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|---|---|
| **From:** | Hendricks, Robert |
| **To:** | MRA-Legal |
| **Cc:** | Johnson, Matthew; Martin, Rodney; Hendricks, Robert; Sheets, Kaitlin; Nimphie, Benjamin; Hajali, Mazen; Chitwood, Alexandra |
| **Subject:** | Comments on proposed rule revisions |
| **Date:** | Monday, September 27, 2021 3:28:05 PM |
| **Attachments:** | image001.jpg<br>22355973_1 Proposed MRA Rule Comments (Combined)-c.DOCX |



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

Attached please find our comments on the proposed revised rules.

Thank you for your attention and assistance.

Respectfully yours,

**Robert A. Hendricks | Senior Counsel**
**Warner Norcross + Judd LLP**
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| Rule Citation | Rule Title | Page Number | Comments |
|---|---|---|---|
| **MARIHUANA LICENSES** | | | |
| R 420.1(1)(o) | Definitions | 3 | Rule adds definition of "Limited access area" meaning a "building, room, or other contiguous area of a marihuana business where marihuana is grown, cultivated, stored, weighed, packaged, sold or processed for sale and that is under the control of the licensee."<br><br>This definition will add greater clarity of limited access areas for licensees. However, what if the licensee has multiple licenses operating at the same location and has a limited access area under the licensee's control, but is not contiguous to the marijuana business? |
| R 420.1(1)(dd) | Definitions | 4 | Rule adds definition of a "Restricted access area" meaning a designated and secure area at a marihuana business where marihuana products are sold, possessed for sale, and displayed for sale.<br><br>The definitions do not define "secure area." I assume this definition adheres to the security requirements in R 420.209, but I would like to see more specific language here, e.g., "secured by four walls and a locking door." |
| R 420.3(3) | Application procedure; requirements | 5 | Rule states that partial applications to obtain prequalification status may be administratively withdrawn if application was filed and has been pending for more than 1 year. After a partial application has been withdrawn, the applicant may be required to submit a new application and pay a new nonrefundable application fee.<br><br>If an application has been partially completed and the application fee paid prior to withdrawal, it seems excessive to make the applicant pay another application fee when they resubmit. |
| R 420.3(4) | Application requirements; financial and criminal background | 5 | Rule states that "an applicant who has been granted prequalification status may have that status revoked by the agency and a marihuana license denied should the agency determine that the applicant is no longer suitable or no longer qualifies for licensure under the acts and these rules. An applicant who has had its prequalification status revoked may request a hearing pursuant to R 420.703."<br><br>This rule concerns me. It gives the MRA complete discretion to revoke prequalification status if "the applicant is no longer suitable." That is a very vague definition. |
| R 420.5(1)(d)(vii) | Application requirements; complete application | 8-9 | Rule states that the applicant must submit confirmation of municipal compliance, specifically an attestation "that the applicant will report any changes that occur with municipal ordinances or zoning regulations that relate to the proposed marihuana facility . . . ."<br><br>This is very broad—any changes that occur with related municipal ordinances? What if an amendment is made but it is not publicly posted? Also, many municipal ordinances covering many topics may apply to the marihuana facility. It seems excessive to expect a licensee to monitor their municipality to report any ordinances that *may* apply. The rule should be written more narrowly to only reference "marihuana licensing or zoning specific" ordinances only. |
| R 420.11a(5) | Prelicensure investigation; proposed marihuana establishment inspection | 15-16 | Rule requires applicant to submit certificate of occupancy to agency for prelicensure inspection. If this certificate is not available, "the agency may accept alterative documentation from the building authority."<br><br>Some of our clients live in small townships without a building authority. I would like this definition to factor that scenario. For example, "from the building authority or **other designated municipal official**." |

| Rule Citation | Rule Title | Page Number | Comments |
|---|---|---|---|
| **MARIJUANA LICENSEES** | | | |
| R 420.105a(8) | Class A marihuana microbusiness license | 7 | Rule says "A Class A marihuana microbusiness may purchase or accept a mature plant from an individual, registered qualifying patient, or registered caregiver.<br><br>What is the statutory authority for authorizing an individual, a registered qualifying patient, or a registered primary caregiver to sell mature marijuana plants to a Class A marijuana microbusiness? |
| R 420.112a | Licensing, management, or other agreements | 13-14 | For clarity, this rule 112a should indicate that the phrase "licensing, management, or other agreement" is as defined in R420.101(1)(m).<br><br>It would appear that the purpose of this rule 112a is to identify agreements between a license holder and another person which are intended to convey the benefits of ownership on the non-license holder, when that non-license holder has not been vetted by MRA. If this is the actual purpose, the rule might be clearer if that were simply stated rather than covered by many words which seem to beat around the bush. |
| **MARIHUANA OPERATIONS** | | | |
| R 420.206a | Standing Operating Procedures | 11 | Rule adds requirement for licensees to have up-to-date written standard operating procedures on site at all times.<br><br>Why is this required in addition to a facility or establishment plan? |
| R 420.207a(4) | Contactless and limited contact transactions | 15-16 | Rule allows licensees to designate area for contactless delivery. Section (4) requires separate standard operating procedure in addition to R 420.206a.<br><br>Why can't the standard operating procedures referenced in R 420.206a cover the contactless delivery? Why does it need to be a separate document? |
| R 420.214b | Adverse reactions | 24 | Rule requires licensees to notify the MRA within 1 business day "of when licensee should have been aware of any adverse reactions to a marihuana product sold or transferred by any licensee."<br><br>First, the rule does not specify how the licensee should notify the MRA. Will the MRA provide notification forms? Is an email to enforcement sufficient?<br><br>Second, the "should have been aware" language concerns me. If a licensee sells a product to a customer and the customer has a bad reaction after consuming the product 3 weeks later, how would the licensee even be aware of that reaction? |
| **MARIJUANA SALE OR TRANSFER** | | | |
| R 420.303(6) | Batch; identification and testing | 4 | Rule allows a cultivator to sell/transfer marihuana products without being tested by a lab to produce live resin, with agency approval but limits the sales/transfer to a producer under this rule if the package contains more than 1 harvest batch. The next line reads "This does not prohibit a cultivator from transferring multiple harvest batches for extraction."<br><br>This reads as internally conflicting and does not make sense, that a cultivator cannot use the testing exemption under the rule if they sell/transfer a package with more than one batch, but still can sell/transfer multiple batches. |

| Rule Citation | Rule Title | Page Number | Comments |
|---|---|---|---|
| R. 420.305(16)(c) | Testing; laboratory requirements | 10 | Rule prohibits a lab from "Cherry pick, which means testing specific material from a batch. All sample increments must have the same chances of being selected."<br><br>Practically, how can this even be enforced and it's unclear what procedures, if any, a lab can put in place to ensure samples have the same chance of being selected. |
| **MARIJUANA SALE OR TRANSFER** | | | |
| R 420.504(4) | Marijuana product sale or transfer; labeling and packaging requirements | 4-5 | New rule requires that both medical and retail sales location to provide customers with pamphlets that includes safety information related to marihuana use by minors and the poison control hotline number and that the pamphlet must substantially conform to the design published on the agency's website.<br><br>This new requirement seems duplicative given that the products already have labels with a safety warning. It also raises numerous practical issues, such as when these pamphlets have to be issued; what information has to be included in the pamphlets; the added cost which will be passed down to the customer/patient; for sales made online or via telephone, will this require some sort of digital pamphlet and if the Agency makes changes to the required information, will that require a whole new set of pamphlets and discarding the old ones? |
| R 420.508(8) and R 420.509(6)-(7) | Trade samples Internal product samples | 8-9 | Rules limit the amount of internal product samples that can be given to an employee within a 30-day period to a total of 1 ounce of marihuana, a total of 2 grams of marihuana concentrate, and marihuana infused products with a total THC content of 2000 mgs. Further, R 420.509(7) requires that internal product samples be tested prior to transfer to its employees.<br><br>This new limitation and testing requirement seem overbroad and limits the ability of licensee's to receive feedback from employees regarding the quality of the product/flower. Also, the testing requirement prior to transfer would mean that if a licensee is interested in knowing the quality of a product/flower before even deciding to put it to market, would have to pay the expensive testing requirements and would discourage product/flower improvement. |
| **MARIHUANA EMPLOYEES** | | | |
| Generally, the changes are stylistic and help make some of the rules with listed requirements easier to read. The substance of most of the rules in this section has not changed. | | | |
| R 420.602(1) | Employees; requirements | 2-4 | Rule has been modified to *require* employee training manuals to include detailed explanations for how employees can monitor and prevent over-intoxication, illegal distribution, etc. Previously, the rule only required such information to be in the employee manual *if applicable*.<br><br>Generally, this isn't a major burden for most licensees, but it seems like the previous language should be considered here, as this seems unnecessary for certain types of cannabis businesses. |
| R 210.602a | Prohibitions | 5 | The major change is adding this rule, which prohibits employees of one type of licensee from being employees of another type. For example, employees of cultivators (growers) may not also be employed by transporters or labs.<br><br>Do we know the reason for this addition? What is MRA trying to do here? The prohibition seems a little silly – are there similar prohibitions in the alcohol or tobacco industries? |

| Rule Citation | Rule Title | Page Number | Comments |
|---|---|---|---|
| **MARIHUANA HEARINGS** | | | |
| As with Rule 601 et seq. above, most of the changes to these sections are stylistic and for readability purposes | | | |
| R 420.702(1)(d) | Hearing procedures; scope and construction of rules | | The rule adds "the denial of the renewal of a marihuana license" to the situations where the "hearing" rules apply.<br><br>This is an important addition. |
| R 420.703(3) | Public investigative hearing | 2-3 | Rule removes the specific requirements of what public investigators must provide in the contents of their notice to an applicant of an investigative hearing.<br><br>It is unclear how often these public investigative hearings happen when a license is denied, and the degree to which this removal of specificity will impact applicants. |
| R 420.704a | Hearing on exclusion of individuals or employees | 4 | Rule has been added, which provides a procedure for a marijuana business to contest MRA's exclusion of a particular individual from the marijuana business.<br><br>The procedures seem reasonable; however, subsection (1) allows the business only 21 days to contest MRA's decision to exclude an individual. From our client's perspective, this is not much time, and I would comment that maybe 45-60 days would be more helpful for our clients. |
| **MARIJUANA DISCIPLINARY PROCEEDINGS** | | | |
| R 420.802(7) | Notification and reporting | 3 | For clarity, R420.802(7) should indicate that the phrase "licensing, management, or other agreement" is as defined in R420.801(1)(j). |

22355973

September 9, 2021

**Samantha K. Balk**
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**To the Marijuana Regulatory Agency:**

The following documentation encompasses the comments of myself and some of my coworkers in the marijuana industry regarding necessary clarifications and/or suggestions about the ruleset. I have it broken down by each rule.

As the compliance manager at 42 Degrees Processing, LLC, a medical and adult use processing facility in Kalkaska, MI, my first priority is to protect our licenses by making sure that our facility is compliant with all requirements set forth by the MRA. Primarily, that goal is accomplished by a clearly defined set of rules to which can be adhered. What follows are observations based on the challenges I have faced as a compliance officer, as well as comments heard in the public. Any criticism and/or request is my own, but proposed as a means toward the end of clear rules that we can follow without further requirement for clarification. If any further clarification on my comments is required, I would be happy to take a phone call.

My greatest concern is with the areas of potential loopholes. I may also mention cost, though this is frequently due to the cost of operations, which I must also be mindful of.

Thank you very much for the time put into clarifying the ruleset and frequently providing guidance, most especially to me. And thanks to everyone at the MRA for providing and supporting this industry that I thoroughly enjoy, as it presents constant challenges that have given me a rewarding and important job here at 42 Degrees.

MARIHUANA DECLARATORY RULINGS

- Definitions
    - Define what is a “declaratory ruling”
    - When would this be used instead of requesting a clarification on the interpretation of a rule?

EMPLOYEES

- R 420.602 Rule 2 (1) “A licensee shall conduct a criminal history background check…”
    - Does this mean a state background check, federal background check, or both?
    - Do subsequent background checks need to be performed after an employee has been hired? At what interval?

SAMPLING AND TESTING

- Definitions:
    - The definition for a “production batch” needs to be clearer, especially considering edibles. If you would, please include this clear definition everywhere a rule discusses production batches.
        - What defines similar conditions? Same operator, same pot, same tools, same formulation, etc. all should be considered.
        - Is there a batch size limit?
        - The current methodology across the industry as I understand it, from talking to testing laboratories, is that there are multiple pots of gummies being formulated in a linear fashion. First pot, then second pot, then third pot, etc, up until an indefinite number of pots, ie, 30-40 pots, defining a single production batch. However, from the standpoint of recipe and formulation, each pot could vary by a variety of small factors. One pot may get more color than another. One pot may get more THC distillate. Even if it is a small amount, it’s still not exactly the same. Although homogeneity testing is intended to account for this variation, it is only performed every 6 months after initial formulation and will not be able to capture if one pot of 30, 60, 100 (what even is the limit?) is out of sorts. Essentially, this is the same as considering 30-40 (or more) tiny single batches of gummies as one uniform batch. This presents potential safety concerns regarding dosing.
    - The definition for a “production batch” needs to be more clearly defined for concentrates as well. If you would, please include this clear definition everywhere a rule discusses production batches.
        - If two different production runs of extracted concentrate are mixed together, is that acceptable? It seems that it would be unlikely to mix two batches of concentrate together into a homogeneous mixture, which could yield a product of an inconsistent potency. For example, if you produce a concentrate that is 60% potency and mix it with a concentrate that is 80% potency, then the resulting product could be inconsistently mixed with a potency that varies between 60-80%. This would be a more pronounced inconsistency if two different product consistencies were mixed, such as a “sugar” and a “sauce” together.
            - If this is acceptable, are any parameters needed?

    - The definition for “final form” versus “in packaging” needs to be crystal clear.
        - In some bulletins and rules, final form further clarifies that it means “not necessarily in its packaging for sale,” but in the laboratory testing handbook entitled Sampling and Testing Technical Guidance for Marijuana Products, it very clearly states “A sample of marijuana edible product must be in final form for a laboratory to accept this material for compliance testing. *Laboratories are not permitted to sample product in bulk without packaging* [italics mine] for compliance testing. Units should be easily distinguishable.”
            - We ended up changing around our entire standard operating procedure to accommodate having to test gummies in their sale packaging, only to then be corrected by a customer, who had an email from the MRA, stating that it was acceptable to test gummies prior to packaging.
- R 420.306. Guidelines for retesting should be clearer. There were times in the past when the rule was not clear enough, as it stated that when a product failed a retest it *must be destroyed*. However, we found out after we destroyed it that remediation was allowed. The following clarifications are needed:
    - Which failed tests can be retested. Please state these specifically (ie, heavy metals, certain pesticides, etc).
    - How many times a retest can be performed. As written, it is currently allowable to retest as many times as needed until a passing result is achieved, which is an irresponsible practice.
    - If retesting is permitted at a different lab than the one that delivered the failing result, and how that should be submitted if so.
    - Is there a time limit on performing a retest, given that there’s now a 90 day deadline for destruction?
    - Which failed tests can be remediated. Please state these specifically (ie, heavy metals, certain pesticides, etc).
- R 420.305, 9(h): states that potency should be reported in milligrams. It should read milligrams per ____.
- R 420.307, Rule 7, 3: states that R&D testing is prohibited after compliance testing has been completed. This needs further clarification to cover the following:
    - Continued quality studies, such as how a product might degrade or change over time.

    - Reserving a subset of a finished product to perform additional small tests upon it not related to safety, such as terpene composition.
    - It sounds as if the intent of the rule is to not perform R&D testing on the same production batch number, which historically created a problem in METRC by reverting Test Passed product into a Testing in Progress state. But if you pull an amount of and give it its own production batch number so as not to affect test results, would it be acceptable to perform R&D testing on this product?
- Requiring safety compliance tests on small batches of new formulations makes formulating new products prohibitively expensive as the recipe or methodology might be tweaked several times prior to being finalized. We would be grateful if alternative rulings could be explored that allows for more creativity and flexibility as new products are developed.

MARIHUANA SALE OR TRANSFER

- Definitions:
    - Need more clarification on *types* of transfers.
        - Define what type of transfer should be used for which purposes. When to use them, which forms are required, where the forms are located, where to send requests, etc.
            - Specifically, we've had some trouble with untested WIP transfers, fresh frozen transfers, infusion transfers.
            - Some forms are simply not listed on the MRA's website, such as the inventory transfer request form. It would be very helpful if all of the forms were listed in one location. Please investigate, and make compliance easier to do.
- Ensure that METRC and AFS are cohesive for financial audits. The rules for processors make tracking monetary value back and forth unnecessarily cumbersome, as it has forced us to assign monetary value to something for which there was no cost (such as for toll processing, where we charge for services).
- 420.508 (Trade Samples), Rule 8, 4, and 420.509 (Internal Samples), Rule 9, 3: The rules need to clarify what needs to be recorded in METRC during sampling. It was clarified to me personally that I should be recording the ID and employee name for Internal sampling, and I have been recording the License and Vendor name for trade samples.
    - Is any other information required for tracking purposes?
    - It is possible that there needs to be a lot more definition regarding trade samples and employee samples in general. This rule has been the one I've been most aggressively questioned on as to what the MRA's language allows versus what the MRA's intent was when writing the rule.
    - Rules are possibly unclear as to whether or not the Processor license is allowed to internally sample flower to its employees.
    - The rules have an issue with loopholes regarding trade and internal samples, as follows:
        - There is a limit on both internal samples and trade samples. However, when asked, and also provided with intent, the MRA clarified that they do not regulate sale prices. It is therefore possible for a processor to sell product to a retailer for a penny, who can then sell it to the processor's own employees for a penny, and thus makes having a rule pertaining to limits pointless.

            - Which means it is also possible to do exactly the same thing for trade samples, and have either a representative of a retailer or a sales representative to purchase products for a penny and offer them for free to anyone.
            - The same could be said of coupons or rebates, or steep discounts of any kind. If there is the ability to legally obtain products for virtually nothing, then why bother with a limit at all?
            - Nothing currently prevents employees from giving all of their samples to someone else outside of work hours, either, which means that it is also possible for employees to band together and pool their samples for a single person, such as sales personnel.
    - I also have concerns about the custody of products after trade sampling, as follows:
        - It is currently stated that up to a certain limit, anyone may transport trade samples to a retailer. I do not think it is wise to allow anyone other than a secure transporter to transport products. There are a lot of strong relationships between retailer management and sales personnel, and I think it may be possible to abuse the trade sample mechanism to funnel products out of the regulated market in this manner. There is currently no control over ensuring that the trade sample actually makes it to the intended recipient in this manner. What is to stop a sales person from requesting samples for a retailer and simply never delivering them?
        - We've heard that frequently, trade samples go only to retailer management and never make it into the hands of budtenders for the purpose of product sampling. I'm not sure that this would be considered an MRA problem, but wanted to bring it to your attention anyway, as trade samples handled in this matter do not bring much value to the processor value stream.
    - Please clarify how a sample intended for an employee should be treated if the employee refuses the sample.
        - Should it be destroyed? Does it now need two adjustments (one to put it back on its tag, and one to destroy it), or can it just go to destruction, since it has already been removed from METRC?

- R 420.504 (Labeling and packaging requirements): Compliance stickers have been unclear for more than a year now. Clarification was promised but never came. Our customers have been told different things by the MRA which has now forced us to operate under two different SOPs. Please make this clearer as to which tags are required on the compliance label.
    - Define that Package ID means the tag that is delivered to a retailer.
        - We maintain that this should not actually be required. A store that receives the package will have the Source tag ID in their METRC should an issue with the customer's product arise, which makes it easy to search. It is the source that would be the issue anyway if an adverse reaction was reported. Being allowed to label all of our products with only the Package's Source ID and Testing ID would significantly improve operational efficiency and greatly reduce the amount of potential for error. If one batch were to be sent to 100 stores, this is the difference between being forced to create 100 different compliance labels instead of only one.
    - Define that Source ID is the parent tag of the Package ID regardless of testing status.
    - Whether or not a Testing ID is required.
        - Define that Testing ID is the tag that was delivered to the testing facility for the purpose of Safety Compliance Test only.
    - Clarify how to treat a retest for potency when stating potency and testing facility information on the compliance label
    - Remove "any" test analysis date, replace with "safety compliance" test analysis date.
    - Release an example scenario or scenarios with an example label to eliminate all potential confusion.
    - Clarify that the universal symbol must be printed in full color (green).
    - Specify whether or not it is acceptable to say either marijuana or marihuana on the universal symbol.
        - Basically, whether or not ANY modifications to the universal symbol are acceptable whatsoever.
    - Specify that the words must be legible/easily read on the compliance label and universal symbol. Is a size requirement needed? Some of them are so tiny they cannot be read.
- R 420.505 Rule 5. (1) Transferring needs two Rs.

OPERATIONS

- R 420.206, Rule 6, 14: “When combining more than 1 form of marihuana or marihuana product into a single marihuana product, each form of marihuana or marihuana product must have passing safety compliance test results in the statewide monitoring system prior to the creation of the new combined product.
    - What defines a “form” of marihuana product?
    - What if products are combined prior to a safety compliance test? Examples:
        - Mixing a distillate with a high terpene content product, which will fill cartridges and go to safety compliance testing as a cartridge.
        - Mixing together two concentrates, ie batter plus batter.
- R 420.214a (Internal analytical testing):
    - For the internal analytical testing area, what defines a “separate” testing area?
- R 420.214b-c:
    - How does a retailer return defective/undesirable products that are *not* involved in an adverse reaction to a processor if they are not allowed to transfer it back?
        - For example, poor product quality, or if it has been on the shelf too long and they wish to trade it in.

LICENSES

- Definitions:
    - Please include more clarity on separate areas.
        - Food and marijuana areas are supposed to be kept separate.
            - Separation includes walls and a ceiling and a locked door.
            - Define the purpose of hallways, clarify the difference between a hallway and a room.
                - No food or marijuana in hallways?
                - Storage in hallways
                - Carrying marijuana through the hallways to get to the next room
                - Carrying food through the hallways to get to the next room.
    - It was clarified to me that areas of different task types are also supposed to be maintained separately with a locked door between them, such as:
        - Laboratory rooms can be connected, but not to packaging or storage
        - Packaging rooms can be connected, but not to any production or storage
        - Storage has to be kept separate from packaging and production.
        - These are not terribly specific. Items will be stored temporarily in production areas. Does an edibles kitchen need to be separated from its own packaging operation? Where are the lines defined?
        - Is this really necessary?
        - Why is further security needed within the building when entry to the building itself is controlled by secure entry?
    - Provide more specificity regarding the storage of inventory. Access should be restricted, but if it is behind a locked door and all the staff has access to the locked door, is it really restricted? So whom should have access?

LICENSEES

No questions

MARIHUANA-INFUSED PRODUCTS AND EDIBLE MARIHUANA PRODUCTS

- R 420.403, rule 3, 2: The potency variance has been changed to +/- 10%, not 15%. If this is not the case, there are multiple points throughout the rule set and bulletins where this variance is not in agreement.
- 420.403, Rule 3, 10(a): There is currently no control expressed in the guidelines for an expiration date. It's too arbitrary and does not require a product to demonstrate quality up until its expiration date. Documentation is required for shelf stability, but not for an expiration date qualification. This seems like an oversight.
- 420.403, Rule 3, 9(e): Clarification is needed on what is considered a "commercially available food product". This could feasibly eliminate most forms that an edible product might take, such as:
    - Other types of candies:
        - Chocolates
        - Fudge
        - Peanut butter cups
    - Granola bars
    - Rice krispies treats
    - Brownies
    - Cookies
- 420.403, Rule 3, 9(f): Packaging specifications could use more clarity as well. "Not produce an edible marihuana product that is associated with or has cartoons, caricatures, toys, designs, shapes, labels, or packaging that would appeal to minors."
    - We've ruled out animals and fruit already. But there are other ways to appeal to children or teenagers. What about such things as:
        - Vehicles such as sailboats, cars, trains, bicycles
        - Color schemes, such as pastels, tie-dyes, bright colors, glitter
        - Other icons, such as moon and stars, clouds, rainbows, flowers, gem stones.

MARIHUANA HEARINGS

No questions

MARIHUANA DISCIPLINARY PROCEEDINGS

- R 420.805, rule 5, 10-11: The list of excluded individuals is kept by the MRA and we do not currently have access to it. How are we going to be able to know that an individual has been excluded from employment or participation in a marihuana business? Would that come up in the background check?
    - Also, we'd like to be able to see this list to protect ourselves and the integrity of the industry.

OTHER QUESTIONS

- With the limitations on names, shapes, and packaging that appeal to children, will there be further restrictions on the names of strains for concentrates and/or vapes?

In conclusion,

Thank you very much for your time and consideration in hearing comments from the public. I fully support clear rules, and greatly appreciate the time and effort that goes into refining this rule set.

Sincerely,

**Samantha K. Balk**
Compliance Manager
42 Degrees Processing, LLC
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September 27, 2021

Marijuana Regulatory Agency
Legal Section
P.O. Box 30205
Lansing, MI 48909
Via Email: MRA-Legal@michigan.gov

Dear Marijuana Regulatory Agency ("MRA"):

Thank you for the opportunity to comment on the proposed rule sets intended to promote clarity and consistency in Michigan's medical and adult-use markets. Cresco Labs Michigan, LLC ("Cresco") holds grower and processor licenses, operating a facility in Marshall. Cresco respectfully submits the following comments to the amended rule sets (proposed additions underlined in blue, proposed deletions in strikethrough red), which balance the clarity and flexibility necessary for operators with the interests of the program's customers and patients and the other objectives essential to the implementation of a safe, secure and effective program:

*MARIHUANA DISCIPLINARY PROCEEDINGS*

**R 420.802 Notification and reporting.**
[. . .]

Rule 2.

[. . .]

(4) A licensee shall notify the agency within ~~1~~ 3 business days of becoming aware or within ~~1~~3 business days of when the licensee should have been aware of any of the following**:**;

~~(a) Adverse reactions to a marihuana product sold or transferred by any licensee.~~

(~~b~~**a**) Criminal convictions, charges, or civil judgments against a licensee in this state or any other state, federal, or foreign jurisdiction.

(~~c~~**b**) Regulatory disciplinary action taken or determined against a licensee by this state or any other state, federal, or foreign jurisdiction, including any pending action.

**(c) Action by another party in actual or alleged violation of the acts or these rules.**

[. . .]

Comment:

Cresco respectfully urges the MRA to consider the above changes, which would afford operators a more reasonable period in which to report certain events. Allowing three businesses days rather

than a single day would not be burdensome on the MRA and presents no risk to the public. Allowing license holders a small amount of additional time to understand whether an event must be reported, including with respect to new subsection (c), simply provides licensees with a fair amount of time in which to report events to the MRA.

**R 420.808a Exclusion.**
**Rule 8a.**
**Rule 8a. (1) A person may be excluded from employment at, or participation in, a marihuana business upon a finding of any of the following:**

[. . .]

**(e) The person is included on any valid and current exclusion list from another jurisdiction in the United States if the basis for the person's inclusion on the exclusion list would also be grounds for exclusion as set forth in this Rule.**

[. . .]

Comment:

Cresco proposes to clarify the language set forth in the above rule, which would permit a person from being excluded from employment at, or participation in, a marihuana business based on that person's exclusion from the cannabis industry in another state. Cresco submits that a person should only be excluded from participating in the cannabis industry in this state if the conduct or grounds for the person being excluded in another state would result in exclusion in this state. Absent clarification such as the above, an otherwise qualified individual may be prevented from participating in the Michigan cannabis industry for conduct that may acceptable under Michigan law.

*MARIHUANA-INFUSED PRODUCTS AND EDIBLE MARIHUANA PRODUCT*

**R 420.403 Requirements and restrictions on marihuana-infused products; edible marihuanaproduct.**
Rule 3.

[. . .]

(7) A producer shall label all marihuana-infused product with all of the following:
(a) The name of the marihuana-infused product. **The name of the product must be an appropriately descriptive phrase that accurately describes the basic nature of the product.**

[. . .]

(2) A producer of edible marihuana product shall comply with all the following:

(a) ~~Edible marihuana product packages shall~~ ~~n~~**N**ot ~~be in~~ **produce an edible marihuana product in** a shape or **with a** label~~ed in a manner~~ that would appeal to minors aged 17 years oryounger. ~~Edible marihuana products shall not be associated with or have cartoons, caricatures,toys, designs, shapes, labels, or packaging that would appeal to minors.~~

**(b) Not produce an edible marihuana product that is associated with or has cartoons,caricatures, toys, designs, shapes, labels, or packaging that would appeal to minors.**

(~~b~~**c**) **Not produce** ~~E~~**e**dible marihuana products ~~shall not be~~ **that can be** easily confused with **a** commercially ~~sold candy~~ **available food product**. The use of the word candy or candies on the packaging or labeling is prohibited. ~~Edible marihuana products shall not be in the distinct shape of a human, animal, or fruit, or a shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings. Edible marihuana products that are geometric shapes and simply fruit flavored are permissible.~~

[. . .]

(9) A producer of edible marihuana product shall comply with all the following:

(a) ~~Edible marihuana product packages shall~~ ~~n~~**N**ot ~~be in~~ **produce an edible marihuana product in** a shape or **with a** label~~ed in a manner~~ that would primarily appeal to minors aged 17 years oryounger. ~~Edible marihuana products shall not be associated with or have cartoons, caricatures,toys, designs, shapes, labels, or packaging that would appeal to minors.~~

**(b) Not produce an edible marihuana product that is associated with or has cartoons, caricatures, toys, designs, shapes, labels, or packaging that would** primarily **appeal to minors.**

[. . .]

(10) A producer shall not produce an edible marihuana product that requires time and temperature control for safety. The agency may publish validation guidance for shelf stable edible marihuana product. The agency may request to review the validation study for a shelfstable edible marihuana product. The end product must be a shelf stable edible marihuana product and state the following information:

(a) A product expiration date, upon which the marihuana product is no longer fit for consumption **and after which it must be destroyed**. Once a label with an expiration date has been affixed to a marihuana product, a licensee shall not alter that expiration date or affix a newlabel with a later expiration date. **The expiration date must consider all the following:**

**(i) The quality and characteristics of the edible marihuana product.**

**(ii) The packaging of the edible marihuana product.**

**(iii) The customary conditions encountered by the edible marihuana product from product to sale.**

[. . .]

Comment:

With regard to the proposed amendment to subsection (7)(a) above, which would require operators to label products in a descriptive manner that accurately describes the basic nature of the product, Cresco respectfully asks the MRA to provide further clarify to operators. While Cresco understands the proposed rule to echoes recent packaging guidance issued by the MRA, the proposed rule is not precise and leaves operators to interpret the MRA's intent with this additional language. Packaging and labeling changes take substantial time to design, implement, and purchase and changes cannot be made easily. Accordingly, to the extent the MRA can provide more specificity, codified in the rule, such would be to the benefit of both operators and the agency and would avoid costly changes to packaging that take considerable time to effectuate.

Regarding subsections (9)(a) and 9(b), Cresco suggests the above change that more accurately reflects the intent of the rule and balances an operator's ability to build brands and design packaging creatively while ensuring that such packaging is not aimed to the appeal of minors. Employment the qualifier "primarily" or "likely" is in line with other adult use jurisdictions and serves to accomplish the aim of the rule change.

Additionally, related to subsection (10)(a)(i), Cresco seeks clarity from the MRA as to what is meant by the phrase "quality and characteristics of the edible marihuana product." As drafted, this new language is subject to interpretation and is not defined within the amended rules. As a result, Cresco asks the MRA to consider providing further clarifying language to provide operators the necessary transparency to comply with the new rule.

*MARIHUANA LICENSEES*

**R 420.106 Marihuana secure transporter license.**

Rule 6. (1) A marihuana secure transporter license authorizes the licensee to store and transport marihuana and money associated with the purchase or sale of marihuana between marihuana establishments for a fee upon request of a person with legal custody of that marihuana or money.It does not authorize transport to a registered qualifying patient or registered primary caregiver. If a marihuana secure transporter has its primary place of business in a municipality that has notadopted an ordinance under section 6 of the MRTMA, MCL 333.27956, prohibiting marihuana establishments, the marihuana secure transporter may travel through any municipality

[. . .]

Comment:

Cresco respectfully asks that the MRA consider permitting operators to self-distribute to entities under common ownership if an operator meets the requirements set forth in the secure transporters Rule 420.106, set forth in part above.

**R 420.101 Definitions.**
[. . .]

(~~c~~**d**) "Applicant" means a person who applies for a marihuana license, subject to paragraphs (i) and (ii) **of this subrule**:

(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 theapplicant, and the following for each type of applicant:

[. . .]

(F) For a publicly held corporation: all corporate officers or persons with equivalent titles ~~and their spouses~~, all directors ~~and their spouses~~, all stockholders, not including those holding a direct or indirect ownership interest of 10% or less~~, and their spouses~~.

[. . .]

Comment:

Cresco urges the MRA to consider the above changes to remove "spouses" from the definition of applicant with respect to publicly held corporations. Simply stated, the spouses of corporate officers, persons with equivalent titles, directors, and certain stockholders should not be construed as applicants under the law. Indeed, Michigan stands as an outlier in making such a determination, which only serves to burden applicants with additional disclosures not required in other similarly situated jurisdictions and does not advance any goal the state may have with regard to transparency.

**PART 3. AGREEMENTS**
**R 420.112a Licensing, management, or other agreements.**
**Rule 12a. (1) A licensee may contract with another party to use the other party's intellectual property or for the other party to provide management or other services necessary for the operation of the licensee pursuant to a licensing, management, or otheragreement approved by the agency.**

**(2) A licensee shall submit a complete, unredacted, signed copy of the licensing, management, or other agreement to the agency for review and approval prior to performance under the agreement. Approval by the agency indicates an agency determination that it does not appear based upon the information provided that the otherparty meets the definition of applicant.**

~~**(3) The agreement must include, but is not limited to, all of the following:**~~

[. . .]

Comment:

While Cresco understands the intent behind the MRA's propose rule, set forth above, and takes no issue with providing a licensing, management, or other agreement to the MRA for review to confirm that any third party does not meet the definition of an applicant, Cresco respectfully urges the MRA to take another approach with respect to the requirements set forth in the proposed rule. As currently drafted, the MRA's requirements come close to dictating the terms of a business agreement, which Cresco respectfully suggests goes beyond the role of a regulator and is not the ultimately intent here. As an alternative approach, Cresco proposes the above rule be amended to plainly set forth what is prohibited from inclusion in such agreements rather than a list of required terms. Such an approach would still provide the MRA discretion over agreements but would not otherwise restrict the terms of such agreements (other than that certain terms cannot be included in such agreements).

*MARIHUANA LICENSES*

**R 420.1 Definitions.**
Rule 1. (1) As used in these rules:

[. . .]

(a) "Applicant" means a person who applies for a marihuana license, subject to paragraphs (i)and (ii) **of this subdivision**:
(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 theapplicant, and the following for each type of applicant:

[. . .]

(F) For a publicly held corporation: all corporate officers or persons with equivalent titles ~~and their spouses~~, all directors ~~and their spouses~~, all stockholders, not including those holding a direct or indirect ownership interest of 10% or less~~, and their spouses~~.

Comment:

Once again, as set forth above, Cresco urges the MRA to consider removing "spouses" from the definition of applicant with respect to publicly held corporations. The spouses of corporate officers, persons with equivalent titles, directors, and certain stockholders should not be construed

as applicants under the law. Indeed, Michigan stands as an outlier in making such a determination, which only serves to burden applicants with additional disclosures not required in other similarly situated jurisdictions and does not advance any goal the state may have with regard to transparency.

**R 420.4 Application requirements; financial and criminal background.**

Rule 4. (1) Each applicant shall disclose the identity of any other person who controls, either directly or indirectly, the applicant, including, but not limited to, date of birth, government issued identification, and any other documents required by the agency.

(2) Each applicant shall disclose the financial information required in the acts and these rules ona form created by the agency, including the following:

(a) For an applicant seeking licensure under the ~~medical marihuana facilities licensingact~~**MMFLA**, required information includes, but is not limited to, all of the following:

**(i)** Financial statements regarding all of the following:

(A) A pecuniary interest.

(B) Any deposit of value of the applicant or made directly or indirectly to the applicant, orboth.

(C) Financial accounts including, but not limited to, all of the following: funds, savings, checking, or other accounts including all applicable account information, such as the name of thefinancial institution, names of the account holders, account type, account balances, and a list of all loan~~s~~ types specified by the agency, amounts, securities, or lender information.

**(ii)** Property ownership information, including, but not limited to, deeds, leases, rentalagreements, real estate trusts, or purchase agreements.

**(iii)** Tax information, including, but not limited to, W-2 and 1099 forms, and any otherinformation required by the agency.

**(iv)** Disclosure by the applicant of the identity of any other person who meets either of thefollowing:

[. . .]

(b) For an applicant seeking licensure under the ~~Michigan regulation and taxation of marihuanaact~~ **MRTMA** ~~required information includes, but is not limited to,~~ **all of** the following **is required**:

(i) Tax information, including, but not limited to:

(A) W-2 forms for the most recent tax year.

(B) 1099 forms for the most recent tax year.

(ii) Any other information required by the agency.

[. . .]

(3) ~~Each applicant shall disclose all shareholders holding a direct or indirect interest of greater than 5%, officers, and directors in the proposed marihuana establishment.~~ **Each applicant shall**

**disclose the identity of every person having a 2.5% or greater ownership interest in the applicant with respect to which the license is sought.**

[. . .]

**(c) If the disclosed entity is a publicly held corporation, the names and addresses of all shareholders holding a direct or indirect interest of greater than 5%, officers, and directors.**

Comment:

As an initial matter, Cresco seeks clarification regarding subsections (2)(a) and (2)(b) of Rule 4, which appear to set forth different requirements for applicants in the medical and adult use programs in terms of financial information required to be disclosed. Cresco respectfully proposes that the MRA seek to align these requirements for consistency and to create parity between the programs. Further, to the extent disclosures are not accompanied by any temporal limitations, Cresco proposes that the MRA take steps to limit the information required to be produced. For example, an applicant under the MMFLA must produce tax information (*see* subsection (2)(a)(iiii)) whereas an applicant under the MRTMA must produce tax information for the most recent tax year (*see* subsection (2)(b)(i)).

Further, Cresco seeks clarity from the MRA as to the required disclosures applicable to a publicly held corporation. The definition of applicant in Rule 420.1 defines an applicant as a person holding an interest of more than 10% in the applicant while subsection (3) of this rule mandates disclosure of the identity of every person having a 2.5% or greater ownership interest and subsection (3)(c) requires a publicly held corporation to disclose certain persons holding a 5% of greater interest in the business.

**R 420.13 Renewal of marihuana license.**
Rule 13.

[. . .]

**(c) For an applicant seeking renewal of a license under the MMFLA, confirmation of municipal compliance on an attestation form provided by the agency that includes all of the following** ~~A**a**ttestation by the municipality on a form created by the agency regarding a licensee who submits an application for marihuana license renewal which shall include, but not be limited to, both of the following~~:

(i) A description of any violation~~, if applicable,~~ of an ordinance or a zoning regulation adoptedpursuant to section 205 of the ~~medical marihuana facilities licensing act~~**MMFLA**, MCL 333.27205~~, or section 6 of the Michigan regulation and taxation of marihuana act, MCL 333.27956,~~ committed by the licensee, but only if the violation relates to activities licensed underthe act~~s~~ or these rules.

(ii) Whether there has been a change to an ordinance or a zoning regulation adopted pursuant to section 205 of the ~~medical marihuana facilities licensing act~~**MMFLA**, MCL 333.2720~~5, or section 6 of the Michigan regulation and taxation of marihuana act, MCL 333.27956,~~ since the marihuana license was issued to the licensee and a description of the change.

**(iii) The date and signature of the clerk of the municipality or his or her designee.**

**(iv) The date and signature of the applicant.**

**(v) The name and address of the marihuana facility.**

**(vi) The license type of the marihuana facility.**

**(d) For an applicant seeking renewal of a license under the MRTMA, confirmation of municipal compliance on an attestation form provided by the agency that includes all of the following:**

**(i) A description of any violation, if applicable, of an ordinance or a zoning regulation consistent with section 6 of the MRTMA, MCL 333.27956, committed by the licensee, butonly if the violation relates to activities licensed under the act or these rules.**

**(ii) Whether there has been a change to an ordinance or a zoning regulation consistent with section 6 of the MRTMA, MCL 333.27956, since the marihuana license was issued tothe licensee and a description of the change.**

**(iii) The following information for the municipality where the marihuana establishmentis located, including, at a minimum, all of the following:**

**(A) The name and address of the marihuana establishment.**

**(B) The license type of the marihuana establishment.**

**(C) The municipality where the marihuana establishment is located.**

**(D) The contact information for the municipality, including, at a minimum, all of thefollowing:**

**(I) The name of the clerk of the municipality or his or her designee.**

**(II) The telephone number of the clerk of the municipality or his or her designee.**

**(III) The email address of the clerk of the municipality or his or her designee.**

**(IV) The mailing address of the clerk of the municipality or his or her designee.**

**(iv) Confirmation that the municipality has not adopted an ordinance prohibiting theproposed marihuana establishment.**

**(v) Confirmation that the applicant is in compliance with any ordinance the municipalityhas adopted relating to marihuana establishments within its jurisdiction, including zoning regulations.**

**(vi) Attestation that the applicant will report any changes that occur with municipal ordinances or zoning regulations that relate to the marihuana establishment, any municipal establishment approvals, or any violations of a municipal or zoning regulation.**

**The date and signature of the applicant.**

[. . .]

Comment:

With respect to the requirements of the above Rule, Cresco asks that the MRA consider the scope of information required of municipalities and how to address situations where a licensee may be unable to procure the necessary information in a timely fashion from a municipality so that the licensee may continue to serve patients and customers without disruption.

**R 420.14 Notification and reporting.**
[. . .]

(4) An applicant shall notify the agency within ~~1~~3 business days of becoming aware of or within ~~1~~3 business days of when the applicant should have been aware of any of the following:

[. . .]

Comment:

Cresco respectfully urges the MRA to consider the above change, which would afford operators a more reasonable period in which to report certain events. Allowing three businesses days rather than a single day would not be burdensome on the MRA and presents no risk to the public. Affording license holders a small amount of additional time to understand whether an event must be reported simply provides licensees with a fair amount of time in which to report events to the MRA.

*MARIHUANA OPERATIONS*

**R 420.1 Definitions.**
Rule 1. (1) As used in these rules:

[. . .]

(d) "Applicant" means a person who applies for a marihuana license, subject to paragraphs (i) and (ii) **of this subdivision**:

(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:

[. . .]

(F) For a publicly held corporation: all corporate officers or persons with equivalent titles ~~and their spouses~~, all directors ~~and their spouses~~, all stockholders, not including those holding a direct or indirect ownership interest of 10% or less~~, and their spouses~~.

Comment:

As stated above, Cresco respectfully asks the MRA to consider removing "spouses" from the definition of applicant with respect to publicly held corporations. The spouses of corporate officers, persons with equivalent titles, directors, and certain stockholders should not be construed as applicants under the law. As noted above, Michigan stands as an outlier in making such a determination, which only serves to burden applicants with additional disclosures not required in other similarly situated jurisdictions and does not advance any goal the state may have with regard to transparency.

**R 420.206 Marihuana business; general requirements.**
Rule 6.

[. . .]

**(13) All ingredients containing cannabinoids, whether naturally occurring or synthetically derived, that are added to marihuana or marihuana products must be from a source licensed to grow, handle, and produce cannabinoids under a license issued by a governmental authority and entered into the statewide monitoring system.**

**(14) When combining more than 1 form of marihuana or marihuana product into a single marihuana product, each form of marihuana or marihuana product must have passing safety compliance test results in the statewide monitoring system prior to the creati on of the new combined product.**

[. . .]

Comment:

Cresco respectfully seeks clarification from the MRA regarding the meaning of the above language. Specifically, does the MRA intend subsection (13) of Rule 6 to mean an operator can procure hemp-derived cannabinoids from outside of Michigan as long as the source of the cannabinoids is licensed in the state in which it operates and the product passes testing, as set forth in subsection (14).

**R 420.207 Marihuana delivery; limited circumstances.**
Rule 7.

[. . .]

(9) ~~To ensure the integrity of the marihuana sales location operation, a~~ **A** marihuana delivery employee shall comply with all the following:

[. . .]

(d) A marihuana delivery employee shall not carry marihuana product in the delivery vehicle with a value in excess of $5,000.00 (pre-tax retail value) at any time. The value of marihuana products carried in the delivery vehicle for which a delivery order was not received and processed by the licensed retailer prior to the delivery employee departing from the marihuana sales location may not exceed $3,000.00 (pre-tax retail value). For the purposes of this subrule, the value of marihuana products must be determined using the current retail price of all marihuana products carried by, or within the delivery vehicle of, the marihuana delivery employee.

[. . .]

Comment:

Cresco respectfully asks the MRA to consider the above change to clarify that value of products is measured before tax. Such is a reasonable clarification and would be easier for operators to navigate compared to determining product value post-tax.

**R 420.214b Adverse reactions.**

**Rule 14b. (1) A licensee shall notify the agency within ~~1~~3 business days of becoming aware ~~or within 1 business day of when the licensee should have been aware~~ of any adverse reactions to a marihuana product sold or transferred by any licensee.**

**(2) A licensee shall enter into the statewide monitoring system within ~~1~~3 business days of becoming aware of ~~or within 1 business day of when the licensee should have been aware of~~ any adverse reactions to a marihuana product sold or transferred by any licensee.**

Comment:

As an initial point, Cresco requests the MRA to consider the above change, which would afford operators a more reasonable period in which to report certain events. Allowing three businesses days rather than a single day would not be burdensome on the MRA and presents no risk to the public. Further, permitting license holders a small amount of additional time to understand whether an adverse reaction has actually occurred must be reported provides licensees with a fair amount of time in which to report adverse reactions.

Additionally, Cresco asks the MRA to consider eliminating language that would mandate a licensee to report (and enter information into the statewide monitoring system) within one business day of when the licensee "should have been aware" of an adverse reaction occurred. Licensees can only fairly report information they are aware of and it is unclear, as a general matter, how a licensee can report and enter information concerning an event which they were not aware of but "should have been." As a result, Cresco proposes the above changes to Rule 420.214b.

**R 420.214c Product returns.**

**Rule 14c. (1) A marihuana sales location may accept the return of marihuana product that is reported to have caused an adverse reaction or is determined to be defective.**

**(2) A marihuana sales location must have a written policy for the return of marihuana product that contains, at a minimum, the following:**

[. . .]

**(g) A marihuana retailer may return a marihuana product that is past its expiration date to the marihuana processor who produced the marihuana product for destruction or retesting and/or remediation instead of destroying the marihuana product.**

Comment:

Cresco respectfully asks the MRA to consider permitting operates to retest and remediate, as necessary, any product that has been returned as being past an expiration date. With appropriate testing and/or the application of remediation, a product can be assured as appropriately dispensed to the public. Such would avoid the unnecessary destruction of products to the expense of operators and ultimately to patients and customers who would not have that product available.

*MARIHUANA SAMPLING AND TESTING*

**R 420.303 Batch; identification and testing.**
Rule 3.

[. . .]

(6) A cultivator may transfer or sell **fresh frozen or dry** marihuana to a producer without first being tested by a laboratory in order to produce ~~fresh frozen~~ **live resin or rosin,** or if the marihuana product willbe ~~refined to a concentrate~~ **extracted**~~, with agency approval~~. **A cultivator may not transfer or sell marihuana to a producer under this rule if the package contains more than 1 harvest batch. This does not prohibit a cultivator from transferring multiple harvest batches for extraction.** After the producer has ~~processed~~ **extracted** the material, the producer shall have the sample tested **for all required safety tests** pursuant to R 420.30**4** and R 420.305. **A producer that received a package under this rule that has not been processed may transfer that package to another producer without having the package first tested by a laboratory to produce live resin or rosin or concentrate** ~~**with agency approval**~~**.** The agency may publish guidance **f**or fresh frozen and concentrate production, transfer, and sale.

Comment:

Cresco asks the MRA to consider the above changes which would provide operators with flexibility while continuing to ensure products meet testing standards before being dispensed to patients or customers. As drafted, the above rule would permit the transfer of fresh frozen

marijuana to a producer to make live resin or marihuana extract without first being tested, with MRA approval. Cresco proposes that rosin be included in the above amended regulation, as a reasonable expansion of this amended rule. Cresco further suggests that the ability to transfer biomass intended for extraction should not be limited to fresh frozen marihuana and should also include dry marihuana. And finally, Cresco proposes removing the requirement that an operator must request and receive approval before transferring materials that will be subject to extraction. The above modifications serve to reasonably expand the intent of the rule and would not result in untested product being offered for sale. Indeed, the above modifications further the purpose of the rule change, by permitting the transfer of biomass that will be subject to extraction without requiring that the marihuana be subject to a pre-transfer test and then tested again following extraction.

*MARIHUANA EMPLOYEES*

**R 420.601 Definitions.**
Rule 1. (1) As used in these rules:

[. . .]

(~~d~~**e**) "Employee" means, except as otherwise provided in these rules, a person performing work or service for direct compensation from the marihuana establishment. "Employee" does not include individuals providing trade or professional services who are not normally engaged in the operation of a marihuana establishment.

[. . .]

Comment:

Cresco proposes the above changes to the definition of employee in this rule set—and in other rule sets that employs the same definition of employee—as the current definition is overly broad. By enacting the above changes, the definition more clearly defines the term "employee."

Thank you for the opportunity to comment on these proposed rule sets. Cresco welcomes the opportunity to provide the MRA with any additional feedback or information.

Sincerely,

Cresco Labs Michigan, LLC

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

MARIJUANA REGULATORY AGENCY

MARIHUANA SAMPLING AND TESTING

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a~~(6)~~**(9)** of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the executive director of the ~~marihuana~~ **marijuana** regulatory agency by section 206 of the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27206, sections 7 and 8 of the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27957 and 333.27958, and Executive Reorganization Order No. 2019-2, MCL 333.27001)

R 420.301, R 420.302, R 420.303, R 420.304, R 420.305, R 420.306, and R 420.307 of the Michigan Administrative Code are amended, and R 420.303a, R 420.305a, and R 420.305b are added, as follows:

R 420.301 Definitions.

Rule 1. (1) As used in these rules:

(a) "Action limit" means the maximum permissible level of a contaminant in marihuana product allowable by the agency.

(b) "Acts" refers to the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27101 to 333.27801, and the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27951 to 333.27967, when applicable.

(c) "Agency" means the marijuana regulatory agency.

(d) "Batch" means all marihuana product of the same variety that has been processed together and exposed to substantially similar conditions throughout processing.

~~(e) "Bureau of fire services" or "BFS" means the bureau of fire services in the department of licensing and regulatory affairs.~~

(~~f~~**e**) "Cultivator" refers to a grower under the medical marihuana facilities licensing act or a marihuana grower under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct, or both.

**(f) "Employee" means, except as otherwise provided in these rules, a person performing work or service for compensation. "Employee" does not include an individual providing trade or professional services who is not normally engaged in the operation of a marihuana establishment.**

(g) "Final form" means the form a marihuana product is in when it is available for sale by a marihuana sales location. For marihuana products intended for inhalation, **"final form" means** the marihuana concentrate in ~~the~~ **an** e-cigarette or **a** vaping device.

(h) "Good agricultural collection practices" or "GACP-GMP" means the World Health ~~Organizations~~ **Organization's** or **the** American Herbal Products ~~Associations~~ **Association's**

guidelines regarding the safety, efficacy**,** and sustainability of medicinal plant material being used in herbal medicines.

(i) "Good manufacturing practices" or "GMP" means the Food and Drug Administration's formal regulations regarding the design, monitoring, control, and maintenance of manufacturing processes and facilities. They are designed to ensure that products manufactured are to specific requirements including identity, strength, quality, and purity.

(j) "Harvest batch" means a designated quantity of harvested marihuana, all of which is identical in strain and has been grown and harvested together and exposed to substantially similar conditions throughout cultivation.

(k) "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.

(l) "Inactive ingredients" means binding materials, dyes, preservatives, flavoring agents, and any other ingredient that is not derived from the plant *Cannabis ~~S~~sativa L.*

(m) "Laboratory" refers to both a safety compliance facility under the medical marihuana facilities licensing act and a marihuana safety compliance facility under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct.

(n) "Limit of quantitation" or "LOQ" means the minimum concentration or mass of an analyte in a given matrix that can be reported as a quantitative result.

(o) "Marihuana business" refers to a marihuana facility under the medical marihuana facilities licensing act or a marihuana establishment under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct, or both.

(p) "Marihuana establishment" means a location at which a licensee is licensed to operate a marihuana grower, marihuana safety compliance facility, marihuana processor, marihuana microbusiness, **class A marihuana microbusiness,** marihuana retailer, marihuana secure transporter, marihuana designated consumption establishment, or any other type of marihuana-related business licensed to operate by the agency under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct.

(q) "Marihuana facility" means a location at which a licensee is licensed to operate under the medical marihuana facilities licensing act.

(r) "Marihuana product" means marihuana or a marihuana-infused product, or both, as those terms are defined in the act unless otherwise provided for in these rules.

(s) "Marihuana sales location" refers to a provisioning center under the medical marihuana facilities licensing act or a marihuana retailer under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct, or both.

(t) "Marihuana tracking act" means the marihuana tracking act, 2016 PA 282, MCL 333.27901 to 333.27904.

(u) "Medical marihuana facilities licensing act" or "MMFLA" means the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27101 to 333.27801.

(v) "Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct" or "MRTMA" means the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27951 to 333.27967.

(w) "Package tag" means an RFID tag supplied through the statewide monitoring system for the purpose of identifying a package containing a marihuana product.

(x) "Plant tag" means an RFID tag supplied through the statewide monitoring system for the purpose of identifying an individual marihuana plant.

(y) "Pre-test~~ing~~" means **to** perform~~ing~~ full compliance testing on samples, ~~then not~~ **without** reporting the results to the agency, and reporting results of subsequent testing to the agency.

(z) "Proficiency test~~ing~~" **means a test that** determines the performance of individual laboratories for specific tests or measurements and is used to monitor laboratories' ~~continuing~~ performance.

(aa) "Producer" refers to both a processor under the medical marihuana facilities licensing act and a marihuana processor under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct.

(bb) "These rules" means the administrative rules promulgated by the agency under the authority of the medical marihuana facilities licensing act, the marihuana tracking act, the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct, and Executive Reorganization Order No. 2019-2, MCL 333.27001.

(cc) "Tag" or "RFID tag" means the unique identification number or Radio Frequency Identification (RFID) issued to a licensee by the ~~agency~~ **statewide monitoring system** for tracking, identifying, and verifying marihuana plants, marihuana products, and packages of marihuana product in the statewide monitoring system.

(dd) "Target analyte" means a non-marihuana inactive ingredient designated for analysis.

(2) Terms defined in the acts have the same meanings when used in these rules unless otherwise indicated.

R 420.302 Adoption by reference.

Rule 2. (1) The following codes, standards, or regulations of nationally recognized organizations or associations are adopted by reference in these rules:

(a) AOAC International Official Methods of Analysis, 21st edition. Copies of the adopted provisions are available for inspection and distribution from **the Association of Official Analytical Collaboration (AOAC) International** ~~AOAC International~~, 2275 Research Boulevard, Suite 300, Rockville, Maryland, 20850, telephone number 1-800-379-2622, for the price of $870.00.

(b) National fire protection association (NFPA) standard 1, 20~~18~~**21** edition, entitled "Fire Code**,**" is adopted by reference as part of these rules. Copies of the adopted provisions are available for inspection and distribution from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, Massachusetts, 02169, telephone number 1-800-344-3555, for the price of $~~106.00~~**114.50**.

(c) The International Organization for Standardization (ISO), ISO 22000 / ISO/TS 22002-1:2009**,** ~~–f~~**F**ood ~~s~~**S**afety ~~b~~**B**undle, available for purchase at: https://webstore.ansi.org/Standards/ISO/ISO22000TS22002FoodSafety, for the price of $275.00.

(d) International Organization for Standardization (ISO), ISO/IEC 17025:2017, ~~g~~**G**eneral ~~r~~**R**equirements for the ~~c~~**C**ompetence of ~~t~~**T**esting and ~~c~~**C**alibration ~~l~~**L**aboratories**,** available at: https://webstore.ansi.org/RecordDetail.aspx?sku=ISO%2fIEC+17025%3a2017, for the price of $162.00.

(2) The standards adopted in subrule (1)(a) to (d) of this rule are available for inspection and distribution at the agency, located at 2407 North Grand River Avenue, Lansing, ~~MI~~**Michigan**, 48906. Copies of these standards may be obtained from the agency at the cost indicated in subrule (1)(a) to (d) of this rule, plus shipping and handling.

R 420.303 Batch; identification and testing.

Rule 3. (1) A cultivator shall uniquely identify each immature plant batch with a single ~~plant tag~~ **batch name** and record the information in the statewide monitoring system. Each immature plant batch must consist of no more than 100 immature plants.

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

(3) A cultivator shall separate the plants as the plants go through different growth stages and ensure that the plant tag is always identified with the plant throughout the ~~growth span~~ **growing cycle** so that all plants can be easily identified and inspected. A cultivator shall ensure that identification information is recorded in the statewide monitoring system in accordance with the acts, the marihuana tracking act, and these rules.

(4) ~~After~~ **A cultivator shall immediately destroy the individual plant tag once** a tagged plant is harvested~~, it~~ **and** is part of a harvest batch so that a sample of the harvest batch can be tested by a licensed laboratory as provided in R 420.304 and R 420.305. A cultivator shall **separate the harvest batch by product type and** quarantine ~~a harvest batch~~ **the harvested batch** from **all** other ~~plants or batches~~ **marihuana and marihuana products when the marihuana batch has** ~~that have~~ test results pending. A harvest batch must be easily distinguishable from other harvest batches until the batch is broken down into packages. **A cultivator may not combine harvest batches.**

(5) Before the **cultivator transfers or sells the** marihuana product ~~leaves the cultivator~~, except as provided in subrule (6) of this rule, a sample of the harvest batch must be tested **for all required safety tests** by a licensed laboratory as provided in R 420.304 and R 420.305. All test results must indicate passed in the statewide monitoring system before the marihuana is packaged **for sale**. A marihuana product from harvest batches ~~must~~**may** not be transferred or sold until tested, packaged, and tagged as required under subrule (4) of this rule. A marihuana product from a harvest batch that fails safety testing may only be sold or transferred under the remediation protocol as provided in R 420.306.

(6) A cultivator may transfer or sell **fresh frozen** marihuana to a producer without first being tested by a laboratory in order to produce ~~fresh frozen~~ **live resin,** or if the marihuana product will be ~~refined to a concentrate~~ **extracted**, with agency approval. **A cultivator may not transfer or sell marihuana to a producer under this rule if the package contains more than 1 harvest batch. This does not prohibit a cultivator from transferring multiple harvest batches for extraction.** After the producer has ~~processed~~ **extracted** the material, the producer shall have the sample tested **for all required safety tests** pursuant to R 420.304 and R 420.305. **A producer that received a package under this rule that has not been processed may transfer that package to another producer without having the package first tested by a laboratory to produce live resin or concentrate with agency approval.** The agency may publish guidance **f**or fresh frozen and concentrate production, transfer, and sale.

(7) After test results ~~show~~ **indicate** ~~a~~ passed test **for all required safety tests** and the harvest batch is packaged, ~~the cultivator shall destroy the individual plant tags. E~~**e**ach package must have a package tag attached. A cultivator shall ensure this information is placed in the statewide monitoring system in accordance with the acts, the marihuana tracking act, and these rules.

(8) A cultivator shall not transfer or sell any marihuana product that ~~has not been packaged with~~ **does not have** a package tag attached and **is not** recorded in the statewide monitoring system in accordance with the acts, the marihuana tracking act, and these rules.

~~(9) After a producer receives or purchases a package in the statewide monitoring system, and the producer proceeds to process the marihuana product in accordance with the scope of a producer license, the acts, and these rules, the producer shall give the marihuana product a new package tag anytime the marihuana product changes form or is incorporated into something else.~~
~~(10) 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. The producer shall not transfer or sell a marihuana product to a marihuana sales location until after test results entered into the statewide monitoring system indicate a passed test. Nothing in this subsection prohibits a producer from transferring or selling a package in accordance with the remediation protocol provided by the agency and these rules.~~
~~(11) A marihuana sales location may sell or transfer marihuana product only to a marihuana customer under both of the following conditions:~~
~~(a) The marihuana product has received passing test results in the statewide monitoring system.~~
~~(b) The marihuana product bears the label required for retail sale, under the acts and these rules.~~

**R 420.303a Producer and sales location packaging and testing requirements.**

**Rule 3a. (1) A producer shall give a marihuana product a new package tag anytime the marihuana product changes form or is incorporated into a different product.**

**(2) A producer of a marihuana product in its final form shall have the sample tested pursuant to R 420.304 and R 420.305. The producer shall quarantine products from all other products when the product has test results pending. The producer shall not transfer or sell a marihuana product to a marihuana sales location until after test results entered into the statewide monitoring system indicate a passed result for all required safety tests. Nothing in this subsection prohibits a producer from transferring or selling a package in accordance with the remediation protocol provided by the agency and these rules.**

**(3) A marihuana sales location may sell or transfer a marihuana product only to a marihuana customer under both of the following conditions:**

**(a) The marihuana product has received passing results for all required safety tests in the statewide monitoring system.**

**(b) The marihuana product bears the label required under the acts and these rules for retail sale.**

R. 420.304 Sampling; testing.

Rule 4. (1) A laboratory shall test samples as provided in the acts and these rules.

(2) A laboratory shall collect samples of a marihuana product from another marihuana business, and that marihuana business shall ~~allow the collection of samples for testing, according to~~ **not interfere or prevent the laboratory from complying with all of** the following requirements:

(a) The laboratory shall physically **collect the** sample the marihuana product from another marihuana business to be tested at the laboratory. A laboratory shall comply with all the following:

(i) The laboratory shall ensure that samples of the marihuana product are identified in the statewide monitoring system and placed in secured, sealed containers that bear the labeling required under these rules.

(ii) The route plan and manifest must be entered into the statewide monitoring system, and a copy must be carried in the transporting vehicle and presented to a law enforcement officer upon request.

(iii) The marihuana must be transported in 1 or more sealed containers and not be accessible while in transit.

(iv) The vehicle a laboratory is using to transport samples of marihuana product must not bear markings or other indication that it is carrying marihuana or a marihuana-infused product.

(b) 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. ~~Prior to September 1, 2020, the maximum harvest batch size is 15 pounds. From September 1, 2020, through December 31, 2020, the maximum harvest batch size is 20 pounds. From January 1, 2021 through March 31, 2021, the maximum harvest batch is 25 pounds. After March 31, 2021, t~~**T**~~he maximum harvest batch is 50 pounds. 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 laboratory must develop a statistically valid sampling method to collect a representative sample from each batch of marijuana product. The laboratory must have access to the entire batch for the purposes of sampling.~~

**(c) The maximum harvest batch is 50 pounds. At least 50% of the sample taken must be homogenized for testing. The agency may publish sample sizes for marihuana products being tested.**

**(d) The laboratory shall develop a statistically valid sampling method and have it approved by the agency to collect a representative sample from each batch of marihuana product. The laboratory shall have access to the entire batch for the purposes of sampling.**

(~~c~~**e**) An employee of the marihuana business from which marihuana product test samples are ~~being taken~~ **collected** shall be physically present to observe the laboratory employee collect the sample of marihuana product for testing and ~~shall~~ ensure that the sample increments are taken from throughout the batch.

(~~d~~f) An employee of a marihuana business shall neither assist the laboratory employee nor touch the marihuana product or the sampling equipment while the laboratory employee is obtaining the sample.

(~~e~~**g**) After samples have been selected, both the employee of the marihuana business **that had the samples collected** and the employee from the laboratory shall sign and date the chain of custody form, attesting to the **following** sample information ~~below~~:

(i) Marihuana product name.

(ii) Weight of marihuana product.

(iii) All marihuana products and samples are correctly identified in the statewide monitoring system.

(iv) 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.

(~~f~~**h**) ~~The~~ **A** marihuana business shall enter in the statewide monitoring system the marihuana product test sample that is collected by a licensed laboratory, including the date and time the marihuana product is collected and transferred. The laboratory shall enter into the statewide monitoring system the test results within 3 business days of test completion.

(~~g~~**i**) If a testing sample is collected from a marihuana business for testing in the statewide monitoring system, that marihuana business shall quarantine the marihuana product that is undergoing the testing from any other marihuana product at the marihuana business. The

quarantined marihuana product ~~must~~ **may** not be packaged, transferred, or sold until passing test results are entered into the statewide monitoring system.

(~~h~~**j**) Any marihuana product that a laboratory collects for testing from a licensee under this rule ~~must~~ **may** not be transferred or sold to any other marihuana business other than the licensee from whom the sample was collected. This provision does not apply to a laboratory ~~who~~ **that** engages another laboratory to perform certain safety tests on a subcontracted basis.

(~~i~~**k**) A laboratory may collect additional sample material from the same licensee from which the original sample was collected for the purposes of completing the required safety tests as long as the requirements of this rule are met.

(~~j~~**l**) The agency may publish guidance that ~~shall~~ **must** be followed by marihuana businesses for chain of custody documentation.

R. 420.305 Testing; laboratory requirements.

Rule 5. (1) A laboratory shall ~~do all of the following:~~

~~(a)~~ **B**become ~~fully~~ accredited ~~for~~ **all required safety tests in at least 1 required matrix** to the International Organization for Standardization (ISO), ISO/IEC 17025:2017**,** by an International Laboratory Accreditation Cooperation (ILAC) recognized accreditation body or by an entity approved by the agency within 1 year after the date the laboratory license is issued and agree to have the inspections**,** ~~and~~ reports**, and all scope documents** ~~of the International Organization for Standardization made available~~ **sent directly** to the agency **from the accrediting body**.

~~(b) Maintain internal standard operating procedures for the required safety tests in subrule (3) of this rule and for sampling of marihuana and marihuana products that conform to ISO/IEC 17025:2017 standards and have been approved by the agency.~~

~~(c) Maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2017 standards and meets the requirements established by the agency.~~

(2) A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency ~~or a third party~~. In the absence of ~~reference to compendia or~~ published**, peer reviewed, validated cannabis** methods, Appendix **J or** K of Official Methods of Analysis authored by the Association of Official ~~Analytical Chemists~~ **Analytical Collaboration (AOAC) International** must be published in full **with guidance from published cannabis standard method performance requirements where available**. The **laboratory shall obtain approval from the agency of its validated methodology, including confirmation that it produces scientifically accurate results for each safety test, prior to conducting any safety testing.** ~~agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts.~~

(3) A laboratory shall conduct the required safety tests specified in subdivisions (a) to (i) of this subrule on marihuana product that is part of the harvest batch as specified in R 420.303, except as provided in subrule (4) **of this rule**. **The agency may publish minimum testing portions to be used in compliance testing.** ~~After the testing on the harvest batch is completed, t~~**T**he agency may publish a guide indicating which of the following safety tests are required based on product type when the marihuana product has changed form:

(a) **Potency analysis.** ~~Potency analysis performed just as the marihuana product is without any corrective factor taken for moisture content that includes concentrations of the following:~~

~~(i) Tetrahydrocannabinol (THC).~~

~~(ii) Tetrahydrocannabinol acid (THC-A).~~
~~(iii) Cannabidiol (CBD).~~
~~(iv) Cannabidiol acid (CBD-A).~~
~~(v) Additional cannabinoids, which may be tested with approval from the agency.~~

**(i) In the preparation of samples intended for potency analysis, the laboratory may not adulterate or attempt to manipulate the total potency of the sample by adding trichomes that were removed during the grinding and homogenization process.**

**(ii) All flower material used for potency testing must be representative of the product used by the end consumer and homogenized in such a way that it is representative of the way a consumer would be using the product. Kief must not be reintroduced to the flower sample during the homogenization process.**

**(iii) Potency analysis performed just as the marihuana product is without any corrective factor taken for moisture content that includes concentrations of the following:**

**(A) Total Tetrahydrocannabinol (THC).**
**(B) Tetrahydrocannabinol acid (THC-A).**
**(C) Total Cannabidiol (CBD).**
**(D) Cannabidiol acid (CBD-A).**
**(E) Additional cannabinoids, which may be tested with approval from the agency.**

(b) **Inspection for** ~~F~~**f**oreign matter ~~inspection~~ **including powdery mildew, organic, and inorganic material**.

(c) Microbial screening **including an optimized incubation period for all non-molecular automated systems methods and all plating-based methods used to report quantitative total yeast and mold results.**

(d) Chemical residue testing ~~that includes all of the following~~ **performed on the list of banned chemical residues and the required LOQs published by the agency.**

~~(i) Pesticides.~~
~~(ii) Fungicides.~~
~~(iii) Insecticides.~~

(e) Heavy metals testing as required in this rule.

(f) Residual solvents. The agency shall publish a list of required residual solvents to be tested for and their action limits.

(g) Water activity.

(h) ~~Under the medical marihuana facilities licensing act, m~~**M**ycotoxin screening if requested by the agency. **The agency shall publish a list of required mycotoxins to be tested.**

(i) Target analytes if requested by the agency. The agency shall publish a list of required target analytes to be tested for and their LOQs.

(4) ~~All~~ marihuana producers 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 standard used for certification for GMP must be American National Standards Institute (ANSI) accredited or equivalent.

(5) All marihuana cultivators may become certified to GACP-GMP by an accrediting body. This accreditation may enable the licensee certain allowances with testing. The agency will publish these allowances and information on how to obtain approval for allowances. The standard used for certification for GACP-GMP must be World Health Organization and American Herbal Products Association or equivalent.

(6) Except as otherwise provided in **R** 420.306, if a sample collected pursuant to R 420.304 or provided to a laboratory pursuant to these rules does not pass the required safety tests, the marihuana business that provided the sample shall ~~dispose of~~ **destroy** the entire batch from which the sample was taken and document the ~~disposal~~ **destruction** of the sample using the statewide monitoring system pursuant to the acts and these rules **within 90 calendar days**.

(7) A laboratory shall conduct residual solvent testing on batches of marihuana concentrates and marihuana-infused products. The agency shall publish a list of required residual solvents to be tested for and their action limits.

(8) A laboratory shall maintain any marihuana samples for at least 30 **calendar** days after test completion and ~~dispose of~~ **destroy** the resulting waste in accordance with R 420.209.

(9) Potency shall include the following cannabinoid concentrations listed in subdivisions (a) to (f) **of this subrule**, subject to subdivisions (g) and (h) **of this subrule**:

(a) **Total** THC concentration.

(b) THC-A concentration.

(c) Total THC**, which includes Delta 7, Delta 8, Delta 9, Delta 10, and Delta 11 THC and THC-A**. The following calculation must be used for calculating Total THC, where M is the mass or mass fraction of delta-9 THC or delta-9 THC-A:

~~M total delta-9 THC = M delta-9 THC + 0.877 x M delta-9 THC-A.~~ **Σ Delta 7-11 THC + Σ ((Delta 7-11 THCA) x 0.877)=Total THC**

(d) **Total** CBD concentration.

(e) CBD-A concentration.

(f) Total CBD. The following calculation must be used for calculating Total CBD, where M is the mass or mass fraction of CBD and CBD-A:

M total CBD = M CBD + 0.877 x M CBD-A.

(g) For marihuana and marihuana concentrates**,** total THC and total CBD must be reported in percentages.

(h) For marihuana infused products**,** potency must be reported as **milligrams of** Delta-9-THC and CBD ~~in milligrams (mg) per serving under MRTMA and in milligrams (mg) per dose under MMFLA~~.

(10) The agency shall publish a list of action limits for the required safety tests in subrule (3) of this rule, except for potency. A marihuana sample with a value that exceeds the published action limit is ~~considered to be~~ a failed sample. A marihuana sample that is at or below the action limit is ~~considered to be~~ a passing sample.

(11) For t~~he purposes of~~ chemical residue ~~testing~~ and target analyte testing, the agency shall publish a list of quantification levels. Any result that exceeds the action limit is a failed sample.

(12) If a sample provided to a laboratory pursuant to this rule and R 420.304 passes the safety tests required under subrule (3) of this rule, the laboratory shall enter the information in the statewide monitoring system of passed test results within 3 business days of test completion. Passed test results must be in the statewide monitoring system for a batch to be released for immediate processing, packaging, and labeling for transfer or sale in accordance with the acts and these rules.

(13) A laboratory shall enter the results into the statewide monitoring system and file with the agency within 3 business days of test completion.

(14) ~~The agency shall establish a proficiency testing program and designate laboratory participation.~~ All laboratories ~~must~~ **shall** participate in the **proficiency testing** program **established by the agency**. A laboratory shall analyze proficiency test samples **from any ISO**

**17043 accredited vendor on an annual basis unless the agency requests additional testing. All testing must use** ~~using~~ the same procedures with the same number of replicate**s** ~~analyses~~, standards, testing analysts, and equipment as used for marihuana product testing. A laboratory shall successfully analyze ~~a~~ **1** set of proficiency testing samples **for all required analytes** not less than annually. A laboratory shall have ~~annual~~ **all** proficiency testing **results** submitted directly to the agency from the ~~proficiency testing~~ vendor for review. ~~The agency will not accept copies.~~ All failed proficiency tests must include corrective action documentation and **must be repeated until the laboratory obtains** an ~~additional~~ acceptable **result for all analytes** proficiency test. Proficiency test**s must be externally graded and** results must be **reported** ~~conveyed as~~ numerical**ly and not as pass or fail results for all quantitative methods.** ~~accuracy percentages, not simply as PASS/FAIL results. Actual PASS/FAIL results must be calculated based on accuracy thresholds generated by reproducibility studies specific to each assay.~~

(15) The agency shall take immediate disciplinary action against any laboratory that falsifies records or does not comply with the provisions of this rule, including sanctions or fines, or both.

(16) A laboratory shall not do any of the following:

(a) Desiccate samples.

(b) Pre-test samples.

**(c) Cherry pick, which means testing specific material from a batch. All sample increments must have the same chances of being selected.**

**(d) Manipulate samples in any way that would decrease or otherwise mask the amount of contaminant in the product.**

(17) A laboratory shall comply with random ~~quality assurance~~ compliance checks ~~upon~~ **at** the request of the agency. The agency or its authorized agents may collect a random sample of a marihuana product from a laboratory or designate another laboratory to collect a random sample of a marihuana product in a secure manner to test that sample for compliance pursuant to these rules.

(18) A laboratory may perform terpene analysis on a marihuana product by a method approved by the agency**, and the method must be accredited on the same frequency as all required safety tests**. There are no established safety standards for this analysis.

(19) A laboratory shall comply with investigations to ensure the health and safety of the public. At the request of the agency, a laboratory may be requested to perform testing as part of an investigation.

(20) ~~Under the medical marihuana facilities licensing act, t~~**T**he 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.

**(21) A laboratory shall have a policy or procedure in place for handling and reporting any potentially hazardous contaminants that may be encountered during routine testing. A laboratory shall notify the agency if a test batch is found to contain levels of a contaminant that could be injurious to human health.**

**(22) Marihuana-infused products found to contain Salmonella spp. or Shiga toxin producing E. coli (STEC) must be reported to the agency immediately.**

**R 420.305a Validations.**

**Rule 5a. (1) All validations must be submitted to the agency for approval with an acceptable proficiency test that meets the standards in R 420.305(14), where all required analytes are shown to have passed.**

**(2) Laboratories shall use microbial testing methodologies for the required safety tests in R 420.305 that are validated by an independent third party and may be monitored on an ongoing basis by the agency. In the absence of published, peer reviewed, validated cannabis methods, Appendix J of Official Methods of Analysis authored by the Association of Official Analytical Collaboration must be published in full with guidance from the cannabis standard method performance requirements where available. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts.**

**(a) All validations must be submitted to the agency for approval with an acceptable and graded external proficiency test by a third party, where all required analytes are shown to have passed.**

**(b) Validation protocols should perform inoculation of marihuana matrices with live organisms where feasible to ensure that both extraction and detection for the assay are tested. To further test the accuracy of the assay, probability of detection (POD) analyses, inclusivity, exclusivity, lot-to-lot stability, and robustness studies must be included in the validation studies.**

**(c) Methods adopted from a matrix specific standard method, inclusivity and exclusivity do not require a comprehensive reassessment, provided that there were no modifications to the methods, including, but not limited to, all of the following:**

**(i) Referenced media.**

**(ii) Primers.**

**(iii) Probes.**

**(iv) Antibodies.**

**(v) Critical chemistries that were not modified.**

**(d) Microbial methods must include environmental monitoring and quality control of all buffers, media, primers, and incubators.**

**R 420.305b Quality assurance and quality control.**

**Rule 5b. (1) A laboratory must have a procedure for monitoring the validity of results.**

**(2) This monitoring must occur on an ongoing basis and be reviewed by the laboratory manager. The monitoring must include all of the following:**

**(a) Use of reference materials or quality control materials.**

**(b) A functional check or checks of measuring and testing equipment.**

**(c) Use of working standards and verification with control charts, where applicable.**

**(d) Intermediate checks on measuring equipment.**

**(e) Review of reported results.**

**(f) Intra-laboratory comparisons, which involve proficiency testing.**

**(3) A laboratory shall adhere to all required quality control procedures specified in the reference method or methods to ensure that routinely generated analytical data is scientifically valid and defensible and is of known and acceptable precision and accuracy.**

**(4) A laboratory shall have a written quality assurance manual that includes, but is not limited to, all of the following items:**

**(a) Laboratory organization and responsibilities.**
**(c) Field sampling procedures.**
**(d) Instrument and equipment preventative maintenance and calibration procedures.**
**(e) Data reduction, validation, reporting, and verification.**
**(f) Identification of laboratory errors, customer complaints, and corrective actions.**
**(5) A laboratory shall prepare a written description of its quality control activities, included as part of a quality control manual. All of the following items must be addressed in the quality control manual:**
**(a) Daily, weekly, monthly, and annual requirements.**
**(b) An analytical testing batch, which is defined as not more than 20 samples.**
**(c) All analytical testing runs must be bracketed with quality controls.**
**(6) Quality control acceptance criteria must be published by the agency and be followed. If the method acceptance criteria are more stringent, then the method acceptance criteria is required.**
**(7) A laboratory shall have standard operating procedures for all sampling and testing performed.**
**(8) All standard operating procedures for the required safety tests in R 420.305 and for sampling and testing of marihuana and marihuana products that conform to ISO/IEC 17025:2017 standards, Good Laboratory Practices, shall be approved by the agency prior to the performance of any safety tests.**
**(9) A laboratory shall maintain a quality control and quality assurance program that conforms to Good Laboratory Practices and ISO/IEC 17025:2017 standards and meets the requirements established by the agency.**

R 420.306 Testing marihuana product after failed initial safety testing and remediation.
Rule 6. (1) A laboratory may test marihuana product that has failed initial safety testing, except as indicated under subrule (3) of this rule.
(2) A failed marihuana product must pass 2 separate tests with new samples consecutively to be eligible to proceed to sale or transfer.
**(3) Products that failed testing for Aspergillus are ineligible for remediation.**
(~~3~~**4**) 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.
(~~4~~**5**) The marihuana business that provided the sample is responsible for all costs involved in a retest.

R 420.307 Research and development testing.
Rule 7. (1) As used in this rule, "research and development testing" means optional testing performed before final compliance testing.
(2) Except for R 420.304(2)(b), when performing research and development testing, the laboratory must comply with these rules.
(3) Punitive action shall not be taken against a marihuana business for conducting research and development testing **when permitted**.
(4) The agency may publish guidance for research and development testing that must be followed by all marihuana businesses.

(5) All research and development testing must be entered into the statewide monitoring system.
**(6) Marihuana that has undergone only research and development testing is not eligible for transfer by a cultivator to a producer under the allowances listed in R 420.303(6).**
~~(7)~~ **(7) Research and development testing is prohibited after compliance testing has been completed.**

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# MICIA COMMENTS ON DRAFT MARIHUANA RULES

(Rule Sets # 2021-29 LR, 2020-117 LR, 2020-118 LR, 2020-119 LR, 2020-120 LR, 2020-121 LR, 2020-122 LR, 2020-123 LR, and 2020-124 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

### I. RULE SET 2021-29 LR (DECLARATORY RULINGS, R. 420.821 ET SEQ.)

Proposed Rules 420.821 through 420.823 create a procedure through which the MRA may issue declaratory rulings as to the applicability to an actual state of facts of a statute, rule, final order, or decision administered, promulgated, or issued by the agency. The MICIA supports the MRA's efforts to promulgate rules outlining the declaratory rulings process and offers the following industry feedback on how those proposed rules may be improved.

*The MRA's Legal Authority for Declaratory Rulings Derives from the APA*

The MRA asserts that its legal authority for this Proposed Rule Set is conferred by "section 5 of the Michigan Medical Marihuana Act, 2008 IL 1, MCL 333.26425, section 206 of the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27206, sections 7 and 8 of the Michigan

Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27957 and 333.27958, and Executive Reorganization Order No. 2019-2, MCL 333.27001)."

None of those statutes expressly confer on the MRA the authority to issue declaratory rulings or issue rules setting the procedure for same. Rather, Section 63 of the Administrative Procedures Act provides the MRA the authority to prescribe the form and procedure for declaratory ruling requests, submissions, consideration, and disposition by administrative rule. MCL 24.263. Specifically, Section 63 states:

> On request of an interested person, an agency may issue a declaratory ruling as to the applicability to an actual state of facts of a statute administered by the agency or of a rule or order of the agency. An agency shall prescribe by rule the form for such a request and procedure for its submission, consideration and disposition. A declaratory ruling is binding on the agency and the person requesting it unless it is altered or set aside by any court. An agency may not retroactively change a declaratory ruling, but nothing in this subsection prevents an agency from prospectively changing a declaratory ruling. A declaratory ruling is subject to judicial review in the same manner as an agency final decision or order in a contested case.

As such, the boilerplate "authority" language at the outset of the Proposed Rule should be amended to reference Section 63 of the APA.

*The MRA's Process Timing is Too Long*

Proposed Rule 420.822 affords the MRA 60 days to issue notification to a party seeking a declaratory ruling as to whether the MRA will issue a declaratory ruling and, if so, another 90 days to issue the ruling "unless the agency notifies the interested person in writing of the need for additional time, and the reasons for the additional time." Consequently, the Proposed Rule would provide the MRA 150 days to issue a declaratory ruling unless the MRA decides to take longer for whatever written reason.

The 150-day window with the potential to be extended further is outside of the standard time frame for a declaratory ruling and inconsistent with best practices. See, e.g., Mich Admin Code, R 324.81(2)(b) (requiring EGLE declaratory ruling to be issue "[w]ithin 60 days of receipt of the request" unless additional information is required); MCL 169.215(2) (requiring SOS to issue a ruling "within 60 business days after a request . . . is received"); Mich Admin Code, R 400.951 (requiring MDHHS ruling "within 60 working days"); Mich Admin Code, R 436.1973(2)(f) (requiring Liquor Control Commission ruling "within 90 days after the receipt of the initial request."). Therefore, the MICIA requests that the MRA consider shortening these timeframes to 45 days and 60 days, respectively, and, rather than grant itself the discretion of unlimited extension, provide that: "A person requesting a declaratory ruling may waive, in writing, the time limitations provided by this section." Timing is often a critical component of regulatory certainty and a more expedited process similar to those employed by other state agencies would better accomplish that objective.

*There is a Lack of Public Transparency and Industry Participation*

The declaratory ruling process outlined by the Proposed Rules lacks transparency and precludes industry participation. For example, Proposed Rule 420.822(5) provides, in part, that:

> Before the issuance of the declaratory ruling, the agency, in its discretion, may choose to do 1 or more of the following: (a) Seek consultation, comments, or advice from legal counsel, experts within or outside the agency, local, state, or federal governmental agencies, or any other source. (b) Request information or clarification from other interested parties. (c) Advise the person requesting the ruling that further clarification of the facts must be provided, or that the agency requires additional time to conduct a review.

But the Proposed Rule neither provides for public notification of a declaratory ruling request nor for participation of interested parties in a declaratory ruling request.

Here, as well, the best practice includes the opportunity for interested persons other than the requestor to participate. See, e.g., MCL 169.215(2) (allowing interested members of the public to comment); Mich Admin Code, R 432.1715(2)(b) (considering "information from other interested persons"). Accordingly, the MICIA asks that the MRA consider amending the Proposed Rule to require the MRA to timely make declaratory ruling requests and decisions open to public view and to further allow for interested persons to submit comments regarding declaratory ruling requests. To accomplish that objective, the MRA could amend the Proposed Rule 420.822(5) to provide that:

> A request for a declaratory ruling that is submitted to the agency will be made available on its website for public inspection within 48 hours after its receipt. An interested person may submit written comments regarding the request to the agency within 10 business days after the date the request is made available to the public. The agency's notification to a party seeking a declaratory ruling as to whether the MRA will issue a declaratory ruling will be made available on its website for public inspection at the time it is issued. If the agency's notification provides that the agency will issue a declaratory ruling, an interested person may submit written comments regarding the subject matter of the declaratory ruling request to the agency within 10 business days after the notification is made available to the public.

The MICIA further asks that the agency amend the Proposed Rule to provide that "The agency will make available to the public an annual summary of the declaratory rulings issued under this rule." This added transparency and participation will aid the MRA in its mission and lead to more well-informed decision-making. An assessible compendium of declaratory rulings will also facilitate the compliance of licensees with applicable laws.

*The Substantive Scope of Review is Too Limited*

Proposed Rule 420.822(9) provides that "[r]equests regarding enforcement issues are not a proper subject for a declaratory ruling." The MICIA asks that the MRA consider deleting or

altering this Proposed Rule for reason that it unnecessarily narrows the scope of subjects on which the agency may provide clarity. By its very nature, as a regulatory agency charged with enforcing the law, a wide swath of the issues that come before the MRA could properly be characterized as "enforcement issues." The intent of an agency declaratory ruling, like a declaratory judgment action within the judiciary, is to provide clarity to affected persons "in order to guide or direct future conduct . . . ." Cf. *UAW v Central Michigan University Trustees*, 295 Mich App 486, 495; 815 NW2d 132 (2012). Nowhere is such guidance more crucial than with respect to controversial matters, where enforcement may become an issue. Further, by limiting the scope of matters that may be addressed by declaratory ruling in this manner, the Proposed rule is far narrower than the controlling statute. MCL 24.263. As an alternative, MRA may consider rewriting Proposed Rule 420.822(9) to clarify only that a matter that has already been referred for enforcement cannot be submitted by that licensee for a declaratory ruling.

*There is Judicial Review of Declaratory Rulings*

Proposed Rule 420.822(8) provides that "[a] denial or adverse decision of a declaratory ruling does not entitle a person to a contested case hearing." This statement may have the inadvertent effect of chilling a licensee's exercise of the right to appeal MRA's decision on a declaratory ruling. For purposes of clarity, the MRA should consider adding additional language acknowledging that, under Section 63 of the Administrative Procedures Act, "[a] declaratory ruling is subject to judicial review in the same manner as an agency final decision or order in a contested case." The MRA should further provide that its decision not to issue a declaratory ruling is subject to judicial review. See *Human Rights Party v. Michigan Corrections Commission*, 76 Mich App 204; 256 NW2d 439 (1977) ("[W]e find that a refusal to issue a declaratory ruling under M.C.L.A. s 24.263 is subject to judicial review as an agency final decision or order in a contested case").

## II. RULE SET 2020-117 LR (DISCIPLINARY PROCEEDINGS, R. 420.801 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.801 through Rule 420.808 to clarify and/or strengthen the MRA's disciplinary processes and notification/reporting requirements. The Proposed Rule Set also seeks to add a new Rule 420.808a which sets forth the grounds on which, and processes by which, the MRA may exclude a person from employment or participation in a marihuana business. The MICIA supports the MRA's efforts to clarify and/or strengthen its disciplinary processes and further agrees with the MRA that clear and transparent disciplinary rules facilitate regulatory compliance and the protection of the public health and safety. The MICIA does, however, highlight that these proposed changes will increase licensee costs and liability but a detailed cost-benefit analysis has not been provided as required by MCL 24.245(3)(h), (3)(k), (3)(l), (3)(n), (3)(p), (3)(q)–(3)(t), & (3)(bb). The MICIA further offers industry feedback on how those Proposed Rules may be improved.

*Grounds for Exclusion of Employment or Participation in a Marihuana Business*

Proposed Rule 420.808a(1)(a)–(1)(f) sets for the grounds on which the MRA may, in its discretion and pursuant to a contested case hearing if requested, exclude a person from employment at, or participation in, a marihuana business. The MICIA generally supports the stated grounds for exclusion with the exception that a previous finding of ineligibility for licensure, as

stated in Rule 420.808a(1)(c), alone is not a proper basis for exclusion of employment where the standard for holding a license is and should be higher than the standard for general employment.

*Contents of Notice of Exclusion*

Proposed Rule 420.808a(2) sets forth the contents of a notice of exclusion filed by the agency including "(a) The identity of the subject. (b) The nature and scope of the circumstances or reasons that the person should be placed on the exclusion list. (c) A recommendation as to whether the exclusion or ejection is permanent." The MICIA supports these general contents for a notice of exclusion but submits that the MRA should also provide to the charged person "a detailed factual statement of the alleged grounds for exclusion accompanied by any supporting documentation or witness statements."

Proposed Rule 420.808a(3) states that "[t]he notice shall also inform the person of the availability of a hearing in compliance with R 420.705." In light of Proposed Rule Set 2020-118 LR, the MICIA queries whether the proper citation here is R. 420.704a which will address the hearing process for notices of exclusion.

*Service of Notice of Exclusion*

Proposed Rule 420.808a(2) provides that the MRA "shall file a notice of exclusion." It is unclear what the term "file" in this context means, and the MICIA submits that the notice of exclusion should be personally served on both the person being excluded and, if applicable, the licensee employing that person.

Proposed Rule 420.808a(6) provides that "[t]he exclusion list must be a public record made available to licensees by the agency and must include information deemed necessary by the agency to facilitate identification of the person placed on the exclusion list." The MICIA submits that the phrase "made available to licensees" lacks detail and that, in light of the resulting disciplinary proceedings that result from employing a person on the exclusion list, the exclusion list should be periodically mailed to licensees, included into the statewide monitoring system, and/or posted on the agency's website. Making this requested change would additionally add clarity to the phrase "knows or reasonably should know is on the exclusion list" in Proposed Rules 420.808a(8),(9).

*Due-Process Concerns Regarding Exclusion List*

Proposed Rule 420.808a(4) states that "[i]f a hearing is not requested, then the subject's name or excluded person's name must remain on the exclusion list." Proposed Rule 420.808a(7) further clarifies the MRA's intention and provides that "[a] person who is placed on the exclusion list or served with a notice of exclusion is prohibited from being employed by or participating in a marihuana business until a determination by the agency or a court to the contrary."

The MICIA acknowledges that there may, at times, exist unique circumstances where a person's continued involvement in a marihuana business presents an immediate threat to the public health and safety and, in those circumstances, immediate placement on the exclusion list may be warranted. However, aside from an immediate threat to public health and safety, the MRA should

provide basic a higher level of due process to the charged person and that person's placement on the exclusion list should occur until after that person has been afforded a hearing pursuant to R. 420.704a.

*Notification and Reporting – Material Changes*

Proposed Rule 420.802(3) requires reporting of proposed material changes to a marihuana business and delineates several examples of what constitute a proposed material change. In an apparent effort to further clarify what constitutes a "proposed material change," the agency now provides that "[a] proposed material change is any action that would result in alterations or changes being made to the marihuana business to effectuate the desired outcome of a material change." The MICIA submits that this clarifying language is unnecessary and overbroad and requests that it be removed or narrowed.

*Notification and Reporting – Third-Party Violations*

Proposed Rule 420.802(4)(c) requires reporting, within 1 business day, of any "[a]ction by another party in actual or alleged violation of the acts or these rules." Proposed Rule 420.801(e) defines "[a]nother party" or "other party" as "an individual or company with which a licensee contracts to use the individual or company's intellectual property or to utilize management or other services provided by the individual or company." The Proposed Rule, which is accompanied by disciplinary action for failure to report, places licensees in an quasi-enforcement role that is unreasonably impracticable and could potentially subject licensees to substantial costs and liability including, but not limited to, third-party litigation for defamation and other claims. The MICIA requests that this aspect of the Proposed Rule be removed or narrowed.

*Notification and Reporting – Licensing and Management Agreements*

Proposed Rule 420.802(7) provides that "[t]he licensee shall notify the agency within 10 business days of terminating a licensing, management, or other agreement." Proposed Rule 420.801(i) defines "[l]icensing agreement" as "any understanding or contract concerning the licensing of intellectual property between a licensee and another party." And, Proposed Rule 420.801(j) defines "[m]anagement or other agreement" as "any understanding or contract between a licensee and another party for the provision of management or other services that would allow the other party to exercise control over or participate in the management of the licensee or to receive more than 10% of the gross or net profit from the licensee during any full or partial calendar or fiscal year."

The MICIA opposes these notification requirements and submits that the agency appears to lack statutory and/or rulemaking authority for this expansion of the notification and reporting requirements, which strictly construed are unreasonably impracticable. The MRA has not articulated a rational basis on which it may justify its exercise of regulatory authority over "licensing agreements" of intellectual property. Moreover, the term "Management or other agreement" is overbroad and cuts against the agency's proposed definition of "employee" which excludes trade or professional services. At a minimum, if the MRA persists with its notification requirements with respect to management agreements, MICIA asks that the agency consider

revising the definition of "management agreement" to mean "any contract between a licensee and another party for the provision of management services that allows the other party to exercise control over or participate in the management of the licensee." Such a definition would more fairly mirror the statutory term "managerial employee" under MCL 333.27102(c).

*Definition of Employee*

Proposed Rule 420.801(h) defines "Employee" as "a person performing work or service for compensation" but "does not include a person providing trade or professional services who is not normally engaged in the operation of a marihuana business." The MICIA supports this common-sense clarification.

## III. RULE SET 2020-118 LR (HEARINGS, R. 420.701 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.701 through Rule 420.706 to clarify and/or strengthen the MRA's hearing processes and to add a new Rule 420.704a which sets forth a hearing process by which a person may challenge the agency's decision to exclude the person from employment or participation in a marihuana business. The MICIA supports, without exception, the MRA's Proposed Rules for hearings.

## IV. RULE SET 2021-10 LR (EMPLOYEES, R. 420.601 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.601 through Rule 420.602 to strengthen the MRA's requirements for, inter alia, employee training manuals and operational plans. The Proposed Rule Set also seeks to add a new Rule 420.602a that, *inter alia*, restricts employees of a cultivator, producer, marihuana sales location, or microbusiness from also being employed by a laboratory or transporter. The MICIA generally supports this Proposed Rules Set and agrees that the changes will facilitate consistency in the hiring and employment practices of marihuana businesses. The MICIA, however, disagrees with the agency's assertion that these changes will not increase compliance costs and submits that the agency's cost-benefit analysis is deficient. See MCL 24.245(3)(h), (3)(k), (3)(l), (3)(n), (3)(p), (3)(q)–(3)(t), & (3)(bb). In particular, MCL 24.245(3)(bb) requires that the MRA identify "the sources the agency relied on in compiling the regulatory impact statement, including the methodology used in determining the existence and extent of the impact of a proposed rule and a cost-benefit analysis of the proposed rule." This has not been done.

## V. RULE SET 2020-119 LR (MARIHUANA-INFUSED PRODUCTS AND EDIBLE MARIHUANA PRODUCTS, R. 420.401 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.401 through Rule 420.403 to continue to refine and make consistent requirements for infused and edible marihuana product to ensure safe handling, production, and labeling. The Rule Set also seeks to update standards referenced for the handling and production of these products. The MICIA's supporting and opposing comments are below.

*Product Labeling Requirements*

Proposed Rule 420.403(2) provides that "[m]arihuana-infused products processed under these rules must be homogenous" and that "[t]he allowable variation for weight and THC and CBD concentrations between the actual results and the intended serving is to be + or – 15%." The MICIA submits that the labeling, homogeneity, and testing variance percentages should be consistent.

Proposed Rule 420.403(7)(a) requires that producers label all marihuana-infused products with not only the name of the product but also that "[t]he name of the product must be an appropriately descriptive phrase that accurately describes the basic nature of the product." The MICIA supports the agency's labeling requirements but takes issue with the language "appropriately descriptive" for reason that it is vague. The MICIA recommends that the sentence read: "[t]he name of the product must accurately describe the basic nature of the product."

Proposed Rule 420.403(7)(b) requires that producers label all marihuana-infused products with not only the ingredients of the product but also the "component ingredients." MICIA highlights that the term "component ingredients" is undefined and finds the term to be somewhat vague in application. The MICIA suggests that the agency consider striking the term and replacing it with the term "excipients."

Proposed Rule 420.403(7)(e) requires that producers label all marihuana-infused products with "[t]he date of the marihuana product was produced." The MICIA supports this common-sense requirement.

Proposed Rule 420.403(9)(b)-(e) clarifies product and labelling requirements to ensure that edible marihuana products are not confused with commercially available food products or attractive to children. The MICIA supports these clarifications but requests that the agency develop additional guidance and/or establish a process for issuing timely labelling approvals.

Proposed Rule 420.403(10)(a) clarifies how producers are to set expiration dates for edible marihuana products and further provides that on the label that the product must be destroyed after the expiration date. The MICIA supports these changes but submits that the term "marihuana product" in this section should read "edible marihuana product."

*Inflexible Product Storage Temperature Mandate*

Proposed Rule 420.403(8)(a) requires that producers of edible marihuana products comply with "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, 21 CFR part 117" but that "[a]ny potentially hazardous ingredients used to process shelf-stable edible marihuana products must be stored at 40 degrees Fahrenheit, 4.4 degrees Celsius, or below."

The MICIA supports application of the federal reference but asserts that the agency's specific storage temperature requirement for hazardous ingredients should be stricken because it is not appropriate in all contexts and not necessarily consistent with the federal reference. See 21 CFR § 117.80(5). Specifically, the specific storage temperature requirement in R. 420.403(8)(a)

requires what is defined in 21 CFR § 117.135 as a "Preventive Control," without offering a licensee the opportunity to conduct a proper Hazard Analysis according to 21 CFR § 117.130 to see if a Preventive Control is warranted. Further, the specific storage temperature requirement in R. 420.403(8)(a) applies this Preventive Control to an undefined sub-category of ingredients ("potentially hazardous ingredients used to process shelf-stable edible marijuana products") without identifying the critical product attribute that is affected by storage temperature.

*Recordkeeping*

Proposed Rule 420.403(8)(b) requires that producers of edible marihuana products keep formulation records which, *inter alia*, include "test results for all ingredients used." The MICIA suggests that because testing is not required for non-active/excipient ingredients, the Proposed Rule is overbroad and should be appropriately narrowed.

## VI. RULE SET 2020-120 LR (LICENSING, R. 420.101 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.101 through Rule 420.11 to prohibit and authorize the purchase of caregiver product depending on licensee type; prohibit certain intra-license product transfers; authorize the provision of marihuana testing for non-licensee adults; and maintain laboratory accreditation exceptions. The Proposed Rule Set also adds a new Rule 420.105a which regulates Class A marihuana microbusiness licenses and a new Rule 420.112a which regulates licensing and management agreements. The MICIA's comments are below.

*Caregiver Product Transfers*

Proposed Rule 420.102(12) provides that "[a] marihuana grower [licensed under MRTMA] may not purchase or accept the transfer of a mature plant from an individual, registered qualifying patient, or registered primary caregiver." Proposed Rule 420.105(8) contains the same prohibition with respect to microbusinesses licensed under MRTMA. Proposed Rule 420.108(10) contains the same prohibition with respect to growers licensed under the MMFLA.

The MICIA does not take a position on whether grower licensees should be permitted to purchase or accept mature plants from registered qualifying patients or caregivers but submits that the various grower license types should be treated uniformly.

*Intra-license Transfers*

Proposed Rules 420.103(3) and 420.104(4), delete language authorizing marihuana processors and retailers, respectively, with two or more licenses at different establishments from transferring inventory between licensed establishments owned by the licensee.

The MICIA opposes this change for reason that such transfers between licensed locations promote flexibility and help prevent product waste. Moreover, these proposed changes will increase licensee costs and a detailed cost benefit analysis has not been provided.

*Class A Microbusinesses*

Proposed Rule 420.105a generally sets forth the rights and obligations of a Class A marihuana microbusiness license including, inter alia, the cultivation of not more than 300 mature plants, packaging of marihuana, purchasing of marihuana concentrate and infused products, sale of marihuana and marihuana products, and the purchase of seeds, tissue cultures, clones or marijuana plants from licensed growers.

The MICIA supports these aspects of the Proposed Rules. However, Proposed Rule 420.105a(8) specifically authorizes such license holders to "purchase or accept a mature plant from an individual, registered qualifying patient, or registered primary caregiver." The MICIA does not take a position on whether grower licensees should be permitted to purchase or accept mature plants from registered qualifying patients or caregivers but submits that the various grower license types should be treated uniformly.

*Adult Marihuana Testing Services*

Proposed Rule 420.107(1)(c) provides that a marihuana safety compliance facility license authorizes the marihuana safety compliance facility to "Receive marihuana from and test marihuana for an individual 21 years of age or older, if the marihuana was produced by the individual and not purchased or obtained from a licensed marihuana business. The marihuana safety compliance facility shall keep documentation for proof of age."

The MICIA asks that the phrase "if the marihuana was produced by the individual and not purchased or obtained from a licensed marihuana business" be stricken. The MICIA's position is that an adult in legal possession of marijuana should not be limited with respect to testing services based upon the legal source of the marijuana. Any adult should have access to product safety testing if they are concerned about the product for any reason, without limitation. When a sample is presented to a lab for testing that was obtained from a licensed business, the chain of custody will be broken on the sample and results cannot be used to represent batch quality. This makes the proposed limiting language unnecessary. Moreover, if a sample is presented to a lab for testing by an adult, the lab has no way of definitively verifying its source, and neither does the MRA. This renders the rule practically unenforceable.

*Laboratory Accreditation Exceptions are no Longer Needed*

Proposed Rule 420.107(2)(c) and 420.112(2) provide that "[a] safety compliance facility must be accredited by an entity approved by the agency by 1 year after the date the license is issued or have previously provided drug testing services to this state or this state's court system and be a vendor in good standing in regard to those services" that "the agency may grant a variance from this requirement upon a finding that the variance is necessary to protect and preserve the public health, safety, or welfare."

The MICIA submits that these provisions should be amended to read only that "[a] marijuana safety compliance facility must be accredited by an entity approved by the agency prior to issuance of a state operating license." Accreditation protects public health and safety and there

is no longer any need for post-licensure accreditation nor the issuance of variances for accreditation. When the MRA was established in 2018, only four labs were operating in the state, and thus good cause existed for these exceptions to accreditation. Now, almost three years later, with fifteen licensed and operating testing laboratories, there is no need for the lower bar. Accreditation ensures that a laboratory has a functional quality system, complete with validated test methods, to ensure the accuracy of published test results.

*Plant Count for MMFLA Grower*

Proposed Rule 420.108(2) provides that "[f]or the purposes of this rule, a marihuana plant that meets the definition of a plant in the MMFLA is included in the plant count in subrule (1) of this rule." The MMFLA, however, defines the term "marihuana plant" and "plant" and it is unclear to which term the agency refers in this language. The MICIA submits that the term "marihuana plant" is the correct term.

*Regulation of Licensing and Management Agreements*

Proposed Rule 420.112a creates a new regulatory regime whereby the MRA seeks to require all "licensing agreements"[1] and "management agreements"[2] of a marihuana licensee to be submitted to the MRA for review and approval prior to performance thereunder and further requires those agreements to specify a litany of detailed contractual terms relating to payment, services, performance, and merger. The Proposed Rule 420.112a(4) further delineates a non-exclusive set of contract terms that would render the non-licensed party subject to the agency's application requirements including: "[a]ny term or condition that would allow the other party to receive more than 10% of the gross or net profit from the licensee during any full or partial calendar or fiscal year" and "[a]ny term or condition that would require the licensee to name the other party as a named insured on any insurance policy required to be maintained as a condition of a marihuana license."

The MICIA opposes these new filing and approval requirements and submits that the agency appears to lack statutory and/or rulemaking authority for this expansion of government regulation, which strictly construed is unreasonably impracticable, and which may retroactively impair contracts. These proposed changes will also increase licensee costs and a detailed cost benefit analysis has not been provided. The MRA has not articulated a rational basis on which it

[1] Proposed Rule 420.101(l) defines "licensing agreement" as "any understanding or contract concerning the licensing of intellectual property between a licensee and another party." Proposed Rule 420.101(k) defines "intellectual property" as "all original data, findings, or other products of the mind or intellect commonly associated with claims, interests, and rights that are protected under trade secret, patent, trademark, copyright, or unfair competition law and includes brands or recipes."

[2] Proposed Rule 420.101(m) defines "management or other agreement" as "any understanding or contract between a licensee and another party for the provision of management or other services that would allow the other party to exercise control over or participate in the management of the licensee or to receive more than 10% of the gross or net profit from the licensee during any full or partial calendar or fiscal year."

may justify its exercise of regulatory authority over "licensing agreements" of intellectual property. Moreover, the term "Management or other agreement" is overbroad and cuts against the agency's proposed definition of "employee" which excludes trade or professional services. At a minimum, if the MRA persists with its filing and approval requirements with respect to management agreements, MICIA asks that the agency consider revising the definition of "management agreement" to mean "any contract between a licensee and another party for the provision of management services that allows the other party to exercise control over or participate in the management of the licensee." Such a definition, albeit broader than the statute, would more fairly mirror the statutory term "managerial employee" under MCL 333.27102(c).

## VII. RULE SET 2020-121 LR (LICENSING, R. 420.1 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.1 through Rule 420.27 to, *inter alia*, provide for administrative withdrawals of license applications; expand applicant disclosure requirements; disclaim vested rights in licenses; lower and streamline renewal application fees; and continue to utilize moral character in licensure determination. The Proposed Rule Set also adds a new Rule 420.27a also creates a new class of regulated marihuana educational research licenses. The MICIA's comments are below.

*Administrative Application Withdrawal*

Proposed Rules 420.3(3) and (6) authorize the MRA to withdraw applications for prequalification and licensure and force applicants to reapply in instances where an application has been pending for over one year. Proposed Rule 420.3(7) further provides that "[t]he agency may administratively withdraw an amendment to any application or marihuana license if the applicant or licensee fails to respond or submit documentation to cure all deficiencies within 30 days after notice of the deficiency."

The MICIA opposes these changes for reason that they are patently unfair. Applicants should not be forced to reapply and/or pay additional licensure fees where, through no fault of their own, the MRA has failed to adjudicate a license application in under one year. Moreover, 60 days would be a more reasonable timeframe in which applicants may cure deficiencies.

*Expanded Application Disclosure Requirements*

Proposed Rule 420.4(3) deletes language providing that "[e]ach applicant shall disclose all shareholders holding a direct or indirect interest of greater than 5%, officers, and directors in the proposed marihuana establishment" and adds language providing that "[e]ach applicant shall disclose the identity of every person having a 2.5% or greater ownership interest in the applicant with respect to which the license is sought. (a) If the disclosed entity is a trust, the applicant shall disclose the names and addresses of the beneficiaries. (b) If the disclosed entity is a privately held corporation, the names and addresses of all shareholders, officers, and directors. (c) If the disclosed entity is a publicly held corporation, the names and addresses of all shareholders holding a direct or indirect interest of greater than 5%, officers, and directors. (d) If the disclosed entity is a partnership or limited liability partnership, the names and addresses of all partners. (e) If the disclosed entity is a limited partnership or limited liability limited partnership, the names of all

partners, both general and limited. (f) If the disclosed entity is a limited liability company, the names and addresses of all members and managers."

The MICIA opposes this more stringent disclosure requirement for a de minimis ownership interest. It is unnecessary, will jeopardize licensee funding, is unreasonably impracticable, and may retroactively impair contracts. The MICIA further submits that the agency appears to lack statutory and/or rulemaking authority for this expansion of the disclosure requirement beyond the bounds of MCL 333.27102. These proposed changes will also increase licensee costs and a detailed cost benefit analysis has not been provided. The MRA has also failed to articulate a rational basis on which it may justify its increased disclosure requirements.

*Vested Rights in Marihuana License*

Proposed Rule 420.6(6) asserts that "[a] marihuana license is a revocable privilege granted by the agency and is not a property right" and that "[g]ranting a marihuana license does not create or vest any right, title, franchise, or other property interest."

The MICIA acknowledges that this language tracks and then expands on the language provided that MCL 333.27409. Nonetheless, the MICIA opposes this language for the reason that it may be legally incorrect where a license has been issued, substantial investments made, and state law only authorizes license revocation for cause. Regardless of whether the MRA's assertions are legally accurate, it is patently unfair to deny the existence of a property right where substantial investments are made based on licensure and such licenses may only be revoked for good causes and pursuant to due process.

*Application Fees*

Proposed Rule 420.7 lowers initial licensure and renewal fees and abandons the process of calculating renewal fees based on gross weight transferred for growers, gross retail sales for retailers and microbusinesses, net weight transported for transporters, and number of tests completed for laboratories. The MICIA supports these common-sense changes.

*Moral Character*

Proposed Rule 420.13(1)(a) retains language for requiring license renewals under the MMFLA to include "information regarding the identification, integrity, moral character, reputation, relevant business experience, ability, probity, financial experience, and responsibility of the licensee and each person required to be qualified for renewal of the license under the MMFLA." The MICIA opposes the inclusion of such subjective attributes of the licensee such as moral character and further notes Senate Bill 619, if enacted, would remove language allowing the MRA to deny a license to any applicant on account of their "moral character" or if they have any previous marijuana-related offenses. License denials based on hyper-subjective criteria create the appearance of arbitrary application.

*Marihuana Educational Research License*

Proposed Rule 420.21(1)(e) adds marihuana educational research licenses to the list of special licenses which may be issued by the agency. And, Proposed Rule 420.27a sets forth the rights and obligations of a person holding a marihuana educational research license. The MICIA supports these changes.

*Excess Grower License Fees*

Proposed Rule 420.23(11) provides that "[a]n applicant for an excess grower license is not required to pay the application fee under these rules."

The MICIA highlights that this provision benefits the largest growers and that many of the growers who are not capable of achieving this license type view this fee waiver as inequitable. The MICIA submits that the various grower license types should be treated uniformly.

## VIII. RULE SET 2020-123 LR (MARIHUANA SALE OR TRANSFER, R. 420.501 ET SEQ)

This Proposed Rule Set seeks to amend portions of Rule 420.501 through Rule 420.510 to, *inter alia*, address the transfer and/or destruction of expired products; product warning labels and advisory pamphlet distribution; and employee limits for internal and trade samples. The Proposed Rule Set also adds a new Rule 420.503a authorizing the transfer of immature plant batches without utilization of a transporter. The MICIA's comments are below.

*Definition of Final Form*

Proposed Rule 420.501(g) defines "final form" as "the form a marihuana product is in when it is available for sale by a marihuana sales location. For marihuana products intended for inhalation, final form means the marihuana concentrate in an e-cigarette or a vaping device."

The MICIA requests that the agency clarify that prerolls, deli-style bulk flower packaged by a retailer, and batches of edibles divided into multiple packages, are not required to undergo an additional level of testing. See also Proposed Rule 420.504(1)(i).

*Destruction of Expired Products*

Proposed Rule 420.502(4) provides that "[a] marihuana business shall not sell or a [SIC] transfer marihuana product after the printed expiration date on the package. An expired marihuana product must be destroyed." Proposed Rule 420.502(6) provides that "[a] marihuana business shall destroy all product required to be destroyed for any reason within 90 calendar days of when the marihuana business became aware of the fact that the product must be destroyed."

The MICIA supports these proposed changes for public safety purposes and requests that the agency clarify that expired product may be transferred from a retailer to a processor for destruction. The MICIA also identifies that this requirement will increase costs and submits that the agency's cost-benefit analysis is deficient.

*Transfer of Immature Plant Batches*

Proposed Rule 420.503a authorizes approved cultivators to sell or transfer immature plant batches to a marihuana sales location without using a marihuana transporter and without conducting testing. The MICIA supports these common-sense regulations.

*Labeling Warnings*

Proposed Rule 420.504(1)(v) creates the following labelling requirement: "In clearly legible type and surrounded by a continuous heavy line: "WARNING: USE BY PREGNANT OR BREASTFEEDING WOMEN, OR BY WOMEN PLANNING TO BECOME PREGNANT, MAY RESULT IN FETAL INJURY, PRETERM BIRTH, LOW BIRTH WEIGHT, OR DEVELOPMENTAL PROBLEMS FOR THE CHILD."

The MICIA supports this labelling requirement which is expressly required by MCL 333.27206. The MICIA nevertheless asserts that this requirement will substantially increase labeling costs and submits that the agency's cost-benefit analysis is incorrect in asserting otherwise.

*Advisory Pamphlet*

Proposed Rule 420.504(4) creates the following requirement: "Before a marihuana product is sold or transferred by a marihuana sales location, the sales location shall make available to each customer a pamphlet measuring at least 3.5 inches by 5 inches, that includes safety information related to marihuana use by minors and the poison control hotline number. The pamphlet must substantially conform to the design published on the agency's website."

The MICIA supports this advisory requirement which is expressly required by MCL 333.27206. The MICIA nevertheless asserts that this requirement will substantially increase labeling costs and submits that the agency's cost-benefit analysis is incorrect in asserting otherwise.

*Employee Transfer Limits for Internal and Trade Samples*

Proposed Rule 420.508(8) provides that "[a] producer or marihuana sales location is limited to transferring a total of 1 ounce of marihuana, a total of 2 grams of marihuana concentrate, and marihuana infused products with a total THC content of 2000 mgs of internal product samples to each of its employees in a 30-day period." Similarly, Proposed Rules 420.509(6) provides that "[a] marihuana sales location, marihuana microbusiness, and class A marihuana microbusiness are limited to transferring a total of 1 ounce of marihuana, a total of 2 grams of marihuana concentrate, and marihuana infused products with a total THC content of 2000 mgs of internal product samples to each of its employees in a 30-day period."

The MICIA supports these additional clarifications regarding internal and trade sample transfers.

## IX. RULE SET 2020-122 LR (OPERATIONS, R. 420.201 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.201 through Rule 420.214 to, *inter alia*, require maintenance of certain financial records and provide for the regulation of natural and synthetic cannabinoid sourcing. The Proposed Rule Set also adds new Rules 420.206a (standard operating plan), 420.207a (contactless tracing), 420.214a (internal analytical testing), 420.214b (adverse reactions), and 420.214c (product returns). The MICIA's comments are below.

*Financial Records*

Proposed Rule 420.204(2) adds new language stating the following: "(i) A licensee shall maintain accurate and comprehensive financial records for each license that clearly documents the licensee's income and expenses. Applicable supporting source documentation must be maintained, including, but not limited to, all of the following: (A) Cash logs. (B) Sales records. (C) Purchase of inventory. (D) Invoices. (E) Receipts. (F) Deposit slips. (G) Cancelled checks. (H) Employee compensation records. (I) Tax records. (ii) Bulk financial deposits or transactions must be traceable to the individual transactions that comprise the bulk deposit or transaction."

These new more granular financial recordkeeping requirements will increase costs and the MRA has failed to engage in any cost-benefit analysis related to the impact of these requirement on the industry. MCL 24.245(3).

*Cannabinoid Sourcing and Synthetically-Derived Cannabinoids*

Proposed Rule 420.206(13) adds new language providing that "[a]ll ingredients containing cannabinoids, whether naturally occurring or synthetically derived, that are added to marihuana or marihuana products must be from a source licensed to grow, handle, and produce cannabinoids under a license issued by a governmental authority and entered into the statewide monitoring system."

The MICIA submits that the use of the term "cannabinoids" in the Proposed Rule may be overbroad and may encompass any and all industrial hemp products. MCL 333.7106(2); MCL 286.842(i). The MICIA requests that the MRA add language providing that "a source authorized to grow, handle, and produce cannabinoids pursuant to an Industrial Hemp Pilot Program created by state statute or regulation" is also acceptable. The MICIA further cautions against the blanket authorization of synthetic cannabinoids and synthetic processing where certain synthetic cannabinoids such as "K2" and "Spice" are extremely dangerous to public health and safety and synthetic production involves a substantial risk of product adulteration by toxic reagents and/or byproducts. The MICIA believes that this rule should be revised to explicitly ban all fully or semi-synthetic cannabinoids from the Michigan marijuana industry, except those produced incidentally by otherwise non-synthetic processing steps that have been approved by the agency.

*Testing for Product Combination*

Proposed Rule 420.206(14) adds new language providing that "[w]hen combining more than 1 form of marihuana or marihuana product into a single marihuana product, each form of

marihuana or marihuana product must have passing safety compliance test results in the statewide monitoring system prior to the creation of the new combined product."

The MICIA flatly opposes this new and non-sensical requirement as both ultra vires and unreasonably impractical. There is no added health or safety benefit gained by testing the same product three different times; only three separate testing fees and three separate samples being destroyed from each batch. These new testing requirements will substantially increase costs and the MRA has failed to engage in any cost-benefit analysis related to the impact of these requirement on the industry. MCL 24.245(3).

*Standard Operating Plan*

Proposed Rule 420.206a adds new language providing that "[a] marihuana business must have up-to-date written standard operating procedures on site at all times . . . [which] must detail the marihuana business operations and activities necessary for the marihuana business to comply with the acts and these rules [and] . . . comply with any guidance issued by the agency."

While not opposed to standard operating plans, which are beneficial to licensees, the MICIA opposes government mandates (and associated regulatory enforcement) of such a broad requirement for licensees to have "up-to-date" and "written" procedures that "detail" compliance with every single present or future statutory, regulatory, or even informal guidance requirement of the MRA. That a mandatory SOP detail compliance with informal guidance is plainly at odds with the APA and this Proposed Rule, as written, is unreasonably impractical. Moreover, this new requirement will substantially and continually increase costs and the MRA has failed to engage in any cost-benefit analysis related to the impact of these requirement on the industry. MCL 24.245(3); MCL 243.203(7) (defining a "guideline" as "an agency statement or declaration of policy that the agency intends to follow, that does not have the force or effect of law, and that binds the agency but does not bind any other person").

*Contactless and Limited Contact Transactions*

Proposed Rule 420.207a adds new language authorizing and regulating the process for contactless and limited contact transactions (including online orders) "unless prohibited by an ordinance adopted by the municipality where the marihuana sales location is located." Such transactions are authorized during normal business hours provided that "the designated area for contactless or limited contact transactions [is] identified in the marihuana business location plan," the "marihuana sales location [has] a written standard operating procedure in place," the "marihuana sales location using a designated area for contactless or limited contact transactions [has] in place an anti-theft policy, procedure, or automatic capability," the "designated area for contactless or limited contact transactions [complies] with R 420.209," the "contactless and limited contact transaction [complies] with R 420.505 and R 420.506," and the "[m]arihuana being transferred during a contactless or limited contact transaction [is] in an opaque bag and the contents [are] not be visible to the general public upon pick up."

The MICIA supports this very necessary Proposed Rule with the exception that any municipal prohibition on contactless transactions should be both direct and specific. As such, the

phrase should read "unless DIRECTLY AND SPECIFICALLY prohibited by an ordinance adopted by the municipality where the marihuana sales location is located."

*Storage of Marihuana Product*

Proposed Rule 420.212(3) requires all chemicals or solved to be "stored separately from marihuana products and kept with a closed lid in locked storage areas."

The MICIA suggests that the phrase "with a closed lid" be replaced with the phrase "in a closed container" for reason that not all chemicals and solvents are packaged in a container with a lid.

*Internal Analytical Testing*

Proposed Rule 420.214a adds new language authorizing and regulating the process for internal analytical testing. The MICIA generally supports this Proposed Rule with the following exceptions:

The MICIA asks for clarification and examples of the meaning of the phrase "fully partitioned" as used in Proposed Rule 420.214a(1)(a) (i.e., whether a partition includes walls, dividers, curtains, etc).

The MICIA requests that the MRA strike the requirement in Proposed Rule 420.214a(1)(c) that the product of only one license may be in co-located internal analytical testing spaces at a time. The MICIA fails to see the necessity of this requirement where such products are required to be disposed of, the products cannot return to the licensee, and the results from the testing cannot be used to release the products to the public.

The MICIA seeks clarification regarding the prohibition in Proposed Rule 420.214a(4) that "[n]o marihuana or marihuana product may be stored in the internal analytical testing space." The MICIA submits that the samples of products being internally tested should be permitted to be stored in the space.

The MICIA opposes the requirement in Proposed Rule 420.214a(8) that "[a]ny batch of marihuana or a marihuana product that has undergone internal analytical testing must undergo full safety compliance testing, with failing test results entered into the statewide monitoring system, prior to making a request for remediation." This requirement seems to impose a requirement of outside finished testing prior to remediation and thus limits the ability of licensees to proactively remediate products. Such a requirement would mark a significant departure from current practice.

*Adverse Reactions*

Proposed Rule 420.214b adds new language requiring that "[a] licensee shall notify the agency within 1 business day of becoming aware or within 1 business day of when the licensee should have been aware of any adverse reactions to a marihuana product sold or transferred by any

licensee" and that "[a] licensee shall enter into the statewide monitoring system within 1 business day of becoming aware of or within 1 business day of when the licensee should have been aware of any adverse reactions to a marihuana product sold or transferred by any licensee."

The MICIA asks that the MRA define what constitutes an "adverse reaction" and clarify whether the phrases "becoming aware" or "should have been aware" encompass only actual adverse reactions or also customer alleged or perceived adverse reactions. The MICIA further requests that the agency issue a form or more detailed guidance as to how to submit such information and identifies that, at present, there is not a method for licensees to upload this information into METRC.

*Product Returns*

Proposed Rule 420.214c(1) adds new language applicable to marihuana sales locations that authorizes "the return of marihuana product that is reported to have caused an adverse reaction or is determined to be defective." Proposed Rule 420.214c(2) further requires that "[a] marihuana sales location must have a written policy for the return of marihuana product that contains, at a minimum, the following: (a) Product returned to a marihuana sales location must be tracked consistently in the statewide monitoring system as waste in compliance with R 420.211. (b) Product returned to a marihuana sales location must be destroyed in compliance with R 420.211 within 90 calendar days of when the marihuana business became aware of the fact that the product must be destroyed. (c) Product returned to a marihuana sales location cannot be re-sold, re-packaged, or otherwise transferred to a customer or another marihuana business. (d) Product returned to a marihuana sales location shall be returned by the customer who purchased the product. (e) Product returned to a marihuana sales location is prohibited from being returned to the marihuana sales location by way of a delivery driver. (f) A marihuana sales location that does not comply with these rules may be subject to disciplinary proceedings. (g) A marihuana retailer may return a marihuana product that is past its expiration date to the marihuana processor who produced the marihuana product for destruction instead of destroying the marihuana product."

The MICIA requests that the agency issue a form or more detailed guidance as to how to submit such information and identifies that, at present, there is not a method for licensees to upload this information into METRC. The MICIA further submits that the phrase "reported to have caused an adverse reaction or is determined to be defective," is vague and potentially overbroad. The agency has neither defined the terms "adverse reaction" nor "defective" and the phrase "reported to have caused," read literally, could mean "alleged by anyone no matter how far removed." Furthermore, the MICIA asks that the agency reconsider the prohibition in Proposed Rule 420.214c(2)(d) that "[p]roduct returned to a marihuana sales location shall be returned by the customer who purchased the product." This requirement may be extraordinarily difficult to enforce and, as set out in the proposed rule, appears to potentially suggest that a marihuana sales location may be subject to disciplinary proceedings as a result of third-party conduct completely outside the location's control.

## X. RULE SET 2020-124 LR (SAMPLING AND TESTING R. 420.301 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.301 through Rule 420.307 to, *inter alia*, set maximum batch sizes, revise laboratory accreditation requirements and testing

methodologies, require safety tests on harvest batches, redefine potency analyses, and mandate laboratory policies for potentially hazardous contaminants. The Proposed Rule Set also adds a new Rule 420.303a, establishing producer and sales location packaging and testing requirements, and Rule 420.305a, establishing certain validation requirements. The MICIA's comments are below.

*Batch Identification and Testing*

Proposed Rule 420.303(4) provides that "[a] cultivator shall immediately destroy the individual plant tag once a tagged plant is harvested and is part of a harvest batch so that a sample of the harvest batch can be tested by a licensed laboratory as provided in R 420.304 and R 420.305."

The MICIA requests that the agency clarify that the individual plant tags (which are used to identify the plants during the drying stage) do not need to be destroyed until after the drying stage is complete.

Proposed Rule 420.303(6) provides that "[a] cultivator may transfer or sell fresh frozen marihuana to a producer without first being tested by a laboratory in order to produce live resin, or if the marihuana product will be extracted, with agency approval."

The MICIA requests that the agency revise the Proposed Rule so that "fresh frozen" includes "any dried biomass" and to replace the term "live resin" with the term "concentrate."

*Producer and Sales Location Packaging and Testing Requirements*

Proposed Rule 420.303a(1) and (2) clarifies that "[a] producer shall give a marihuana product a new package tag anytime the marihuana product changes form or is incorporated into a different product," "[a] producer of a marihuana product in its final form shall have the sample tested pursuant to R 420.304 and R 420.305," "[t]he producer shall quarantine products from all other products when the product has test results pending," "[t]he producer shall not transfer or sell a marihuana product to a marihuana sales location until after test results entered into the statewide monitoring system indicate a passed result for all required safety tests," and that "[n]othing in this subsection prohibits a producer from transferring or selling a package in accordance with the remediation protocol provided by the agency and these rules." Proposed Rule 420.303a(3) further clarifies that "[a] marihuana sales location may sell or transfer a marihuana product only to a marihuana customer under both of the following conditions: (a) The marihuana product has received passing results for all required safety tests in the statewide monitoring system. (b) The marihuana product bears the label required under the acts and these rules for retail sale."

The MICIA supports these proposed clarifications.

*Sample Collection*

Proposed Rule 420.304(2)(a) provides that "[t]he laboratory shall physically collect the sample the marijuana product from another business to be tested at the laboratory."

MICIA's only comment is that it appears a typographic error exists; the sentence should read: "The laboratory shall physically collect the marijuana product sample from another business to be tested at the laboratory."

*Maximum Batch Size*

Proposed Rule 420.304(2)(d) further provides that "[t]he laboratory shall develop a statistically valid sampling method and have it approved by the agency to collect a representative sample from each batch of marihuana product. The laboratory shall have access to the entire batch for the purposes of sampling."

The MICIA submits that "statistically valid sampling method" is too vague and that additional guidance should be provided in the proposed rule.

*Laboratory Accreditation Requirements*

Proposed Rule 420.305(1) provides that "A laboratory shall become fully accredited for all required safety tests in at least 1 required matrix to the International Organization for Standardization (ISO), ISO/IEC 17025:2017, by an International Laboratory Accreditation Corporation (ILAC) recognized accreditation body or by an entity approved by the agency within 1 year after the date the laboratory license is issued and agree to have the inspections, reports, and all scope documents sent directly to the agency from the accreditation body."

The MICIA submits that these provisions should be amended to read only that:

> A laboratory shall become fully accredited for all required safety tests in all required matrices to the International Organization for Standardization (ISO), ISO/IEC 17025:2017, by an International Laboratory Accreditation Corporation (ILAC) recognized accreditation body or by an entity approved by the agency prior to and as a condition of license issuance and agree to have the inspections, reports, and all scope documents sent directly to the agency from the accreditation body.

Accreditation protects public health and safety and there is no longer any need for post-licensure accreditation nor the issuance of variances for accreditation. When the MRA was established in 2018, only four labs were operating in the state, and thus good cause existed for these exceptions to accreditation. Now, almost three years later, with fifteen licensed and operating testing laboratories, there is no need for the lower bar. Accreditation ensures that a laboratory has a functional quality system, complete with validated test methods, to ensure the accuracy of published test results.

*Laboratory Testing Methodologies*

Proposed Rule 420.305(2) provides, in part, that "[a] laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency. In the absence of published, peer reviewed, validated cannabis methods, Appendix J or K of Official Methods of

Analysis authored by the Association of Official Analytical Collaboration (AOAC) International must be published in full with guidance from published cannabis standard method performance requirements where available."

The MICIA submits that the proposed language does not clearly reflect the intent of the Rule nor the way in which the Rule has been enforced to date. In its place, the MICIA asks the MRA to consider the following language:

> A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are based upon published peer-reviewed methods, have been validated for cannabis testing by an independent third party, may be monitored on an ongoing basis by the agency, and have been internally verified by the licensed laboratory according to Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Collaboration (AOAC) International, with guidance from published cannabis standard method performance requirements where available. In the absence of published, peer-reviewed, validated cannabis methods, method validation requirements of Appendix K of Official Methods of Analysis must be met in full with guidance from published cannabis standard method performance requirements where available.

*Safety Tests on Harvest Batches*

Proposed Rule 420.305(3) provides, in part, that "[a] laboratory shall conduct the required safety tests specified in subdivisions (a) through (i) of this subrule on marijuana product that is part of a harvest batch as specified in R420.303, except as provided in subrule (4) of this rule. The agency may publish minimum testing portions to be used in compliance testing."

The MICIA reads this language as limiting safety testing to marijuana product that is part of a harvest batch (which is only plant material by definition) and thus as excluding testing requirements for marijuana products that are not part of a harvest batch such as concentrates and infused products. The agency should clarify its intention in that regard. The MICIA supports the agency publishing minimum testing portions to be used in compliance testing.

*Potency Analysis*

Proposed Rule 420.305(3)(a)(i) states that "[i]n the preparation of samples intended for potency analysis, the laboratory may not adulterate or attempt to manipulate the total potency of the sample by adding trichomes that were removed during the grinding and homogenization process."

The MICIA opposes this prohibition for reason that it leads to results that are not representative. Simply because a testing lab "damages" or knocks portions off of a licensee's product, does not mean that those portions should not be included in the potency test.

Proposed Rule 420.305(3)(a)(ii) states, in part, that "Kief must not be reintroduced to the flower sample during the homogenization process."

The MICIA opposes this prohibition for reason that it leads to results that are not representative. Kief created during the grinding process is customarily kept and reintroduced by the average consumer.

Proposed Rule 420.305(3)(a)(iii) defines the list of legally required cannabinoids for potency testing as: "(A) Total Tetrahydrocannabinol (THC); (B) Tetrahydrocannabinol Acid (THC-A); (C) Total Cannabidiol (CBD); (D) Cannabidiol Acid (CBDA); [and] (E) Additional cannabinoids may be tested with approval from the agency."

The MICIA reads the rule as only requiring potency test results for the four cannabinoids in items (A) through (D) of the subrule. Consequently, the subrule does not authorize potency testing of d9-THC or Cannabidiol. By default, these two important compounds fall into optional analyte category (E). Omitting mandatory reporting of d9-THC and Cannabidiol test results is not recommended. The MICIA also submits that the correct term for "Tetrahydrocannabinol Acid" is "Tetrahydrocannabinoic Acid" and the correct term for "Cannabidiol Acid" is "Cannabidiolic Acid."

Proposed Rule 420.305(9) further defines the list of legally required cannabinoids for potency testing and provides that "[p]otency shall include the following cannabinoid concentrations listed in subdivisions (a) to (f) of this subrule, subject to subdivisions (g) and (h) of this subrule:

> (a) Total THC concentration;
> (b) THC-A concentration;
> (c) Total THC, which includes Delta 7, Delta 8, Delta 9, Delta 10, and Delta 11 THC and THC-A. The following calculation must be used for calculating Total THC, where M is the mass or mass fraction of delta-9 THC or delta-9 THC-A: Σ Delta 7-11 THC + Σ ((Delta 7-11 THCA) x 0.877)=Total THC;
> (d) Total CBD concentration;
> (e) CBD-A concentration;
> (f) Total CBD. The following calculation must be used for calculating Total CBD, where M is the mass or mass fraction of CBD and CBD-A: M total CBD = M CBD + 0.877 x M CBD-A;
> (g) For marihuana and marihuana concentrates, total THC and total CBD must be reported in percentages; [and]
> (h) For marihuana infused products, potency must be reported as milligrams of Delta-9-THC and CBD."

The MICIA reads the proposed rule as only requiring reporting of test results for items (a) through (f) of the subrule. As such, this list no longer mandates individually reporting of d9-THC or Cannabidiol test results. By default, these important compounds fall into optional analyte category (E). Omitting mandatory reporting of d9-THC and Cannabidiol test results is not recommended. The MICIA also submits that Rules 420.305(9)(a) and (c) are redundant. The

agency should change "Total THC concentration" in Rule 420.305(9)(a) to "delta-9 THC Concentration."

Furthermore, the definition in Rule 420.305(9)(c) of compounds that comprise "Total THC" is problematic such that reporting of Total THC results, as defined, cannot be met at this time where (i) certified analytical reference standards for Delta7-THC (a fully synthetic and non-psychoactive cannabinoid) may not be fully and commercially available at this time; (ii) certified reference standards for Delta 10-THC (a fully synthetic cannabinoid) are available for two separate enantiomers: Delta 10 (6aR, 9S), which is not psychoactive, and Delta 10 (6aR, 9R), which is psychoactive;[3] (iii) although there are various forms of nomenclature, the term "Delta 11 THC" is not a consistently recognized term in current scientific literature;[4] and (iv) the calculation provided for determining Total THC includes summing the concentrations of "Delta 7-11 THCA."[5] Consequently, MICIA recommends that the potency testing requirements be revised to allow the MRA to publish a list of cannabinoids for mandatory testing and reporting and to update the list as needed via bulletins separately from the Rules. It is important to address the emergence of additional THC isomers (like delta-8 THC) without prematurely and unnecessarily complicating the Proposed Rule.

*Residual Solvent Testing as Part of Harvest Batch*

Proposed Rule 420.305(3)(f) includes "Residual Solvents" as a required safety test for a marijuana product that is part of a harvest batch. Because residual solvent testing has not been required for plant material to date, the MICIA suggests that this subrule be deleted, especially where subrule 420.305(7) properly addresses residual solvent testing.

*Reporting Units for CBD*

Proposed Rule 420.305(9)(h) states that "[f]or marijuana infused products, potency must be reported in milligrams of Delta-9 THC and CBD."

The MICIA suggests that this language does not adequately define reporting units for CBD. While the definition provides a magnitude (milligrams), it does not specify the quantity. That is, the language does not specify whether the quantity be a milliliter of analytical solution, gram of product, serving, etc. By requiring reporting of individual test results for Delta 9-THC and CBD for infused products, the subrule also seems to conflict with Proposed Rules 420.305(3)(a)(iii) and 420.305(9) which provide that these analytes are defined as optional.

[3] The Proposed Rule should clarify whether both enantiomers or, if only one, which enantiomer must be quantified.

[4] Provided that the term "Delta 11 THC" intends to describe THC with a double bond between carbon atoms 9 and 11, the MICIA would prefer the nomenclature "exo-THC," as certified reference standards are available for "exo-THC."

[5] This requires a laboratory to individually quantify delta 7, delta 8, delta 10, and delta 11 THC acids. Certified reference standards for these cannabinoic acids do not currently exist in the literature, and the delta-9 THC acid isomers themselves may not be known compounds at all at this time.

*Terpene Analysis*

Proposed Rule 420.305(18) states that "[a] laboratory may perform terpene analysis on a marijuana product by a method approved by the agency, and the method must be accredited on the same frequency as all required safety tests. There are no established safety standards for this analysis."

The MICIA recommends that the phrase "[t]here are no established safety standards for this analysis" be omitted, because safety tests for beverages include a requirement to test for phytol.

*Laboratory Policy for Potentially Hazardous Contaminants*

Proposed Rule 420.305(21) states that "[a] laboratory shall have a policy or procedure in place for handling and reporting any potentially hazardous contaminants that may be encountered during routine testing. A laboratory shall notify the agency if a test batch is found to contain levels of a contaminant that could be injurious to human health."

The MICIA suggests that this requirement is vague and overbroad and should not be included in the Proposed Rules without further clarification. Licensed laboratories are not equipped or otherwise required to identify unknown compounds of any type in product samples. In addition, under the right conditions and without further clarification, just about any compound fits the terms "potentially hazardous" and "potentially injurious to human health."

*STEC Reporting Deadline*

Proposed Rule 420.305(22) states that "[m]arihuana-infused products found to contain Salmonella spp. or Shiga toxin producing E. coli (STEC) must be reported to the agency immediately."

The MICIA submits that it is unclear how immediate reporting for STEC required under this Proposed Rule fits with Rules 420.305(12) and (13) which requires reporting within three business days. The MRA should consider omitting or clarifying this Proposed Rule. If the MRA chooses to clarify this Proposed Rule, the MICIA suggests that the term "immediately" should be replaced with the phrase "within one business day."

*Validation Protocols*

Proposed Rule 420.305a sets forth a litany of new validation protocols and requirements. The MICIA submits that these new requirements will increase laboratory costs and that the MRA has failed to engage in any cost-benefit analysis related to the impact of these requirement on the industry. MCL 24.245(3).

Proposed Rule 420.305a(2)(b) provides that "[v]alidation protocols should perform inoculation of marihuana matrices with live organisms where feasible to ensure that both extraction and detection for the assay are tested. To further test the accuracy of the assay, probability of

detection (POD) analyses, inclusivity, exclusivity, lot-to-lot stability, and robustness studies must be included in the validation studies."

The MICIA submits that "lot-to-lot stability" testing is not appropriate as a test method validation requirement and should be removed from this sub-rule. "Lot-to-lot stability" is a process validation, typically included in validation of a manufacturing process, and is not appropriately employed as an element of analytical method validation.

*Quality Assurance and Control*

Proposed Rule 420.305b creates a quality assurance and quality control monitoring regime and requires that laboratories adopt and follow detailed written quality assurance measures and standard operating procedures approved by the agency.

The MICIA is concerned that the quality control acceptance criteria currently published by the agency exceed the capabilities of established, industry-accepted test methods, and are more stringent than criteria assigned to those methods by the method authors / innovators. MICIA submits that while published MRA guidance is essential and appropriate, where available, method author / innovator quality control acceptance criteria should prevail. The MICIA further submits that these new requirements are likely to substantially increase laboratory costs and that the MRA has failed to engage in any cost-benefit analysis related to the impact of these requirement on the industry. MCL 24.245(3). Abandoning existing, approved and accredited methods simply to meet tightened MRA specifications without regard to actual existing method capabilities may include major financial impact, including purchasing expensive new equipment and discarding perfectly adequate existing equipment.

The MICIA additionally identifies that the phrase "method acceptance criteria **is** required" in Rule 420.305b(6) should be revised to "method acceptance criteria **are** required."

*Aspergillus Remediation*

Proposed Rule 420.306(3) provides that "[p]roducts that failed testing for Aspergillus are ineligible for remediation."

The MICIA suggests that products which fail testing for Aspergillus should be further tested and, if applicable, remediated for Mycotoxins. Testing for mycotoxins identifies the presence of aspergillus which, itself, is ubiquitous. This proposed process is similar to the process followed by the USDA https://www.ams.usda.gov/publications/content/fgis%E2%80%99s-role-aflatoxin-testing

*Retest Costs*

Proposed Rule 420.306(5) provides that "[t]he marihuana business that provided the sample is responsible for all costs involved in a retest."

The MICIA highlights that the various license types have different perspectives on this provision. The MICIA submits that the MRA should not inflexibly dictate commercial terms but should instead leave it to the individual businesses to contract amongst themselves for apportioning such costs.

## 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, 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
www.MICannabisIndustryAssociation.org

# AUGUST 2021, PROPOSED MRA ADMINISTRATIVE RULE COMMENTS FROM THE SPOTT LABORATORY

**MARIJUANA DECLARATORY RULINGS**

No Comments

**MARIJUANA DISCIPLINARY PROCEEDINGS**

No Comments

**MARIJUANA EMPLOYEES**

No Comments.

**MARIJUANA HEARINGS**

No Comments.

**MARIJUANA SALE OR TRANSFER**

No Comments

**MARIJUANA LICENSES**

1. R420.13(1)(a) states:

   *"For a licensee seeking renewal under the MMFLA, required information may also be related to the suitability and general fitness of the licensee and include without limitation, information regarding the identification, integrity, moral character, reputation, relevant business experience, ability, probity, financial experience, and responsibility of the licensee and each person required to be qualified for renewal of the license under the MMFLA."*

   The required license renewal information listed in this section of the Rule is blatantly discriminatory, based upon subjective attributes of the licensee that are not required for initial licensure and are not enforceable. **This section of the Rule should be omitted in its entirety.**

**MARIJUANA-INFUSED PRODUCTS AND EDIBLE MARIJUANA PRODUCT**

1. R420.402(2) states:

   *Copies of these standards may be obtained by the agency at the cost indicated in subrule (1)(a) to (c) of this rule, plus shipping and handling."*

   Copying and resale of copyrighted material is very likely a constitutional and legal violation. Government agencies are not immune to the Fair Use Doctrine found in Article I, section 8 of the Constitution or to the Copyright Act of 1976.

2. R420.403(8)(a) states:

   *"(8) A producer of edible marihuana product shall comply with all the following:*

   *(a) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, 21CFR part 117.- Any potentially hazardous ingredients used to process shelf-stable edible marijuana products must be stored at 40 degrees Fahrenheit, 4.4 degrees Celsius, or below."*

   **It is recommended that "- *Any potentially hazardous ingredients used to process shelf-stable edible marijuana products must be stored at 40 degrees Fahrenheit, 4.4 degrees Celsius, or below"* is removed from the Rule.**

   This type of detail is better placed in a clarifying bulletin/ guideline issued subsequent to the Rules where more clarity can be established.

   21CFR Part 117, § 117.80 - Processes and controls, provides the following adequate statement regarding storage of ingredients:

   *(5) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.*

   The quoted language in R420.403(8)(a) attempts to require what is defined in 21CFR Part 117, § 117.135 as a "Preventive Control," without offering a licensee the opportunity to conduct a proper Hazard Analysis according to 21CFR Part 117, § 117.130 - Hazard Analysis to see if a Preventive Control is warranted. Further, the quoted language in R420.403(8)(a) applies this Preventive Control to an undefined sub-category of ingredients ("*potentially hazardous ingredients used to process shelf-stable edible marijuana products*") without identifying the critical product attribute that is affected by storage temperature.

3. R420.403(8)(b) states:

   *"These records at a minimum must include the recipe, any additional processing documentation that demonstrates the product to be shelf stable and* ***test results for all ingredients used****."*

   **It is recommended that "*and test results for all ingredients used*" is removed from the Rule.**

   The quoted language implies that "all ingredients used" must be tested, without defining test requirements for non-active/ excipient ingredients.

4. R420.403(11) provides a definition for "edible marijuana product." This may be better placed in section 420.401, Definitions.

**MARIJUANA LICENSEES**

1. R420.107(1)(c) allows a testing lab to:

   *"Receive marijuana from and test marijuana for an individual 21 years of age or older, if the marijuana was produced by the individual and not purchased or obtained from a licensed marijuana business."*

   **It is recommended that this be changed to read: "*Receive marijuana from and test marijuana for an individual 21 years of age or older."***

   An adult in legal possession of marijuana should not be limited with respect to testing services based upon the legal source of the marijuana. Any adult should have access to product safety testing if they are concerned about the product for any reason, without limitation.

   - Notably, when a sample is presented to a lab for testing that was obtained from a licensed business, the chain of custody will be broken on the sample and results cannot be used to represent batch quality. This makes the proposed limiting language unnecessary.
   - If a sample is presented to a lab for testing by an adult, the lab has no way of definitively verifying/ proving its source, and neither does the MRA. This renders the rule unenforceable.

2. R420.107(2)(c) and R420.112(2)state:

   *"A marijuana safety compliance facility must be accredited by an entity approved by the agency within 1 year* after *the date the marijuana safety compliance facility license is issued…."*

   This should be changed to read: "*A marijuana safety compliance facility must be accredited by an entity approved by the agency* ***prior to issuance of a state operating license****."*

   When the MRA was established in 2018, and only four labs were operating in the state, licensure issuance concurrently with accreditation efforts by a new lab made sense. This was a necessary approach to accelerate industry development. Now, almost three years later, with 15+ fully operating state cannabis labs, it is time to tighten accreditation requirements.

   Accreditation ensures that a lab has a functional Quality System, complete with validated test methods, to **ensure the accuracy of published test results**. This protects public health and safety.

   If a lab enters the industry without prior accreditation, the accuracy of test results that they generate cannot be guaranteed. The lab may operate for up to a full year with a sub-standard quality system and release potentially inaccurate results. In effect, this Rule codifies a double standard in which some labs are fully compliant, while newer labs are not. Public perception of the industry suffers and the Rule, as proposed, perpetuates the ongoing national problem of inconsistent cannabis lab results and associated 'lab shopping' within the state of Michigan.

   The very least that the state of Michigan must do is to level the playing field with respect to laboratory accreditation and make it a pre-condition of licensing at this point in the development of the industry.

**MARIJUANA OPERATIONS**

1. R420.206(2) states:

   *Copies of these standards may be obtained by the agency at the cost indicated in subrule (1)(a) and (b) of this rule, plus shipping and handling."*

   Copying and resale of copyrighted material is very likely a constitutional and legal violation. Government agencies are not immune to the Fair Use Doctrine found in Article I, section 8 of the Constitution or to the Copyright Act of 1976.

2. R420.202(13) states:

   *"All ingredients containing cannabinoids, whether naturally occurring or synthetically derived, that are added to marijuana or marijuana products must be from a source licensed to grow, handle, and produce cannabinoids under a license issued by a governmental authority and entered into the statewide monitoring system."*

   This language implies that synthetic cannabinoids are acceptable in Michigan, and that a license is available that allows for synthetic processing.

   ***Allowance for synthetic cannabinoids in the state of Michigan is not advised. Synthetic cannabinoids exist that are extremely dangerous to public health and safety, as evidenced by the "K2" or "Spice" synthetics that have previously emerged. These are not addressed by the rule as currently written. Even if a cannabinoid is a synthetically derived, but naturally occurring compound, synthetic production involves a substantial risk of product adulteration by toxic reagents and/ or byproducts. These Rules do not adequately regulate synthetic processing to protect public health and safety as currently written. The State of Michigan does not currently provide licensure for cannabinoid synthesis.***

   ***This rule should be revised to explicitly ban all fully or semi-synthetic cannabinoids from the Michigan marijuana industry, except those produced incidentally by otherwise non-synthetic processing steps that have been approved by the agency.***

**MARIJUANA SAMPLING AND TESTING**

3. R420.302(2) states:

   *Copies of these standards may be obtained by the agency at the cost indicated in subrule (1)(a) to (c) of this rule, plus shipping and handling."*

   Copying and resale of copyrighted material is very likely a constitutional and legal violation. Government agencies are not immune to the Fair Use Doctrine found in Article I, section 8 of the Constitution or to the Copyright Act of 1976.

4. R420.304(2)(a) states:

   *"The laboratory shall physically* ***collect the sample the*** *marijuana product from another business..."*

   A typographic error exists; the verbiage should read: *"The laboratory shall physically collect the ~~sample the~~ marijuana product sample from another business...."*

5. R420.305(1) states:

   "*A laboratory shall become fully accredited for all required safety tests in at least 1 required matrix to the International Organization for Standardization (ISO), ISO/IEC 17025:2017, by an International Laboratory Accreditation Corporation (ILAC) recognized accreditation body or by an entity approved by the agency within 1 year after the date the laboratory license is issued and agree to have the inspections, reports, and all scope documents sent directly to the agency from the accreditation body."*

   This should be changed to read: *"A laboratory shall become fully accredited for all required safety tests in* ***all required matrices*** *to the International Organization for Standardization (ISO), ISO/IEC 17025:2017, by an International Laboratory Accreditation Corporation (ILAC) recognized accreditation body or by an entity approved by the agency* ***prior to and as a condition of license issuance*** *and agree to have the inspections, reports, and all scope documents sent directly to the agency from the accreditation body."*

   When the MRA was established in 2018, and only four labs were operating in the state, licensure issuance concurrently with accreditation efforts by a new lab made sense. This was a necessary approach to accelerate industry development. Now, almost three years later, with 15+ fully operating state cannabis labs, it is time to tighten accreditation requirements.

   Accreditation ensures that a lab has a functional Quality System, complete with validated test methods, to **ensure the accuracy of published test results**. This protects public health and safety. If a lab enters the industry without prior accreditation, the accuracy of test results that they generate cannot be guaranteed. The lab may operate for up to a full year with a sub-standard quality system and release potentially inaccurate results. In effect, this Rule codifies a double standard in which some labs are fully compliant, while newer labs are not. Public perception of the industry suffers and the Rule, as proposed, perpetuates the ongoing national problem of inconsistent cannabis lab results and associated 'lab shopping' within the state of Michigan.

   Also note that the statement "*A laboratory shall become fully accredited for all required safety tests in at least 1 required matrix..."* establishes that accreditation involves only one required matrix. This will limit the ability of MRA to require accreditation for additional matrices.

   The very least that the state of Michigan must do is to level the playing field with respect to laboratory accreditation and make it a pre-condition of licensing at this point in the development of the industry.

6. R420.305(2) states:

   *"A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency. In the absence of published, per-reviewed, validated cannabis methods, Appendix J or K of Official Methods of Analysis authored by the Association of Official Analytical Collaboration (AOAC) International must be published in full with guidance from published cannabis standard method performance requirements where available."*

   This language does not clearly reflect the intent of the Rule nor the way in which the Rule has been enforced to date. Alternate clarified verbiage is:

   ***"A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are based upon published peer-reviewed methods, have been validated for cannabis testing by an independent third party, may be monitored on an ongoing basis by the agency, and have been internally verified by the licensed laboratory according to Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Collaboration (AOAC) International, with guidance from published cannabis standard method performance requirements where available. In the absence of published, per-reviewed, validated cannabis methods, method validation requirements of Appendix K of Official Methods of Analysis must be met in full with guidance from published cannabis standard method performance requirements where available."***

   *(Note: Appendix K is specific to analytical testing and Appendix J is specific to microbial testing.*

7. R420.305(3) states:

   *"A laboratory shall conduct the required safety tests specified in subdivisions (a) through (i) of this subrule on marijuana product that is part of a harvest batch as specified in R420.303, except as provided in subrule (4) of this rule."*

   Note that this statement limits safety testing to ***marijuana product that is part of a harvest batch*** which is only plant material by definition. **This excludes testing requirements for marijuana products that are not part of a harvest batch such as concentrates and infused products.**

8. R420.305(3)(f) includes Residual Solvents as a required safety test for marijuana product that is part of a harvest batch. **Residual solvent testing has not been required for plant material to date. This sub-rule should be deleted, as subrule R420.305(7) properly addresses residual solvent testing.**

9. R420.305(3)(a)(iii) defines the list of legally required cannabinoids for potency testing as:

   *"(A) Total Tetrahydrocannabinol (THC)*

   *(B) Tetrahydrocannabinol Acid (THC-A)*

   *(C) Total Cannabidiol(CBD)*

   *(D) Cannabidiol Acid" (CBDA)*

   *(E) Additional cannabinoids may be tested with approval from the agency."*

   The following points are relevant and must be resolved prior to adoption of the Rule:

   a. Reporting of test results is legally required ONLY for the four entities in items (A) through (D) of the subrule as written. **This list no longer mandates individually reporting of d9-THC or Cannabidiol test results – by default these important compounds fall into optional analyte category (E)**. Omitting mandatory reporting of d9-THC and Cannabidiol test results is not recommended.

   b. The correct terms for acid forms of cannabinoids are *"Tetrahydrocannbino**ic**"* and *"Cannbidiol**ic**,"* not *"Tetrahydrocannabin**ol**"* or *"Cannabidi**ol**."*

10. R420.305(9) further defines the list of legally required cannabinoids for potency testing.

    **It is critical that the following points are resolved prior to adoption of the Rule:**

    a. Reporting of test results is legally required ONLY for the four entities in items (a) through (f) of the subrule as written. **This list no longer mandates individually reporting of d9-THC or Cannabidiol test results – by default these important compounds fall into optional analyte category (E)**. Omitting mandatory reporting of d9-THC and Cannabidiol test results is not recommended.

    b. R420.305(9)(a) and (c) are redundant. R420.305(9)(a) should be changed to "delta-9 THC Concentration."

    c. R420.305(9)(c) defines mandatory compounds that comprise "Total THC." This definition is extremely problematic such that reporting of Total THC results as defined cannot be met at this time:

    - **Certified analytical reference standards for Delta7-THC** (a fully synthetic and non-psychoactive cannabinoid) **are not commercially available at this time**.
    - Delta 10-THC (a fully synthetic cannabinoid) certified reference standards are available for two separate enantiomers: Delta 10 (6aR, 9S) which is not psychoactive, and Delta 10 (6aR, 9R) which is psychoactive. The Rule needs to clarify which enantiomer must be quantified.
    - "Delta 11" THC is not a recognized term in the current scientific literature. Provided that the term intends to describe THC with a double bond between carbon atoms 9 and 11, the correct nomenclature is "exo-THC." This requires clarification in the Rule as certified reference standards that are available for this compound are named "exo-THC."
    - The calculation provided for determining Total THC includes summing the concentrations of *"Delta 7-11 THCA."*

      ***This requires a laboratory to individually quantify delta 7, delta 8, delta 10, and delta 11 THC acids***. Certified reference standards for these cannabinoic acids do not currently exist in the literature, and the delta-9 THC acid isomers themselves may not be known compounds at all at this time.

    It is recommended that this language be revised to allow MRA to publish a list of cannabinoids for mandatory testing and reporting and to update the list as needed via bulletins separately from the Rules. It is important to address the emergence of additional THC isomers (like delta-8 THC) without prematurely and unnecessarily complicating the Rule set.

11. R420.305(9)(h) does not adequately define reporting units for CBD:

    "*For marijuana infused products, potency must be reported in milligrams of Delta-9 THC and CBD."*

    a. While this definition provides a *magnitude* (milligrams) it does not specify the *quantity* (per what?). Shall the quantity be milliliter of analytical solution, gram of product, serving, etc.? This needs to be clarified in the Rule.

    b. This sub-rule conflicts with R420.305(3)(a)(iii) and R420.305(9) in that it requires reporting individual test results for Delta 9-THC and CBD for infused products, while these analytes are defined as optional in R420.305(3)(a)(iii) and R420.305(9).

12. R420.305(18) states:

    *"A laboratory may perform terpene analysis on a marijuana product by a method approved by the agency, and the method must be accredited on the same frequency as all required safety tests. There are no established safety standards for this analysis.*

    The line that reads *"There are no established safety standards for this analysis"* should be omitted, as safety tests for beverages include a requirement to test for phytol.

13. **R420.305(21) is not enforceable as written and should not be included in the Rules.** Licensed laboratories are not equipped to nor otherwise required to identify unknown compounds of any type in product samples. In addition "potentially hazardous" and "potentially injurious to human health" are ambiguous, as any compound fits these terms" under the right conditions. Consider for example, that water is fatal if inhaled, and therefore fits the definition of "potentially hazardous" and potentially injurious to human health."

14. R420.305(22) conflicts with R420.305(12) and R420.305(13) as it requires reporting of STEC and Salmonella *"immediately"* without defining how that term compares with reporting *"within 3 days of test completion."* This sub-rule should be omitted.

15. R420.305a(2) should be revised to read"

    ***"Laboratories shall use microbial testing methodologies for the required safety tests in subrule R420.305 that are sourced from published peer-reviewed methods, have been validated for cannabis testing by an independent third party, may be monitored on an ongoing basis by the agency, and have been internally verified by the licensed laboratory according to Appendix J of Official Methods of Analysis authored by the Association of Official Analytical Collaboration (AOAC) International, with guidance from published cannabis standard method performance requirements where available. In the absence of published, per-reviewed, validated cannabis methods, method validation requirements of Appendix J of Official Methods of Analysis must be met in full with guidance from published cannabis standard method performance requirements where available. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts. All of the following apply to validated methodologies under this rule:"***

    *(Note: Appendix K is specific to analytical testing and Appendix J is specific to microbial testing.*

16. R420.305b(2)(b) states:

    *"To further test the accuracy of the assay, probability of detection (POD) analyses, inclusivity, exclusivity, lot-to-lot stability, and robustness studies must be included in validation studies."*

    Lot-to-lot stability testing is not appropriate as a method validation requirement and should be removed from this sub-rule. For example:

    - Stability testing could be conducted on cannabis products. In this case, the stability testing is not appropriately included as a test method validation requirement; rather it is a product/ process validation item.
    - Stability testing could be conducted on perishable microbial test reagents. This is a reagent manufacturer item, and reagent expiration dates are provided with such reagents, not a method validation requirement.

17. R420.305a(6) states:

    *Quality Control acceptance criteria must be published by the agency and be followed. If the method acceptance criteria are more stringent, then the method acceptance criteria* ***are (sic)*** *required.****"***

    This should be changed to read: *Quality Control acceptance criteria must be published by the agency and be followed. If method-specific acceptance criteria exist, then the method acceptance criteria* ***are (sic)*** *required."*

    Quality control acceptance criteria currently published by the agency are known to exceed the capabilities of established, industry-accepted test methods, and are more stringent than criteria assigned to those methods by the method authors/ innovators.

    Accordingly, this rule will require licensed laboratories with established test methods to abandon those methods and seek or develop alternate methods that are likely not available. The cost of this may rise to the level that labs will opt to close rather than comply.

September 27, 2021

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MRA-Legal@michigan.gov

**SENT VIA EMAIL ONLY**

**Re: Comments/Response to MRA Proposed Rules**

Dear Sir or Madam,

PSI Labs has some recommendations in response to the MRA's Proposed Rules.

Thank you in advance for your consideration.

Benjamin J. Rosman
CEO & Co-Founder, PSI Labs

Encl:

# Comments/Response to MRA Proposed Rules

## Sample Size Requirements:

**R. 420.304(2)(b) 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.**

The MRA has specified that all compliance flower testing events need to be sampled at no less than 0 .5% of the batch, this includes all re-testing.

Growers that require retesting could easily lose 1.5% or more of their batch for testing. *We recommend MRA not change its sampling size requirements for flower.*

## Potency Adulteration/Manipulation:

**R. 420.305 Testing; laboratory requirements.**
**(i) In the preparation of samples intended for potency analysis, the laboratory may not adulterate or attempt to manipulate the total potency of the sample by adding trichomes that were removed during the grinding and homogenization process.**
**(ii) All flower material used for potency testing must be representative of the product used by the end consumer and homogenized in such a way that it is representative of the way a consumer would be using the product. Kief must not be reintroduced to the flower sample during the homogenization process.**

The two guidelines outlined in (i) and (ii) describe methods for a lab to boost the potency of a cannabis flower sample. The statements could be combined for efficiency. The first statement could also be shortened to say: **In the preparation of samples intended for potency analysis, the laboratory may not adulterate or attempt to manipulate the total potency of the sample by any means.** There is no need to qualify specific actions that a lab attempting to manipulate the potency of a sample might perform, as any process performed by a lab with the intention of manipulating the potency is unacceptable and a risk to consumer safety.

## Delta 7-11:

**(c) Total THC, which includes Delta 7, Delta 8, Delta 9, Delta 10, and Delta 11 THC and THC-A**

Some of these compounds are not readily available to testing laboratories as certified reference materials, and requiring labs to test for their presence and

abundance in cannabis products is problematic at this time. The current guidelines requiring the quantification of Delta 8 and Delta 9 THC are sufficient as of now.

Delta 8:

**R420.305(9)h For marihuana infused products, potency must be reported as milligrams of Delta-9-THC and CBD.**

Milligrams of Delta-8-THC should also be included in the potency reporting requirements of a marijuana infused product.

Reporting Unknown Compounds:

**R420.305(21) A laboratory shall have a policy or procedure in place for handling and reporting any potentially hazardous contaminants that may be encountered during routine testing. A laboratory shall notify the agency if a test batch is found to contain levels of a contaminant that could be injurious to human health.**

Would like to confirm that this revision speaks only to those contaminants for which the laboratory is screening or testing, and does not include unknown compounds that the laboratory does not test for.

It is very difficult, if not impossible for a lab to identify unknown potentially hazardous compounds through routine analysis. The detection of any compound during routine analysis requires that specific parameters are used to ensure the identification and quantification of that specific contaminant.

An alternative interpretation of this rule is that a lab shall have a policy for reporting any contaminant found during routine analysis that is over the action limits set forth by the MRA (and thus at a level that could be injurious to human health). If so, is reporting failures to metrc insufficient and will additional notification to MRA required when a contaminant we currently test is present at failing levels.

Restrictions on R&D Testing:

**R 420.307 Research and development testing.**
**(7) Research and development testing is prohibited after compliance testing has been completed.**

In many cases, a grower with failed flower may want to check if their remediation was successful prior to submitting an official re-test. This is not allowed per MRA rules, and instead the grower must submit an official .5% sample, potentially multiple times until their remediation is successful.

No clear reason exists for disallowing R&D testing after compliance testing is complete. A license holder should be allowed to R&D test a product at any time for any reason, including after the initial compliance testing has already been completed.

We believe R&D testing represents an activity that helps improve the health and safety of cannabis products, and should be encouraged - not limited. Those opting for R&D testing are looking to improve their products and meet or exceed state guidelines. Putting limitations on this activity forces increased levels of market manipulations that are unnecessary and do not benefit consumers.

Aspergillus as Outlier:

**R 420.306 Testing marihuana product after failed initial safety testing and remediation. Rule 6.**
**(3) Products that failed testing for Aspergillus are ineligible for remediation.**

It is not clear why aspergillus is the sole analyte for which a failed product cannot be remediated. This should be removed if there is no justification and clarification on why aspergillus presents such a high threat level to consumer safety that it is the only analyte failure that makes a product ineligible for remediation.

The safety concern with aspergillus contamination in cannabis has to do with the possibility of opportunistic fungal infections in the lungs of people with compromised immune systems from smoking aspergillus contaminated plant material. There are a few documented cases of such infections in immunocompromised people who were being treated for cancer (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3103256/).

However, as the threat is due to opportunistic infection by living aspergillus fungus, remediation techniques that kill the aspergillus should be acceptable for neutralizing the health risks associated with smoking cannabis flower contaminated with this potentially pathogenic organism. Many techniques that are used to remediate cannabis flower by reducing or eliminating microbial contamination (e.g., treatment with oxidizers, irradiation, solvent extraction, etc.) could also be effective at killing aspergillus and therefore eliminating the health threat to consumers.

Comments

R. 420.305 Testing; laboratory requirements.

Rule 5. (1) A laboratory shall do all of the following:

R 420.302 Adoption by reference.

Comment-Remove the costs out for all standards. These may change.

R. 420.305 Testing; laboratory requirements.
Rule 5. (1) A laboratory shall do all of the following:

(a) **b**ecome fully accredited **for all required safety tests in at least 1 required matrix** to the International Organization for Standardization (ISO), ISO/IEC 17025:2017**,** by an International Laboratory Accreditation Cooperation (ILAC) recognized accreditation body or by an entity approved by the agency within 1 year after the date the laboratory license is issued and agree to have the inspections**,** and reports**, and all scope documents** of the International Organization for Standardization made available **sent directly** to the agency **from the accrediting body**.

Comment

agree to have the ISO/IEC 17025: 2017 or latest version assessment report and final certificate directly sent to the agency from the accreditation body. (recommend a timeframe is added here). Do you want the assessment report and the certificate sent together. When do you want this by?

Also consider adding the requirement for matrix or analyte additions that is currently being practiced. Laboratories shall provide evidence that an assessment is scheduled with their accreditation body in order to receive approval from the agency to continue to perform tests.

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(5) All marihuana cultivators may become certified to GACP-GMP by an accrediting body. This accreditation may enable the licensee certain allowances with testing. The agency will publish these allowances and information on how to obtain approval for allowances. The standard used for certification for GACP-GMP must be World Health Organization and American Herbal Products Association or equivalent.

Comment these are conducted by certification bodies recommend to change to

4) ISO 17065 accredited certification body

5) change accreditation body to certification body

Note items 4-5 above may need to be moved to documents related to producers and cultivators. Otherwise, these will be overlooked.

If they want their lab accredited, consider recommending ISO. IEC 17025 accreditation as required for compliance safety facilities or they can have their laboratory operation accredited to GMP by an accreditation body.

(14) All laboratories shall participate in the proficiency testing program established by the agency. A laboratory shall analyze proficiency test samples from any ISO 17043 accredited vendor on an annual basis unless the agency requests additional testing.

Comment : Recommend changing this to:

A laboratory shall participate in a third-party proficiency testing with an ISO 17043 accredited provider. The proficiency testing provider shall be accredited for all relevant tests required by the agency and by an accreditation body recognized under the international laboratory accreditation cooperation (ILAC).

Submitted By

Tracy Szerszen, President Perry Johnson Laboratory Accreditation

9/24/2021

**Draft Rules 2020-124: Marihuana Sampling and Testing**

**Viridis Laboratory Comments**

**Title**

"Marijuana" is spelled inconsistently throughout this document. It is spelled two different ways in the title alone. One spelling should be chosen and used consistently.

**R 420.301 Definitions**

**(y) "Pre-testing".** This definition is imprecise. Testing must be repeated sometimes for analytical reasons – equipment failure, ambiguous or anomalous results, etc. It would be very bad science to insist on results being reported that are uncertain; and whether an analysis should be repeated is an operational decision that should be made at the laboratory level. This definition should be clarified to exclude retesting for operational or technical reasons.

**(dd) "Target Analyte**"

The definition given is incorrect. A target analyte is something an assay is designed to detect. It has nothing to do with the pharmacological activity of the analyte.

**R 420.302 Adoption by Reference**

This entire section appears to direct licensees to purchase pricey documents from the organizations listed or from MRA for the same price. If the MRA is adopting these references and expecting licensees to adhere to them they should provide these documents to licensees.

**R. 420.303 Batch Identification and Testing**

**(6). "After the producer has extracted the material the producer shall have the sample tested…"** It is unclear what "extracted" means in this context. The previous wording had "processed" instead of "extracted". "Processed" is clearer in meaning and should be retained.

**R 420.305 Testing Laboratory Requirements**

**Rule 5 (1) "A laboratory shall become fully accredited for all required safety tests in at least 1 required matrix.."** "Required matrix" is nowhere defined. There is a list of matrices published elsewhere in this document but they do not say which are "required". Laboratories have been approved to test in some matrices but not others in the past. This is unclear and seems to add a new layer of regulation without defining it.

**Rule 5 (2). A laboratory shall use analytical testing methodologies for the required safety tests in**

**subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency. In the absence of published, peer reviewed, validated cannabis methods, Appendix J or K of Official Methods of Analysis authored by the Association of Official Analytical Chemists Analytical Collaboration (AOAC) International must be published in full with guidance from published cannabis standard method performance requirements where available. The laboratory shall obtain approval from the agency of its validated methodology, including confirmation that it produces scientifically accurate results for each safety test, prior to conducting any safety testing.**

The underlined sentence does not make sense. It states that Appendix J or K must be published in full with guidance from performance requirements where available. Presumably MRA means to say that requirements listed in Appendix J or K must be met in full but saying they must be "published" appears to impute a requirement to submit for publications somewhere. Submission to the agency is not the same as "publishing", as a laboratory's submission to the agency is not meant to be publicly distributed.

**(3) A laboratory shall conduct the required safety tests specified in subdivisions (a) to (i) of this subrule on marihuana product that is part of the harvest batch as specified in R 420.303, except as provided in subrule (4) of this rule. The agency may publish minimum testing portions to be used in compliance testing.**

If a method is validated with a specific testing aliquot, arbitrarily specifying that those aliquots be changed is not advisable as it could interfere with detection of contaminants of concern. Laboratories should use the sample size specified during method validation.

**(i) In the preparation of samples intended for potency analysis, the laboratory may not adulterate or attempt to manipulate the total potency of the sample by adding trichomes that were removed during the grinding and homogenization process.**
**(ii) All flower material used for potency testing must be representative of the product used by the end consumer and homogenized in such a way that it is representative of the way a consumer would be using the product. Kief must not be reintroduced to the flower sample during the homogenization process.**

These two sections are contradictory; and the two sentences in paragraph ii contradict each other. Consumers absolutely try to recover kief or trichromes if they grind flower material themselves. There are many articles and even Youtube videos demonstrating this. For health and safety reasons laboratories should indeed try to obtain a sample representative of what the consumer would use or be exposed to, and that involves minimizing loss of trichromes or kief. It makes no sense to stipulate that some amount of material should be lost; and begs the question of how

much “should” be lost and how much “should” be retained. In theory everything should be retained.

**(9) Potency shall include the following cannabinoid concentrations listed in subdivisions (a) to (f) of this subrule, subject to subdivisions (g) and (h) of this subrule:**
**(a) Total THC concentration.**
**(b) THC-A concentration.**
**(c) Total THC, which includes Delta 7, Delta 8, Delta 9, Delta 10, and Delta 11 THC and THC-A. The following calculation must be used for calculating Total THC, where M is the mass or mass fraction of delta-9 THC or delta-9 THC-A:**
**M total delta-9 THC = M delta-9 THC + 0.877 x M delta-9 THC-A. Σ Delta 7-11 THC + Σ ((Delta 7-11 THCA) x 0.877)=Total THC**

There are no reference standards available for Delta-7 THC. How does the agency expect laboratories to test for this? There are multiple isomers of Delta-10 available. Which does the agency wish laboratories to test for? There are no standards available for Delta-11, although there are standards for exo-THC. Does Delta-11-THC refer to exo-THC?

**(h) For marihuana infused products, potency must be reported as milligrams of Delta-9-THC and CBD.**

Reported as milligrams per what? Dose, package, gram? The original wording had “per serving” and “per dose” but this has been removed. It would be better to retain them.

**(16) A laboratory shall not do any of the following: (a) Desiccate samples. (b) Pre-test samples. (c) Cherry pick, which means testing specific material from a batch. All sample increments must have the same chances of being selected.**

If “Pre-test” means “test more than once”, this can negatively impact the quality of the science and is an inappropriate criterion to impose. See also comments under the Definitions section above.

“Cherry pick” is not a scientific term. This is a colloquial term and does not belong in this document. “Testing specific material from a batch” is also meaningless. Any material chosen could be called “specific material”.

**(21) A laboratory shall have a policy or procedure in place for handling and reporting any potentially hazardous contaminants that may be encountered during routine testing. A laboratory shall notify the agency if a test batch is found to contain levels of a contaminant that could be injurious to human health.**

Please define “potentially hazardous” if by this you mean something other than the target analytes compliance testing is required to look for.

**Rule 420.305a Validations**

**(2) Laboratories shall use microbial testing methodologies for the required safety tests in R 420.305 that are validated by an independent third party and may be monitored on an ongoing basis by the agency. In the absence of published, peer reviewed, validated cannabis methods, Appendix J of Official Methods of Analysis authored by the Association of Official Analytical Collaboration must be published in full with guidance from the cannabis standard method performance requirements where available.**

This sentence makes no sense. See comments under 420.305 Rule 5(2) above**.**

**(d) Microbial methods must include environmental monitoring and quality control of all buffers, media, primers, and incubators.**

What does “quality control of buffers, media, primers and incubators” mean?

**R 420.305b Quality assurance and quality control.**
**(f) Intra-laboratory comparisons, which involve proficiency testing.**

This should read “inter-laboratory”. Inter-laboratory comparisons are not the same thing as proficiency testing.

**(5) A laboratory shall prepare a written description of its quality control activities, included as part of a quality control manual. All of the following items must be addressed in the quality control manual: (a) Daily, weekly, monthly, and annual requirements. (b) An analytical testing batch, which is defined as not more than 20 samples. (c) All analytical testing runs must be bracketed with quality controls.**

It is over-reach to specify how many samples must be in any analytical batch. No other regulatory agency or accrediting body does this.

**8) All standard operating procedures for the required safety tests in R 420.305 and for sampling and testing of marihuana and marihuana products that conform to ISO/IEC 17025:2017 standards, Good Laboratory Practices, shall be approved by the agency prior to the performance of any safety tests. (9) A laboratory shall maintain a quality control and quality assurance program that conforms to Good Laboratory Practices and ISO/IEC 17025:2017 standards and meets the requirements established by the agency.**

Please define what Good Laboratory Practices means. It appears to be something other than ISO/IEC 17025:2017. Please provide the reference so labs may know that they are meeting this standard.

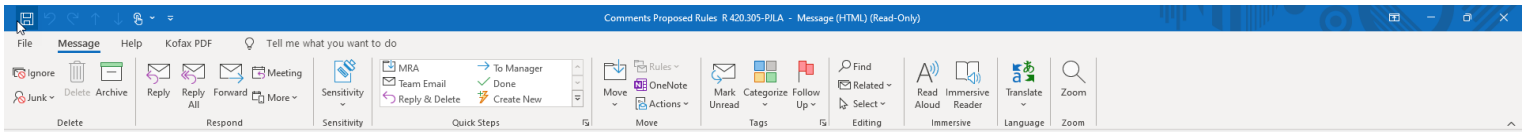
**R 420.307 Research and development testing.**
**(3) Punitive action shall not be taken against a marihuana business for conducting research and development testing when permitted.**

This is a tautology.

**(7) Research and development testing is prohibited after compliance testing has been completed.**

This appears to forbid producers from trying to improve their products.

Most of Rule 420.305 appears to be micromanaging of laboratory operations, and an attempt to specify details of analysis that are better left to the individual laboratories or should be in the technical guidance. Specifying with the force of law how many samples should be in a batch or forbidding ill-defined “cherry-picking” is inappropriate regulatory overreach.




# Comments Proposed Rules R 420.305-PJLA

Szerszen, Tracy <Tszerszen@PJLabs.COM>
To MRA-Legal

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R 420.305 Testing laboratory requirements-Comments PJLA.docx
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Hello we are one of the accreditation bodies that support the MRA in relation to 17025:2017 accreditation. Attached are our comments in relation the proposed updated rules for compliance facilities/test labs.
If you have any questions, please let me know.
Thank you,
Tracy Szerszen
President
Perry Johnson Laboratory Accreditation, Inc.
755 West Big Beaver Road, Suite 1325
Troy, MI 48084
Telephone: 248-519-2603
www.pjlabs.com

Comments

R. 420.305 Testing; laboratory requirements.

Rule 5. (1) A laboratory shall do all of the following:

R 420.302 Adoption by reference.

Comment-Remove the costs out for all standards. These may change.

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