DH, MMRegulations

From: Julia Naccarato <jnaccarato@mcrlabs.com>
Sent: Monday, March 22, 2021 5:45 PM
To: DH, MMRegulations
Subject: [External] Proposed Rulemaking Medical Marijuana Proposed Regulations Comments - MCR Labs Pennsylvania
Attachments: PROPOSED RULEMAKING Medical Marijuana Proposed Regulations MCR Labs - 22Mar21.pdf

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Dear Mr. Collins,
Please see the attached with MCR Labs Pennsylvania's comments regarding the Proposed Rulemaking Medical Marijuana Proposed Regulations.
If I can provide any additional information, please let me know.
Thank you for opportunity to submit our comments.
Regards,
Julia Naccarato

mcr labs
Julia Naccarato
General Manager
610-737-0174

Send via email RA-DHMMregulations@pa.gov

To: Director, John J. Collins
Office of Medical Marijuana, Department of Health
Room 628, Health and Welfare Building
625 Forster Street, Harrisburg, PA 17120

From: Julia Naccarato, PA General Manager

Date: March 22, 2021

Subject: PROPOSED RULEMAKING Medical Marijuana Proposed Regulations Comments

Dear Mr. Collins,

MCR Labs Pennsylvania, LLC would like to submit the following comments regarding the proposed regulations.

We support §1171a.29 (c). This will be a means for the state to determine and evaluate the pass/failure rates of laboratories and will minimize lab shopping to one lab where samples will not be failed. While PA is its own unique program, we encourage them to seek other states failure rates to gain additional insight of what the norms are.

Proposed Section 1171(d) places an affirmative obligation on testing laboratories to notify the department of intent to retest a failed sample. We believe this obligation would more fittingly fall on Grower/Processors (GP) since the GP ultimately makes the decision on retesting. Our intent to retest would be based solely on the GP's intent to have us do so. We suggest the deletion of this requirement altogether as the Department of Health will already have notice of any failed test via MJ Freeway, and it is a near certainty that all failures will result in retesting since this is the only available option to avoid destruction of a lot. Thus, this proposal seems both redundant and administratively burdensome to the Department of Health, to GPs, and to labs.

The proposed final regulations have not provided any remediation relief to the GPs for failed microbiological screening. We support that any lot that fails microbiological testing is fit to be safely remediated into Marijuana Infused Products, etc. in which subsequent testing of finished products can affirm product safety.

Laboratories should not be required to submit R&D test results to the state unless they fail for pesticides as this is the only indication of product that is unsafe to be distributed regardless of where they are in the product's lifecycle. Should these new regulations proceed as written, it is reasonable to assume that the State would be inundated with R&D testing results, which would represent an additional and unnecessary administrative burden.

While noted in § 1171a.27.(b).2., “Sampling procedures be in accordance with guidance provided by the Department,” there is no such requirement under testing in § 1171a.29, which renders “GUIDANCE FOR QUALITY TESTING AND SAMPLING BY APPROVED LABORATORIES” (updated August, 2018) moot. Without state leadership identifying which technologies are appropriate, this allows for a variety of improper methods to be used as for enumeration of total yeast in mold. In § 1171a.31.(e).2.iii.(B.), please define total yeast mold count to ensure proper testing methodologies are employed.

A review of scopes of accreditation indicates many laboratories in the Pennsylvania Medical Marijuana Program are approved for yeast and mold testing via qPCR. As this method does not require the additional incubation time required by plating methods, it is suspected this method is used to enumerate for compliance in the interest of speed rather than efficacy due to production timeline concerns of GPs.

Furthermore, independent assessment has found qPCR is not fit for purpose for quantitation of organisms for three main reasons:

1. qPCR is only capable of providing an estimate of starting concentration of DNA in a sample. The starting concentration of the gene of interest does not correspond to the amount of CFUs that exist in a starting sample. One sample of aspergillus fumigatus could have 13x the amount of the gene of interest within its genome relative to another sample of that same species from a different isolate. This is due to copy number variation, which exists across all organisms these regulations are meant to detect.

2. DNA extraction approaches used in qPCR do not work uniformly across various species. An extraction approach for thin-walled organisms will not lyse thick-walled organisms, so they may go completely un-noticed by a DNA-based assay. An extraction approach for a thick-walled organism may destroy a thin-walled organism so aggressively that PCR inhibitors are released into the sample, artificially deflating the Cq value used to calculate CFU. Extraction approaches do not carry the same efficiency across the same organism at different stages of its life, e.g., a thick-walled resting spore produced by an organism as a stress-response may be uncrackable by an extraction process tuned in for the non-stressed typical reproductive model of that same organism.

3. Utilizing a standard curve to generate a CFU response from a Cq is unreliable due to factors that impact PCR reaction efficiency. A curve built on Cq values for an organism with a perfect reaction efficiency is not usable to generate meaningful CFU values on any other organism in any other non-perfect laboratory condition. Any changes to the matrix that inhibit PCR will significantly shift the final CFU values produced. Organisms with higher GC content may react slower and push Cq values back, artificially deflating CFU values significantly. Because all organisms will have varying reaction efficiency when the gene of interest is amplified, a standard curve for Cq to CFU conversion for multiple species cannot be accurate.

Furthermore, specifically for total yeast and mold, there is no method available to test for total yeast and mold by its classical definition based on plating. The technology is testing a small number of species (4-6) of molds only. The large and diverse group of microscopic yeasts and molds (fungi) includes several hundred species. The ability of these organisms to attack cannabis and many cannabis related products is due in large part to their relatively versatile environmental requirements.

The FDA's Bacteriological Analytical Manual methods (i.e., Plate Count Method APHA 2001 for Yeasts and Molds in Foods, American Public Health Association) of the 4th Edition of the Compendium of Methods for the Microbiological Examination of Foods are all plating culture methods, as well as <61> USP acknowledges that even the precision and accuracy of the MPN Method is less than that of the Membrane Filtration method or the Plate Count Method. Unreliable results are obtained particularly for the enumeration of molds. For these reasons, the MPN Method is reserved for the enumeration of total aerobic microbial count in situations where no other method is available.

In addition, we are seeking clarification on the minimal laboratory sample preparation "test portion," "analytical unit" or "analytical portion" for microbiological samples, however named. By this we mean the part of the "sample" that is actually tested by the laboratory.

Current guidance is related to sample sizes based on grow size. Whereas for chemistry there may be a more uniform distribution of a contaminant of concern, in microbiology, it is common to have sporadic organisms throughout and then hot spots of growth. Leaving it up to a lab to define the "test portion" size of a very small, non-statistical sample leads to non-comparable data and minimizes the likelihood of finding contamination. The current approach does little to protect patients and allows Grower/Processors to seek out a laboratory which uses the least amount of sample, thus increasing the potential for contaminated products to go to marketplace.

Thank you for giving MCR Lab Pennsylvania the opportunity to provide our feedback.

Regards,

Julia Naccarato
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