



DH, MMRegulations

From: Sam Tracy <sam@vsstrategies.com>
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To: DH, MMRegulations; RADHMMregulations@pa.gov
Subject: [External] Comments on Proposed Medical Marijuana Regulations - Milan Patel, PathogenDx
Attachments: Comments on Proposed Medical Marijuana Regulations - Milan Patel, PathogenDx.pdf

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Hello,

Please find attached comments on the proposed Medical Marijuana regulations, submitted on behalf of Milan Patel, CEO of PathogenDx.

Please let me know if you have any questions or need anything else from us.

Thank you,
Sam

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Comments on Proposed Medical Marijuana Regulations

Pennsylvania Department of Health — Office of Medical Marijuana

Submitted by:
Milan Patel, Founder & CEO
PathogenDx

Thank you for the opportunity to comment on the proposed permanent regulations for Pennsylvania's medical marijuana program. We are happy to see the state moving beyond the temporary regulations so that the cannabis industry can have more clarity and certainty regarding requirements for operators.

As a company focused on the microbial testing of medical marijuana, we strongly support the proposed regulations on microbiological impurities found in § 1171 a.31 (e) (2) (iii). However, we believe that these could be strengthened in the interest of patient safety by adding additional contaminants, and specifying action levels for the most harmful contaminants, directly into the regulations. This will help resolve some conflicting information in state documents, and provide more clarity to growers, laboratories and patients.

Recommendation:

Add testing for Shiga-toxin producing *Escherichia coli* (STEC 1 and STEC 2) and *Salmonella* Enterica species to the regulations, and specify that these contaminants and *Aspergillus Flavus*, *Aspergillus Fumigatus*, *Aspergillus Niger* and *Aspergillus Terreus* shall be absent in a 1-gram sample.

Suggested language:

(e) An approved laboratory shall issue to a grower/processor a certificate of analysis, including the supporting data, for each harvest batch, harvest lot or process lot sample that was tested at the request of the grower/processor. The certificate of analysis must include the following information:

...

(2) That the presence of the following contaminants within the harvest batch, harvest lot or process lot does not exceed the following levels, or when no level is specified, the level as determined by the Department for the following:

- (i) Heavy metals, mercury, lead, cadmium or arsenic.
- (ii) Foreign material such as hair, insects, or any similar or related adulterant.
- (iii) Any microbiological impurity, including:
 - (A) Total aerobic microbial count.
 - (B) Total yeast mold count.
 - (C) *P. aeruginosa*.
 - (D) *Aspergillus spp.* - absence in 1 gram

(E) Shiga-toxin producing Escherichia coli (STEC) - absence in 1 gram

(F) Salmonella species - absence in 1 gram

~~(E)~~(G) *S. aureus*.

~~(F)~~(H) Aflatoxin B1, B2, G1 and G2.

~~(G)~~(I) Ochratoxin A.

~~(H)~~(J) Pesticide residue.

Reasoning:

There are currently two major gaps between the proposed regulations and the latest guidance issued by the Department of Health¹ in regards to testing for Aspergillus, STEC, and Salmonella:

1. The proposed regulations mandate testing for Aspergillus, but the DOH guidance does not set an action level for Aspergillus.
2. The proposed regulations do not mention testing for E. coli STEC or Salmonella, but the DOH guidance sets action levels for both of these contaminants at absence in 1 gram.

We support testing for all three of these contaminants, as they can each be incredibly dangerous for medical marijuana patients. For example, inhaling Aspergillus can be fatal in immunocompromised people,² and is the leading cause of infection-related death among people who receive a stem cell transplant.³

We support enshrining the action levels for these three contaminants in regulation because of the severity of the risks involved, and to align Pennsylvania with the large majority of other states with medical marijuana programs. Nearly every state with testing requirements sets the action levels for STEC and Salmonella at non-detection in a 1 gram sample.⁴ While fewer states test for Aspergillus, nearly every state that does so also sets the action level at non-detection in a 1 gram sample.⁵

Adding STEC and Salmonella to the regulations, rather than only addressing them in guidance documents, will provide clarity to growers and laboratories who are trying to operate in a compliant manner. Establishing these three action levels in regulation, rather than administratively, will also provide certainty to operators and patients seeking information on testing requirements in Pennsylvania.

¹ See "Guidance for Quality Testing and Sampling by Approved Laboratories" at <https://www.health.pa.gov/topics/Documents/Programs/Medical%20Marijuana/2018.8.10%20MM%20-%20Updated%20Guidance%20for%20Quality%20Testing%20and%20Sampling%20by%20Approved%20Laboratories.pdf>

² Hamadeh et al, "Fatal Aspergillosis Associated with Smoking Contaminated Marijuana, in A Marrow Transplant Recipient"

³ Ben-Ami et al, "Invasive mould infections in the setting of hematopoietic cell transplantation: current trends and new challenges" <https://pubmed.ncbi.nlm.nih.gov/19491674/>

⁴ For example, California, Florida, Hawaii, Massachusetts, Michigan, Missouri, Nevada, and Oklahoma.

⁵ For example, Arizona, California, Michigan, Missouri, and Nevada.

Conclusion:

To provide more clarity to operators and patients, we respectfully request that you add testing for Shiga-toxin producing Escherichia coli (STEC) and Salmonella species to the regulations, and specify that these contaminants and Aspergillus shall be absent in a 1-gram sample.

Thank you again for your consideration. Please do not hesitate to contact us if you have any questions or would like additional information.



Milan Patel
Founder & CEO
PathogenDx
<https://pathogendx.com/>

PathogenDx's mission: To become the industry standard for DNA-based microbial testing technology in the cannabis, agriculture, food and beverage industries, promoting growing businesses, safer products and healthier lives.