting are not allowed—an order from MRA to destroy the material.

Modern laboratory equipment is so sensitive that it can pick up contamination into the single-digit parts per billion. There must be some level at which a product can be considered **reasonably free** of the chemical residue.

Extremely low levels of chemical residue in test results indicate contamination in the environment or in the equipment, rather than use of a banned pesticide.

Growers are vulnerable to environmental contamination from neighboring farms. Processors are vulnerable to low levels of contamination when they process material on equipment that has previously been used to process caregiver material or industrial hemp.

In cases of low-level environmental or equipment contamination where the licensee has not used a banned pesticide, we believe MRA should allow material that fails testing for chemical residue to be remediated or used in edibles (assuming the level of chemical residue is below the EPA's Maximum Residue Limit for food).

We have an additional concern that MRA's suggested approach of setting "Limits of Quantitation", rather than action limits, incentivises laboratories to use older testing equipment so as not to detect contamination below the LOQs set by MRA.

This approach is akin to closing our eyes and hoping the problem isn't there. It's not the right approach. Growers, processors, and regulators need more data—not less data—in the event of low-level environmental contamination, so the problem can be understood and corrected. Instead of reporting a result as "not detected" (below the LOQ), laboratories should be incentivised to calibrate their equipment as accurately as possible and report the actual result detected. Accurate residue data is crucial to the grower, the processor, and the regulator. All three parties are aligned in their goal of eliminating the source of the contamination and removing the residue contamination from the material.

We feel strongly that the LOQ approach is the wrong path forward for Michigan and the Cannabis Industry. This standard goes far beyond the statutory requirement that marijuana be **reasonably free** of chemical residue. And, it creates a situation where growers and processors can have massive financial losses due to 1 or 2 parts per billion of chemical residue.

We ask that MRA use an approach more similar to the EPA's approach in setting Maximum Residue Limits for food, and/or the FDA's approach in setting Maximum Residue Limits for tobacco products.

R. 420.307 (1) defines “research and development testing” as “optional testing performed before final compliance testing.”

Expanding the definition to allow for R&D testing **before or after** final compliance testing would provide valuable data to growers, processors, and regulators.

When material fails a final compliance test, the grower or processor has no way to know whether the failed result was accurate or due to laboratory error. Having an R&D test performed after the failed compliance test would allow the grower or processor to gather additional data. If the R&D test result conflicted with the final compliance test, the grower or processor would then have data to provide MRA when asking MRA to investigate the accuracy of the final compliance result.

Accurate results and clean, safe products are in everyone’s interest. We see no downside to allowing R&D testing after final compliance testing.

If MRA is concerned growers or processors may use R&D testing for “lab shopping”, we would point out that lab shopping would more likely occur prior to final compliance testing.

Additionally, we’d point out that R&D testing after final compliance testing would give MRA access to valuable data about disparities between safety compliance facilities. To the extent there are disparities in results issued by different laboratories, MRA would surely want to identify and fix these issues as quickly as possible.

R&D testing after final compliance testing is an important tool for growers and processors to help MRA identify false positives and other laboratory errors.

R. 420.306 (3) A marihuana product is prohibited from being retested if a final test for chemical residue failed pursuant to these rules. If the amount of chemical residue found is not permissible by the agency, the marihuana product is ineligible for retesting and remediation, and the product must be destroyed. This subrule does not apply to marihuana product that has been obtained under a Resolution on Marijuana Product Access for Patients adopted by the medical marihuana licensing board.

This rule is problematic for several reasons:

1. In the past 12 months we've learned that safety compliance facilities do make errors from time-to-time. The Choice Labs Processor Facility has had at least three false positives where material failed testing for chemical residue, and that failed result was later updated in Metrc when the lab acknowledged their mistake. We had an additional 8 samples where the lab admitted mistakes that amplified the result, but was unwilling to correct the results in Metrc without permission from MRA, which was not granted.

This rule is written under the assumption that labs don't make errors, and that just isn't the case.

What is the statutory justification for denying a facility the ability to retest an item that failed testing for chemical residue? Are the labs so unreliable that a contaminated item could pass two subsequent retests? If yes, that underscores the importance of allowing retests.

In fact, the labs do make mistakes. Samples are prepared by humans. There is always the potential for contamination within the lab equipment, glassware, utensils, or elsewhere in the facility. Retesting is the best way to find out whether the lab made an error. Why is retesting prohibited? Retesting should be encouraged. Confirmation and reproducibility of data are cornerstones of the scientific process.

2. The rule does not distinguish between growers who intentionally sprayed banned pesticides on their plants, and growers or processors who suffered extremely low-level (but detectable) environmental contamination.

Ultra-low levels of chemical residue indicate accidental contamination rather than use of a banned pesticide. In the event of accidental contamination, processors should be allowed to remediate the material to remove the chemical residue. The rule as written will result in needless financial losses for licensees, and needless shortages of material for patients and customers.

Growers are vulnerable to large losses from environmental contamination.

Processors are vulnerable to chemical residue contamination or accumulation during processing, even though the processor never has used a banned pesticide.

Consider a processor who purchases trim from an outdoor grower intending to process the trim into THC Distillate. The grower's crop passes chemical residue testing. The processor takes that material, extracts it, and concentrates it into THC Distillate. When the processor sends the THC Distillate for testing, he discovers the concentrated material has failed testing. In other words, the trim was below the LOQ, but the concentrated material is now above the LOQ.

Under the proposed rule, the material would be ordered destroyed. No retest would be allowed. The parties negatively impacted by the failed test result would not even be able to verify that the result was in fact accurate through an R&D test after the final compliance test.

We urge MRA to differentiate between banned pesticide use and accidental environmental or equipment contamination. Licensees that haven't used banned pesticides should be allowed to remediate and/or retest in the event of low-level fails.

R. 420.306 (4) says, “The agency may publish a remediation protocol including, but not limited to, the sale or transfer of marihuana product after a failed safety test as provided in these rules.”

We’ve been told by MRA that they’re currently not allowing a processor to transfer failed material to another processor for remediation. We cannot see any way in which this policy benefits licensees, regulators, or patients. A processor is unlikely to have every piece of remediation and processing equipment.

We believe the rules and remediation protocol should allow a processor to transfer material to another processor for remediation. As a processor, we intended to offer remediation services to other processors who may not have the equipment we have. We were disappointed not to be able to offer this service.

R 420.404 says, “A marihuana sales location shall not sell or transfer marihuana-infused products that exceed the maximum THC concentrations established by the agency. For the purposes of maximum THC concentrations for marihuana-infused products, the agency shall publish a list of maximum THC concentrations and serving size limits.”

The maximum THC concentrations and serving size limits—as currently enforced by MRA—are hard ceilings.

Given that potency results themselves have a margin of error, we ask that MRA allow for a +/- range above the maximum THC concentrations and serving size limits that mirrors the acceptable laboratory margin of error.

One additional suggestion:

Throughout the past year, we’ve seen potency variations of approximately 10% between labs.

It is our understanding that there is currently no mechanism in the rules to ensure that two different labs would give the same (or nearly same) result.

We encourage MRA to create a rule or internal process designed to reduce variations in results between labs.

It is our view that growers and processors should be able to have their products sampled by any licensed lab and receive the same results within a very tight tolerance.

Sincerely,

Maxwell Murphy
Compliance Department
Choice Labs, LLC

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Royal Oak, Michigan 48067

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Fax: (855) 541-2600

CANNABIS
LEGAL GROUP

To: Marijuana Regulatory Agency

From: Nickolas Galendez, on behalf of Cannabis Legal Group

Date: February 17, 2020

Re: Public Comment on Proposed Combined Topic-Based Rule Sets

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Dear Marijuana Regulatory Agency,

After reviewing the proposed combined topic-based rule sets for the Medical Marihuana Facilities Licensing Act ("MMFLA") and Michigan Regulation and Taxation of Marihuana Act ("MRTMA"), please see below for public comment on behalf of Cannabis Legal Group.

Sincerely,

Nickolas Galendez, Esq.
Cannabis Legal Group

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CANNABIS LEGAL GROUP

Public Comment on Proposed Combined Topic-Based Rule Sets for the MMFLA and MRTMA

I. Definitions

It is clear that the Marijuana Regulatory Agency (MRA) has taken feedback from licensees, applicants, and other stakeholders in order to add new definitions to the proposed rules and clarify other existing terms and phrases. However, there are a couple of terms and phrases in the proposed rules that Cannabis Legal Group strongly urges the MRA to clarify so that licensees, applicants, and other stakeholders are able to better navigate the regulatory requirements:

Definition of "Applicant" and the phrase "exercise control over or participate in the management" of the partnership/company

R 420.1 Definitions[1]

(1)(c) "Applicant" means a person who applies for a marihuana license, subject to paragraphs (i) and (ii):

(i) For purposes of this definition, an applicant includes a managerial employee of the applicant, a person holding a direct or indirect ownership interest of more than 10% in the applicant, and the following for each type of applicant:

(C) For a limited partnership and limited liability limited partnership: all general and limited partners, not including a limited partner holding a direct or indirect ownership interest of 10% or less **who does not exercise control over or participate in the management** of the partnership, and their spouses.

(D) For a limited liability company: all members and managers, not including a member holding a direct or indirect ownership interest of 10% or less **who does not exercise control over or participate in the management of the company**, and their spouses.

- **ISSUE**
  - The phrase "exercise control over or participate in the management" as it applies to the definition of "applicant" is not 100% clear and contains no

[1] For ease of reference, this definition is contained in 2019-67 LR, but the definition also appears in other proposed rule sets. Any changes or revisions made by the MRA to this definition should be incorporated throughout all proposed rule sets.

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- guiding principle or clarification, which may result in both under- and over-disclosure of an "applicant."
- In other words, on the one hand there are likely individuals and entities who have an ownership interest of 10% or less who "exercise control over or participate in the management" that have not been characterized as an "applicant." Licensees and applicants may take a liberal approach with this phrase in order to prevent characterizing an individual or entity as an "applicant."
- On the other hand, there are likely individuals and entities with an ownership interest of 10% or less who have been identified as an "applicant" even though they do not "exercise control over or participate in the management." Licensees and applicants may take a conservative approach with this phrase which may result in the unnecessary submission of a Supplemental Application for an individual or entity who does not meet the definition of "applicant."

- **SUGGESTION** – The MRA should determine precisely what the phrase "exercise control over or participate in the management" means in terms of who should be disclosed as an "applicant" and provide additional clarification/guidance so that there is no under- or over-disclosure of "applicants" on a license or application.

Definition of "Managerial Employee"

R 420.1 Definitions[2]

(1)(q) "Managerial employee" means those employees who have **the ability to control and direct the affairs of the marihuana business or have the ability to make policy concerning the marihuana business,** or both

- **ISSUE**
  - Similar to the issue identified above, the definition of "managerial employee" and the phrase "the ability to control and direct the affairs of the marihuana business or have the ability to make policy concerning the marihuana business" are not 100% clear and contains no guiding principle or clarification, which may result in both under- and over-disclosure of an "applicant."

[2] Similar to the definition of "applicant," this definition of "managerial employee" is contained in 2019-67 LR, but the definition also appears in other proposed rule sets. Any changes or revisions made by the MRA to this definition should be incorporated throughout all proposed rule sets.

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- In other words, on the one hand there are likely individuals who are employed by a licensee or applicant that have not been characterized as a "managerial employee." Licensees and applicants may take a liberal approach with this phrase in order to prevent characterizing an individual or entity as a "managerial employee."
- On the other hand, there are likely individuals who have been identified as a "managerial employee" even though they do not actually "have the ability to control and direct the affairs of the marihuana business or have the ability to make policy concerning the marihuana business." Licensees and applicants may take a conservative approach with this phrase which may result in the unnecessary submission of a Supplemental Application for an individual or entity who does not meet the definition of a "managerial employee."

- **SUGGESTION** – The MRA should determine precisely what the phrase "the ability to control and direct the affairs of the marihuana business or have the ability to make policy concerning the marihuana business" means in terms of who should be disclosed as an "applicant" and provide additional clarification/guidance so that there is no under- or over-disclosure of "applicants" on a license or application.

Definition of "Applicant" re: Spouses and Criminal History

The definition of "Applicant" generally requires that an individual's spouse submit a Supplemental Application.

- **ISSUE**
  - There are certain instances where an individual's spouse has a disqualifying felony within the past ten (10) years or a disqualifying misdemeanor conviction within the past five (5) years which prohibits the individual from being an "Applicant."
  - Cannabis Legal Group supports this requirement overall and agrees that spouses should be vetted.
  - However, we believe that the automatic disqualification of an individual based on his or her spouse's felony or misdemeanor conviction is discriminatory and would be better decided on a case-by-case basis.

- **SUGGESTION**
  - We strongly urge the MRA to implement a policy that does not punish an individual for his or her spouse's conviction.

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- While we understand that the primary purpose behind this requirement may be to prevent an ineligible individual from "swapping" ownership with his or her spouse, it also has the undesired effect of preventing otherwise eligible and suitable individuals from applying and obtaining a license.
- If an otherwise eligible and suitable individual has a spouse that has a disqualifying felony or misdemeanor conviction, the individual should be permitted to petition to the MRA to allow his or her ownership of the applicant company notwithstanding the spouse's disqualifying conviction.

Definition of "Commercial License or Certificate"

R 420.4 Application requirements; financial and criminal background

(9) Each applicant shall disclose any application or issuance of **any commercial license or certificate** issued in this state or any other jurisdiction that meets the requirements under the acts and these rules.

- **ISSUE**
  - There is no definition of what constitutes "any commercial license or certificate."
  - This results in under- and over-disclosure of licenses, permits, etc.
    - For example, in certain instances Cannabis Legal Group has assisted applicants who are a registered primary caregiver. This is not, by definition, a "commercial license or certificate" yet the applicant has been asked to include this information on Disclosure 6.

- **SUGGESTION**
  - Add language to the administrative rules, include more examples in the instruction book, or issue an advisory bulletin regarding what qualifies as "any commercial license or certificate" so that licensees and applicants are able to identify and correctly disclose any commercial licenses and certificates.

II. Calendar Days vs. Business Days

The MRA should insert language in the proposed rules to clarify the method upon which to calculate "days" (calendar vs. business). For example, R 420.24 specifically indicates that a temporary marihuana event application must be submitted not less than 90 calendar

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days before the first day of the temporary marihuana event. Additionally, R 420.305(11) provides that a laboratory must enter in test results within 3 business days of test completion.

However, the majority of instances where "days" are mentioned does not include whether they should be counted as "calendar" days or "business" days. This proposed change should be implemented in order to ensure that licensees and applicants are on the same page with the MRA regarding when application items, fees, etc. are due.

R 420.3

(3) The agency may request additional disclosures and documentation to be furnished to the agency. The applicant shall submit the information requested by the agency **within 5 days** pursuant to R. 420.5 or the application may be denied.

R 420.5

(4) If the agency identifies a deficiency in an application, the agency shall notify the applicant and the applicant shall submit the missing information or proof that the deficiency has been corrected to the agency **within 5 days** of the date the applicant received the deficiency notice.

(5) The failure of an applicant to correct a deficiency **within 5 days** of notification by the agency may result in the denial of the application. An applicant denied under this subrule is not barred from reapplying by submitting a new application and application fee.

R 420.6

(1) The agency shall issue a state license under the Michigan regulation and taxation of marihuana act to a qualified applicant whose application has been approved for issuance and who pays the required licensure or excess background investigation fees **within 10 days** of the state license being approved for issuance. Failure to pay the fees required under R 420.7 may result in a denial of state license.

R 420.7

(12) The agency shall not issue a marihuana license until a complete application is submitted, the fees required under these rules are paid, and the agency determines that the applicant is qualified to receive a marihuana license under the acts and these rules. An applicant must pay initial licensure fees **within 10 days** of approval of the marihuana license or **within 90 days** of a complete application being submitted, whichever date is first. An applicant must pay renewal fees upon submission of the application for renewal. Failure to pay the required fee may be grounds for the denial of a marihuana license in accordance with Rule 420.12.

R 420.12

(2)(e) The applicant failed to correct a deficiency **within 5 days** of notification by the agency in accordance with the acts and these rules.

R 420.13

(5) If a license renewal application for a license under the medical marihuana facilities licensing act is not submitted by the license expiration date, the license may be renewed **within 60 days** after its expiration date upon submission of the required application, payment of the required fees, and satisfaction of any renewal requirements. The licensee may continue to operate during the **60 days** after the license expiration date if the licensee submits the renewal application to the agency and complies with the other requirements for renewal.

(8) If the licensee does not request a hearing in writing **within 21 days** after service of the notice of nonrenewal, the notice of nonrenewal becomes the final order of the agency.

R 420.22

(11) An applicant shall pay the initial licensure fee for an excess grower license **within 10 days** of approval or **within 90 days** of a complete application being submitted, whichever date is first.

R 420.809

(3) The licensee must request a compliance conference or contested case hearing, or both, **within 21 days** of receipt of the formal

complaint. If the licensee does not respond, the agency shall request a contested case hearing.

III. Labor Peace Agreement Application Requirement

R 420.5

(6) The applicant shall attest, on a form provided by the agency and signed by a bona fide labor organization, that the applicant has entered into a labor peace agreement and will abide by the terms of the agreement. Copies of the labor peace agreements must be maintained and made available to the agency upon request

- **ISSUE**
  - While Cannabis Legal Group favors unions, this application requirement is too restrictive and prohibitive in the sense that it may allow bona fide labor organizations to wrongfully and unreasonably withhold entering into a labor peace agreement with an applicant.

- **SUGGESTION**
  - 1) Eliminate the labor peace agreement application requirement entirely
  - 2) Allow an application to be submitted and move forward in the application process without a signed labor peace agreement

IV. Testing for Mycotoxins

R 420.305

(3)(h) Under the medical marihuana facilities licensing act, mycotoxin screening if requested by the agency.

(19) Under the medical marihuana facilities licensing act, the agency may request mycotoxin testing. A marihuana sample with a value that exceeds the published acceptable level is considered to be a failed sample. A marihuana sample that is below the acceptable value is considered to be a passing sample.

- **ISSUE -** Mycotoxin screening should be required for both MMFLA/MRTMA.
- **SUGGESTION –** Add language requiring mycotoxin screening for MRTMA in addition to MMFLA

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V. Clarification on R 420.306

R 420.306

(3) A marihuana product is prohibited from being retested if a final test for chemical residue failed pursuant to these rules. If the amount of chemical residue found is not permissible by the agency, the marihuana product is ineligible for retesting and remediation, and the product must be destroyed. This subrule does not apply to marihuana product that has been obtained under a Resolution on Marijuana Product Access for Patients adopted by the medical marihuana licensing board.

- **ISSUE –** R 420.306 refers to the Resolution passed by the MMLB, but does not mention the new Advisory Bulletin promulgated by the MRA effective 3/1/2020. It is unclear whether this proposed rule would apply to the Advisory Bulletin.

- **SUGGESTION –** Add language to clarify whether the new Advisory Bulletin for caregiver sourcing of product is affected by this proposed rule

VI. Warnings and Citations

R 420.807 and R 420.808

- **ISSUE/SUGGESTION**
  - The proposed rules regarding warnings and citations are vague.
    - At a minimum, the proposed rules should indicate more precisely the definition of a "warning" and "citation" and its consequences, as well as a minimum burden of proof that must be satisfied in order for the MRA to issue a "warning" or a "citation" to a licensee.
  - R 420.808(7)'s 1-page response limit is too restrictive and does not afford licensees due process.
    - The page limit should be eliminated.

VII. Conclusion

Thank you for your consideration of these proposed rule changes and clarifications.

From: Roma Thurin
To: MRA-Legal
Cc: Gabriel Thurin
Subject: Comments to the Proposed MMFLA/MRTMA Rules
Date: Monday, February 17, 2020 2:10:56 PM

Good afternoon,

Please find below, comments to proposed rules:

Extension of Pre-Qualification longer than one year	
CONSIDERATION:	Applicants were initially encouraged to apply with BMMR/MRA for pre-qualification prior to many municipalities passing ordinances. It takes a significant amount of time – much longer than one year, to obtain property, build out a facility and obtain municipal special use permits, certificate of occupancy, and permission to operate. There are many unforeseen circumstances, additional costs and construction delays with many municipalities permitting facilities in areas with a lot of blight and abandoned buildings.
RECOMMENDATION:	Remove this unnecessary requirement that all pre-qualified entities received an MRA state license within one year. At a minimum require only an extension application attesting to no changes in an entity's organizational structure and supplemental applicants' status.

Support Labor Peace Agreements for cannabis licensees with more than 20 employees	
CONSIDERATION:	Assist with social equity into an industry where minorities and women are marginalized. It does not necessarily mean unionization. Assist with creating a solid labor workforce.
RECOMMENDATION:	Keep the requirement

Allow vertically integrated entities to have one access point for entrance and exist (R 420.204)	
CONSIDERATION:	This would create more efficiency in cultivator security measures on-premise such would be controlled through a single access point.
RECOMMENDATION:	Remove this unnecessary requirement.

One security camera system for multiple entities (R 420.204)	
CONSIDERATION:	Creating multiple security systems that are not integrated creates administrative burden and can lead to security risks as opposed to one centralized system that can be easily monitored.

RECOMMENDATION:	Allow one security system for multiple entities under the same location

Escorting non-employees rule is too restrictive 420.209 (2)	
CONSIDERATION:	As the industry expands, cultivators should have access to "trusted contractors" who have been background checked to be allowed to go unescorted in areas where there is no marijuana product.
RECOMMENDATION:	Modify current language to read: ***"A licensee shall ensure that any person at the marihuana business, except for employees of the licensee trusted contractors of the licensee, are escorted at all times by the licensee or an employee of the licensee when in the limited access areas and restricted access areas at the marihuana business."***

A licensee required to have cameras that record continuously 24 hours per day 402.209 (9)	
CONSIDERATION:	The current rule requires cameras to record constantly, which drains resources and makes it harder to find sections of recordings that have actual activity in them.
RECOMMENDATION:	Remove "record continuously" language and replace it with motion detection language.

Waste management /onsite mulching (420.211, Rule 11)	
CONSIDERATIONS:	Currently there are no environmentally friendly ways of disposing of cannabis waste products. As an outdoor grower that is trying to limit the carbon footprint of the cultivation facility, we would like for the rules to reflect more environmentally friendly manners of repurposing the waste vs the option of incineration or transportation, both of which have an adverse effect on the environment. The size of in-vessel digester it would take to do this at a large-scale operation is impractical.
RECOMMENDATION:	Allow outdoor grow operations to bury this waste within the secure perimeter in a green-friendly manner.

The stringency of heavy metals tests (R 420.306)	
CONSIDERATIONS:	There are ways to remediate cannabis flower and trim without compromising safety or the other important qualities of the plant.

	Consideration should be given to the fact that there is no standardized testing or exact science to remediation and thus it may require more than a couple of tests to get the plant to meet the required testing standards.
RECOMMENDATION:	Ability to retest a failed sample more than twice.

Grace periods / ample warning for new rules and standards	
CONSIDERATIONS:	In the 2019 calendar year, Nickel was added to the list of heavy metals without warning to cultivators who already had their harvests in the ground. Due to the sudden addition of the test, cultivators were not able to react accordingly and remediate or course-correct the issue in order to find a solution.
RECOMMENDATION:	For future implementations of restrictive rules changes allow a nine-month grace period unless it's an emergency situation that presents a clear and present danger.

Testing prior to moving product between entities (R 420.303 Sub-rule 6, R 420.304 and R 430.305)	
CONSIDERATIONS:	When moving product between cultivation and processing, the proposed system of testing would be inefficient. If product is tested prior to moving between a cultivator and a processor, and then again before it reaches consumers, it would have an adverse effect on the industry due to costs. It also has adverse effects on testing facilities which are already overburdened and have been the source of bottlenecking flower getting to market.
RECOMMENDATION:	Remove or do not move forward with this unnecessary requirement, not only between co-located entities, but between co-owned entities as well.

Requiring permission to remediate failed product (Rule 46 R 333.246)	
CONSIDERATION:	The product will need to pass testing in order to enter the market. However, requiring permission to remediate creates additional and unnecessary steps that slow down the production process.
RECOMMENDATION:	Remove this unnecessary requirement.

Sale and Transfer (420.501-511)	
CONSIDERATIONS:	With a supply shortage of cannabis biomass and the high retail

	price of flower, there are no current processors that are producing excess distillate for resale. This will have an adverse effect on any processor that does not have an associated cultivation facility that produces biomass for extraction.
RECOMMENDATION:	Allow for the intake of caregiver concentrate for infused product production and caregiver RSO for medical. Allow for the ability to transfer 100% of medical flower to adult-use if it passes all testing requirements.

Background checks (to R 420.602)	
CONSIDERATION:	In order to create and expand upon the existing employment opportunities for residents of Michigan in the industry we would propose making the background check process more efficient.
RECOMMENDATION:	Begin tracking individual background checks and issue permits based on their status vs. forcing background checks for every job they apply for or are hired to do, within the cannabis industry. This could possibly be done through METRC in order to build efficiencies into the system.

The requirement to weigh individual plants as they are removed from the field of outdoor grows.	
CONSIDERATION:	Presently we need to weigh each individual plant as it's removed from the field, which is tedious and time-consuming.
RECOMMENDATION:	Allow outdoor grow operators to weigh removed plants in bulk to improve efficiency while maintaining the accuracy of data. Delete this requirement.

Warmest regards,

Roma

Roma Thurin, Esq.
Managing Partner | Executive Consultant

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addressee, any disclosure, copying, distribution, or use of the contents of this message are prohibited. If you have received this email in error, please destroy it and notify me immediately.

From: Kale, Kavita (LARA)
To: Fox, Jessica (LARA)
Subject: Fwd: November 15, 2019 Technical Bulletin and Rule 46
Date: Tuesday, December 10, 2019 12:38:59 PM

See below for rules input...

Kavita Kale
Marijuana Regulatory Agency

Sent from my iPhone

Begin forwarded message:

> **From:** "Brisbo, Andrew (LARA)" <BrisboA@michigan.gov>
> **Date:** December 10, 2019 at 12:17:50 PM EST
> **To:** "Kale, Kavita (LARA)" <KaleK@michigan.gov>
> **Subject: FW: November 15, 2019 Technical Bulletin and Rule 46**
>
> Input for the rules.
>
> Andrew Brisbo, Executive Director
> Marijuana Regulatory Agency
>
> ---
>
> **From:** Hendricks, Robert <rhendricks@wnj.com>
> **Sent:** Tuesday, December 10, 2019 11:31 AM
> **To:** Brisbo, Andrew (LARA) <BrisboA@michigan.gov>
> **Cc:** Steve Goldner <sgoldner@pure.green>; Hendricks, Robert <rhendricks@wnj.com>
> **Subject:** November 15, 2019 Technical Bulletin and Rule 46
>
> Dear Andrew - thank you for your prompt feedback last week to our inquiries concerning inhalation device testing. Our client Pure Green, LLC has another testing related issue on which we would like your, or your staff's, feedback.
>
> The Technical Bulletin on remediation issued November 15, 2019, implements Rule 333.246 of the Administrative Rules. We believe that the bulletin and Rule 46 are unduly restricting scientific based development of processing and reprocessing cannabis biomass. The prohibition of repeated testing and remediation effectively prevents discovery of "out of specification" ("OOS") results. We also believe that the application of the bulletin and the Rule prevent root cause

analysis of marijuana crop failures.

Like MRA, our objective is to produce safe and effective cannabis-based medicines. Without the ability to repeatedly remediate and retest, we feel that we do not have a scientifically viable methodology for continuous improvement of our products.

Again, thank you for your prompt attention to this concern. Mr. Steve Goldner of Pure Green and I are available for whatever form of communication is appropriate to address these concerns.

Respectfully yours

Robert A. Hendricks | Senior Counsel
Warner Norcross + Judd LLP
1500 Warner Building, 150 Ottawa Ave., NW, Grand Rapids, MI 49503
d 616.752.2291 | m 616.302.3480 | rhendricks@wnj.com

GREAT LAKES
CANNABIS
CHAMBER
OF COMMERCE

Marijuana Regulatory Agency
Legal Section
P.O. Box 30205
Lansing, MI 48909

RE: Proposed Marijuana Rule Set

On behalf of our members, the Great Lakes Cannabis Chamber of Commerce appreciates the opportunity to share comments regarding the proposed marijuana rules. The GLCCOC represents licensed operators in Michigan's cannabis industry. We support any and all changes to make the operation of business in the Medical and Adult Use industries consistent. Any deviation between these two industries creates confusion and is a risk to public health to safety.

Although we recognize that the proposed rules would be step in the right direction for consistency between the Medical and Adult Use industries, we share the concerns voiced by many others in regard to the proposed rules:

- **Labor Peace Agreements.** As our testimony in support of Senate Concurrent Resolution (SCR) 18 indicates we find this requirement to be unlawful as burdensome to the licensees.

- **Home Delivery Requirements.** We support the requirement that a delivery service must be affiliated with a licensed provisioning center in order to operate in Michigan. Failure to require this creates a lack of control regarding integrity on the part of the licensee. It also creates chain of custody errors and the potential for unqualified individuals to involve themselves in the market. This requirement also helps local government and law enforcement know who is impacted by a licensed business.

- **Testing Batch Sizes.** In the interest of public safety, we support implementing sampling requirements as written in the current Medical rules. The proposed rule set does not take certain factors, such batch weight, into account. This creates variation between test results and the potential for bad actors to attempt to manipulate the system to move unsafe product to the market. Unless a scale based on batch weight and sample size taken is implemented, the standards found in the current Medical rules must stay in effect. Members have also voiced concerns regarding which substances are tested.

- **Container Transportation.** Michigan statute currently requires that medical product be transported in a secured and sealed container. However, the terms "secured" and "sealed"

have never been defined in statute or rule. The improper transportation of product can lead to mold and other issues showing up on the plants, which is hazardous for consumers. The proposed adult use rules have no requirements regarding sealing or securing containers. With discussions ongoing with regards to failed testing and the ultimate disposition of failed product, proper transportation and storage while awaiting testing/processing is necessary.

- **Department Collaboration.** We suggest the formation of a task force or council to help facilitate collaboration and communication regarding the various areas of overlap that LARA and other departments have in regard to this industry. For example, there are certain food and drug issues that are found under DHHS that could be useful here. Allowing their expertise to be utilized will help in protecting consumers.

We appreciate the time and effort devoted by the department to not only developing but hearing feedback on these proposed rules. We believe that it is in the best interests of public health and safety, the emerging industry, and the State of Michigan to make sure that rule sets are consistent and the industry concerns highlighted here are addressed. The GLCCOC looks forward to continuing a positive working relationship with the department and is happy to meet with Marijuana Regulatory Agency representatives to discuss our concerns more thoroughly.

Thank you,

Sandra McCormick
Communications and Membership Director
Great Lakes Cannabis Chamber of Commerce
sandra@glccoc.com
(517) 420.5417

From: Jim LaPorte
To: MRA-Legal
Subject: Live Resin-Fresh Frozen
Date: Tuesday, February 11, 2020 10:06:03 AM

MRA,

Could you please change the phrase “Live Resin” to “Fresh Frozen”. Live Resin is made from Fresh Frozen.

Thank you.

James B LaPorte
Vice President
E: jlaporte@highlifefarms.com
D: 248.465.1550 Ext. 2225
C: 940.867.9904

To: Director Brisbo, Marijuana Regulatory Agency

Re: Emergency Adult-use Rule Comments

Proposed Change: Rule 1(o)

(o) "Immature plant" means a nonflowering marihuana plant that is no taller than 8 inches from the growing or cultivating medium and no wider than 8 inches produced from a cutting, clipping, tissue culture, or seedling that is in a growing or cultivating medium or in a growing or cultivating container. PLANTS MEETING THESE REQUIREMENTS ARE NOT ATTRIBUTABLE TO A LICENSEE'S MAXIMUM ALLOWABLE PLANT COUNT, BUT MUST BE FULLY ACCOUNTED FOR IN THE INVENTORY TRACKING SYSTEM.

Rational: This has become an industry standard, a number of plants at this stage do not survive the cultivation process therefore we usually plant more of these than we need anticipating a loss in plants throughout the process.

Proposed Change: Rule 35(9)

(9) A licensee shall have cameras that record continuously 24 hours per day and recorded images must clearly and accurately display the time and date. THE USE OF MOTION DETECTION IS AUTHORIZED WHEN A LICENSEE CAN DEMONSTRATE THAT MONITORED ACTIVITIES ARE ADEQUATELY RECORDED.

Rational: For example, a low-traffic hallway could be motion activated, while the entrance and exits of the facility remain 24-hours. Allowing motion activated cameras helps the business know when there is activity in low-traffic areas, especially during times of the day when there should not be any activity. Using motion-activated cameras will save time during investigations, rather than having to scroll through hours of footage to find when a given event took place, the person reviewing the cameras will know exactly when activity took place at a given area.

Proposed Change: Rule 40

Option 1 – allow for growing of just regulated marijuana then designation as "medical" or "adult-use" upon first transfer out of cultivation facility

Rational: This will allow cultivation facilities to use the market to determine how much product to produce for medical or adult-use based on current supply and demand, rather than making the decision 3 months in advance

Option 2 – allow new adult-use licensees a window to "re-designate" their medical plants as adult-use

Rational: This will allow cultivators an opportunity to have some inventory available immediately upon receiving licensure for adult-use cultivation and ensure supply is available to adult-use consumers

Proposed Change: Rule 41(2)

(2) A marihuana grower shall tag each plant that is greater than 8 inches in height from the growing or cultivating medium ~~or~~ AND more than 8 inches in width with an individual plant tag and record the identification information in the statewide monitoring system.

Rational: attaching a physical tag to an immature plant that is only 8 inches tall is next to impossible to achieve, the plant is not strong enough at the stage to support a tag. Additionally, this requirement is inconsistent with the definition of "immature plant" Rule 1(o).

Alternatively: (2) A marihuana grower shall ENSURE ALL IMMATURE PLANTS WITHIN A GROWING OR CULTIVATING MEDIUM ARE APPORPRIATELY IDENTIFIED AND ACCOUNTED FOR WITHIN THE STATES SEED TO SALE TRACKING SYSTEM. ONCE A PLANT HAS REACHED A VIABLE POINT TO SUPPORT THE WEIGHT OF THE RFID TAG AND ATTACHMENT STRAP, THE MARIHUANA GROWER SHALL tag each plant ~~that is greater than 8 inches in height from the growing or cultivating medium or AND more than 8 inches in width~~ with an individual plant tag and record the identification information in the statewide monitoring system.

Proposed Change: Rule 42(b)

(b) The marihuana safety compliance facility shall collect a sample size sufficient to complete all analyses required, ~~but the sample shall not be less than 0.5% of the weight of the harvest batch. The maximum harvest batch size must be 15 pounds. The agency may publish requirements for this subdivision based on the type of marihuana product being tested.~~ BASED ON THE FOLLOWING GUIDELINES:

(i) FOR HARVEST BATCHES WEIGHING UP TO 10 POUNDS, A MINIMUM OF EIGHT SEPARATE 0.5 GRAM SAMPLES MUST BE COMBINED INTO ONE 4 GRAM SAMPLE AND SUBMITTED AS ONE TEST BATCH.

(ii) FOR HARVEST BATCHES WEIGHING MORE THAN 10 POUNDS BUT LESS THAN 20 POUNDS, A MINIMUM OF 12 SEPARATE 0.5 GRAM SAMPLES MUST BE COMBINED INTO ONE 6 GRAM SAMPLE AND SUBMITTED AS ONE TEST BATCH.

(iii) FOR HARVEST BATCHES WEIGHING 20 POUNDS OR MORE BUT LESS THAN 30 POUNDS, A MINIMUM OF 15 SEPARATE 0.5 GRAM SAMPLES MUST BE COMBINED INTO ONE 7.5 GRAM SAMPLE AND SUBMITTED AS ONE TEST BATCH.

(iv) FOR HARVEST BATCHES WEIGHING 30 POUNDS OR MORE BUT LESS THAN 40 POUNDS, A MINIMUM OF 18 SEPARATE 0.5 GRAM SAMPLES MUST BE COMBINED INTO ONE 9 GRAM SAMPLE AND SUBMITTED AS ONE TEST BATCH.

(v) FOR HARVEST BATCHES OR WEIGHING 40 POUNDS OR MORE BUT LESS THAN 100 POUNDS, A MINIMUM OF 23 SEPARATE 0.5 GRAM SAMPLES MUST BE COMBINED INTO ONE 11.5 GRAM SAMPLE AND SUBMITTED AS ONE TEST BATCH.

(vi) FOR HARVEST BATCHES WEIGHING 100 POUNDS OR MORE, A MINIMUM OF 29 SEPARATE 0.5 GRAM SAMPLES MUST BE COMBINED INTO ONE 14.5 GRAM SAMPLE AND SUBMITTED AS ONE TEST BATCH.

Rational: The current requirement for sample size is too large based on the harvest batch size, based on the current requirement each harvest batch will be required to submit 34 grams for testing. Safety compliance facilities do not need that much product to conduct all applicable tests and the remaining sample will be wasted. These guidelines provide an adequate sample to reflect the different harvest batch sizes while not wasting product that can be placed into commerce.

Proposed Change: Rule 49(h)

~~(h) Activation time expressed in words or through a pictogram~~

Rational: Currently, there is no credible research to support any claims based on this requirement. Each person is different and different products effect every consumer differently. Additionally, this information may subject licensees to potential litigation

Proposed Change: Rule 49(i)

(i) Name of the marihuana safety compliance facility that performed any test, ~~any associated test batch number, and any test analysis date.~~

Rational: This information is available from both the cultivation facility and testing facility. There needs to be a delicate balance between providing enough information to preserve public safety, but not include too much information that it will take up the entire container. So long as the METRC ID number is included on the label anyone interested in testing analysis information that is not already contained on the label can easily obtain that information.

NORTH COAST
TESTING LABORATORIES OF MICHIGAN, LLC

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P.O. Box 30205
Lansing, MI 48909
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SUBMITTED VIA EMAIL

Re: Draft Rules – Safety Compliance Facility Sampling & Testing

Dear Sir or Madam:

I write today to add the support of North Coast Testing Laboratories of Michigan, LLC to each of the comments on the draft rules for safety compliance facility sampling and testing that were submitted on January 8, 2020 by the Michigan Coalition of Independent Cannabis Testing Laboratories (MICIL) (copy attached).

In particular, we note that the "unlimited" batch size proposed in R 420.304(2)(b), in lieu of the present 15 lb. maximum batch size, poses an unnecessary risk to patient health and safety.

In our view, maximum batch sizes are necessary to protect patient health and safety from potentially hazardous contamination. Unlimited batch sizes – with no corresponding incremental testing requirement – allow far too much opportunity for hazardous contamination to go undetected.

We strongly believe that, as a statistical matter, it will only be a matter of time before an "unlimited batch" allowance will result in a "false negative" for an unreasonably-sized batch that "passes" testing, despite significant amounts of contamination actually present.

To take MICIL's illustration using a 1,500 lb. batch, 3 lbs. of toxically-contaminated marijuana would only represent 0.2% of the batch – which would almost certainly be missed by any viable sampling and homogenization protocol, and would ultimately be consumed by patients.

The 15 lb. maximum batch size, or an equivalent incremental testing requirement, fairly balances questions of testing costs against the potentially catastrophic health hazards posed by undetected contamination.

In conclusion, in addition to supporting MICIL's commentary on all rules, we particularly urge MRA to revise the draft rules in a manner that re-incorporates the 15 lb. maximum batch size.

Sincerely,

David A. Moorhead
President, North Coast Testing Laboratories of Michigan, LLC

MICIL

MICHIGAN COALITION OF INDEPENDENT CANNABIS TESTING LABORATORIES

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.**

MICIL

MICHIGAN COALITION OF INDEPENDENT CANNABIS TESTING LABORATORIES

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.**

<u>Potency Test</u>

- 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).**

From:	Ching Ho
To:	MRA-Legal
Subject:	Ruleset public comment submission
Date:	Monday, February 17, 2020 11:14:59 PM
Attachments:	Nickel soil tests x8.pdf Department_Approved_Pesticide_List_Update_620231_7 (1).pdf

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MRA Public Comment - Email Submission

Five suggested submissions from Dragonfly licensed cultivator on proposed MRA ruleset revisions. Additionally, we also spoke with Director Brisbo and Kavita Kale on these issues - specifically the recent changes to copper and nickel.

1. Permanent organic heavy metal removal

We are 100% organic sun-grown cultivators - we use no pesticides and grow in 100% composted organic soil. Our eight soil tests attached below show that all forms of soil - whether potted, organic, or native soil - naturally contain copper, nickel, and chromium often 20X the current PPM limit. These are defined "essential minerals" that occur naturally and organically and cannabis, as a bio-accumulator, will naturally absorb these heavy metals.

Should this regulation stand, licensed cannabis in Michigan cannot grow in most all forms of natural soil - and impossible organically. Simply put, most licensees, especially outdoor cultivators like us, would have no recourse but to retool our facilities and cultivate in an artificial base.

Michigan is also the only state that tests for the recently added nickel and copper:

CA - no nickel, no copper
CO - no nickel, no copper
WA - no nickel, no copper
NV - no nickel, no copper
MA - no nickel, no copper
PA - no nickel, no copper
IL - no heavy metal testing
FL - no heavy metal testing
OR - no heavy metal testing

Please reconsider nickel, copper, and chromium as tested heavy metals.

2. Minimum six month advance notice on changes

When nickel and copper were published in the technical bulletins, ours and many licensed producers' inventory were effectively frozen for a two to three month period. For example, it took one lab an entire month to be able to test for these elements, and other labs over two months before they could even start.

The lab testing process itself takes a month, so all combined = 2 to 3 months total frozen inventory.

During this time, producers counting on sale were running low on capital as their inventory was frozen.

All nickel tests were subcontracted out to one single compliance lab (Psi), and most every soil based cultivator we've spoken to is failing nickel - statewide about 80% we believe. Furthermore, licensees were not notified before nickel was enforced as a surprise testing requirement. As our cultivation began in April, this unfortunate timing provided absolutely no recourse for adjustment.

On copper, we were made aware that copper was being tested as a banned heavy metal in the published Testing Guide 5.0 published October 25, however based on your MRA Technical Bulletin attached, copper is listed as an approved ingredient on Feb 4 and July 15.

Because of this guidance, we sprayed an organic, OMRI-listed (Organic Material Research Institute certified) copper octanoate over the summer, the exact same copper octanoate in the "MRA Department Approved Active Ingredients for Growers".

Our chemist has determined that a single recommended application of this product listed in the approved ingredient list would now result in a PPM 25X in excess of the new guideline limit.

Because of this flip flop, our licenses, investment, and business viability were at risk of being invalidated, even as we followed the exact MRA published guidance and used only approved ingredients. We are asking that the MRA provide licensees with a minimum production cycle advance notice (6 months) before instituting such changes.

3. Raise heavy metal and microbial limits, 10-gram consumption unrealistic

Even if nickel, copper, and chromium were to stand, the published guidelines assumes an aggressive 10-gram a day consumption for an essential mineral which would not be inhaled until the melting point of 2650-degree Fahrenheit.

We ask that the MRA not only consider melting points of specific heavy metals for consumption but to also raise the PPM microbial and heavy metal limits based on realistic daily consumption, which are currently based on 10 grams daily.

For reference, your typical joint is less than one gram and often shared within a group of multiple people - a discrepancy of 10X-30X regular adult use consumption. We've researched that most states only test for arsenic, cadmium, and lead, and even then at much higher limits - and no other heavy metal.

4. Specific microbial testing > TYVM, no retesting limits

As organic outdoor cultivators, we also ask that the MRA consider testing for specific yeast and mold that negatively impact health - many states typically test for specific microbial such as coliforms, aspergillum, and e-coli. These states do not include "total yeast and mold" as they recognize that good bacteria included in TYVM are often used to fight bad bacteria, much like the healthy gut fauna example.

In organic cultivation, we use good bugs such as ladybugs to fight bad bugs, and good bacteria

to fight bad bacteria. Total yeast and mold TYVM often disregards the benefit of good and non-harmful bacteria as natural competition against bad bacteria. Most all cultivators are currently remediating for TYVM - and licensees should be able to retest as often as necessary without having to destroy the product, as the product cannot be sold until testing is passed.

5. Eliminate cultivation to processing testing redundancy

We are asking the MRA to eliminate redundant biomass testing on the cultivation size and to raise batch size weights above 15 pounds.

Currently, we must test processing biomass such as trim on the cultivation side which are intended for processing conversion. These tests automatically fail, after which we are allowed to transfer the 15-pound batch size. The processor then extracts the biomass (which kills yeast, mold), retests it once as an R&D test, and then a third time as an official test.

No other state has this redundant testing on processing biomass because it is unnecessary and expensive.

This is three rounds of testing on processing biomass that is intended for automatic transfer to processor. Trim often sells in established licensed markets for $100 per pound, so testing and transport eat up one third to one half of the sale value.

Along this same logic, the fifteen pound batch size is impractical. Our sun grown wet weight this year was 131,000 pounds - had this been all wet weight trim, this would be 8,333 tests - $4M in testing fees at today's rates. As you can see from our METRC inventory, we have not been able to move our processing biomass not because of demand but due to the massive bottlenecks from regulatory changes and lab delays.

Thank you for listening. Please reach out to me anytime if you'd like to further discuss these issues.

Ching Ho
(732) 540-0308