Notice of Decision to Take Action
On Proposed Regulation

Re: Regulation Concerning Medical Marijuana Laboratory Testing

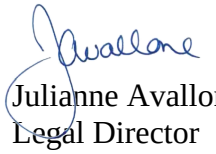
The Department of Consumer Protection opened a public comment period from December 29, 2021 through February 1, 2022 to solicit public input regarding proposed changes to an existing administrative regulation concerning laboratory testing of medical marijuana.

The purpose of the proposed changes to the existing regulation is to update microbial testing standards for medical marijuana to better protect public health and safety, and to create clarity and consistency for laboratories and medical marijuana patients. This amended regulation will replace the existing language of Section 21a-408-60 currently in effect.

The document attached summarizes the comments received and the Department's intended revisions of the proposed regulations in response.

The regulations, as modified based on the comments received, will be published on the website of the Secretary of the State. The Department will continue the process by forwarding these regulations to the Office of the Attorney General for review. Thank you for your interest in this proposed regulation and the work of the Department of Consumer Protection.

Very truly yours,



Julianne Avallone
Legal Director

Dated: March 16, 2022

Proposed Amendments to Regulation Concerning Medical Marijuana Laboratory Testing

Summary of Public Comments and DCP Response

March 16, 2022

The Department of Consumer Protection ("Department") received several comments from medical marijuana patients as well as from the following entities: Medicinal Genomics Corporation (MGC); Fine Fettle LLC (FF); Northeast Laboratories LLC (NL); AltaSci LLC (AS); PathogenDx (PDX); Willow Industries (WI); and Scientific Solutions (SS). No other public comments were received during the public comment period.

Total Yeast and Mold Standard

FF, WI, PDX, and medical marijuana patients expressed opposition to the 10^5 cfu/g standard, which has a prohibition on the presence of the *Aspergillus* species, proposed for the total yeast and mold count (the "TC Standard") as confirmed by existing testing methods (the "TC Testing"). Some commenters misstated the existing standard as 10^3 and the proposed TC Standard as 10^6, and some expressed a preference for 10^4 cfu/g, arguing that other states have adopted it. Most of these comments, however, failed to specifically identify any of the states referenced, or incorrectly attributed a 10^4 cfu/g standard to states such as California, where no such standard exists. (*See* Department of Cannabis Control Medicinal and Adult-Use Commercial Cannabis Regulations California Code of Regulations Title 4 Division 19. Department of Cannabis Control §15720).

Some commentary expressing preference for 10^4 cfu/g made comparisons to states without (1) independent reference laboratories that enable regulations to be based predominantly on dedicated cannabis-specific study and analysis and less driven by stakeholder interests and, (2) required testing for specific microbes, including known harmful microbe species such as *Aspergillus*. (*See* Massachusetts Cannabis Control Commission Protocols for Sampling and Analysis, Exhibit 6; *compare with* Department of Cannabis Control Medicinal and Adult-Use Commercial Cannabis Regulations California Code of Regulations Title 4 Division 19. Department of Cannabis Control §15720). These characteristics lessened the comparison value of such states.

NL supported all proposed changes as "reasonable from a safety perspective and reflective of the approach taken by other states to ensure medical marijuana products are safe for use."

Prior to drafting and after the comment period closed, the Department reviewed the TC Standard with several professional microbiologists and other laboratories both inside and outside of Connecticut. The Department also consulted with regulators in other states.

Specifically, the Department's review included consultation with: (1) the Director of the Connecticut Agricultural Experiment Station, (2) the Director of Scientific Support at

Maryland's Medical Marijuana Commission and a staff microbiologist; (3) the Deputy Director of the California Department of Cannabis Control's Laboratory Services Division and staff of microbiologists; (4) the directors and staff of the two laboratories authorized to test medical marijuana in Connecticut, AS and NL; (5) the Founder/ CSO and Director of Regulatory Affairs at MGC (both of whom are microbiologists); and (6) two pharmaceutical-microbiologist consultants.

The consensus of the experts was that the TC Standard is appropriate and safe in the context of the rest of Connecticut's medical marijuana testing requirements, namely the inclusion of requirements pertaining to *Aspergillus*. A general limit of 10^4 cfu/g would only concern the presence of microbes without delineating specific types, some of which are harmless or beneficial, while others, including the *Aspergillus* species, are proven harmful. Accordingly, the Department is retaining the TC Standard as originally proposed.

Testing Methods

MGC proposed removing the plating method of TC Testing in favor of molecular DNA testing for specific known harmful microbes, such as quantitative polymerase chain reaction (qPCR) testing, arguing that the suggested method would yield more accurate and specific results.

The Department's review, described above, also confirmed that the plating method of TC Testing detects the presence of microbes, but does not identify specific types. Additionally, plating methods often cannot detect endophytes (molds that spend all or part of their life cycle inside the plant's cell walls) and can produce variable results due to differences in growth media, temperature, climate, and duration of test periods.

After follow-up consultation with experts in this area, the Department required molecular DNA testing methods for microbiological testing, and liquid chromatography–mass spectrometry (LC-MS) and enzyme-linked immunosorbent assay (ELISA) testing methods for mycotoxin testing. Existing laboratories will have a six-month period in which to come into compliance with the qPCR testing method requirements to provide them sufficient time to procure the necessary equipment and accreditation.

Remediation

WI suggested that the Department afford producers an opportunity to remediate non-conforming cannabis, with an emphasis on its particular method of ozone remediation. In follow-up consultation with experts in this area, the Department learned that the reliability and effectiveness of remediation varies widely based on the method used. Given this variability, and that the request to implement remediation was not substantially reiterated by other commenters, the Department is not adopting WI's suggestion at this time.