Shannon, Taylor (OMC)

From: Murphy, Peter S. [redacted]
Sent: Tuesday, July 9, 2024 5:15 PM
To: OMC
Subject: Comment to Proposed Rules of the Marijuana Commissioner

Follow Up Flag: Flag for follow up
Flag Status: Completed

Dear OMC,

Please accept this email as a comment to the proposed Rules of the Marijuana Commissioner issued on July 1, 2024.

As written, the rules do not indicate whether pre-rolls are a manufactured product. This could result in confusion regarding whether cultivators or retailers are permitted to make pre-rolls for sale to consumers. Please clarify this ambiguity in the final regulations so potential applicants aware of the scope of permissible activities under cultivation, manufacturing and retail licenses.

Thank you,
Peter Murphy

Peter S. Murphy
Partner
[redacted]
Read my bio >>

SAUL EWING
LLP

Shannon, Taylor (OMC)

From: Drew Rysanek <[redacted]
Sent: Tuesday, July 16, 2024 10:42 AM
To: OMC
Subject: Public Comment for Proposed Regulations

I'm curious as to how the number 400cfu/g for yeast and mold in cannabis flower was arrived at? The standard in nearly every legal state is 10,000cfu/g for adult use and 1000cfu/g in stricter States (typically for medical). This is because yeast and molds are everywhere in our environment and cannabis is a spongy absorbent plant that will easily accumulate them. Most are completely harmless and other states will separately test for more harmful molds and mycotoxins. The proposed threshold being more than an order of magnitude lower than the national standard will cause many large operations to remediate their grow rooms with things like ozone and other reactive oxygens which degrade the quality of the flower and pose health risks for employees. Additionally if outdoor cultivation is to ever be licensed and permitted under these adult use regulations it will be nearly impossible without post-harvest remediation.

Regards,

Drew Rysanek

Shannon, Taylor (OMC)

From: Sharon Brunelle <[redacted]>
Sent: Tuesday, July 23, 2024 2:16 PM
To: OMC
Subject: Comments on Proposed Regulations

I am a Technical Consultant for AOAC INTERNATIONAL and submit the following comments on the proposed DE OMC regulations published July 1, 2024 for your consideration. My comments are focused on Section 11.0, Testing and Sampling. These are my personal comments and not necessarily those of AOAC INTERNATIONAL. Many of my comments on the inconsistencies in the previous proposed version published in May were not addressed in this revision.

1. 11.2.1.3 Aerobic bacteria: The formatting of this section implies that yeasts and molds are within the category of aerobic bacteria, but they are not. They are fungi. Yeasts and molds are typically a single test with a total count output. "E. coli" should be written out as "*Escherichia coli*" to be more clear.
2. 11.3.2 – 11.3.4: Formatting here indicates that yeast and mold are aerobic bacteria, but coliforms and E. coli are not. Coliforms and E. coli should be subsections under aerobic bacteria. Yeast and mold are fungi and should not be subsections of aerobic bacteria. Why is there no limit for total aerobic bacterial counts? Typically there is a regulatory limit for "total yeast and mold" counts, not individual limits for yeasts and molds. Does DE intend to have individual limits? This places an additional burden on the laboratories to distinguish these fungal types. The requirements listed in these sections are not consistent with Table 5. Please make them consistent.
3. 11.3.3 and 11.3.4: It is unusual to see no coliforms allowed. Typically there is a limit such as 100 cfu/g for coliforms with no *E. coli* detected. For any qualitative result, such as "no E. coli detected", the test portion size with have a huge influence on the limit of detection of the method. Please specify the minimum test portion size required for all methods. Does a sample pass if not detected in 1 g? Not detected in 10 g? The smaller the test portion, the easier it is to not detect E. coli. What is the requirement to protect public health?
4. Table 1: The table indicates a minimum sample size of 6 g to be submitted for testing, but 11.4.3.1.2 indicates a minimum sample size of 3 g. Which is correct? Is this sufficient to accomplish all of the required testing?
5. 11.6.5: If a batch fails yeast and mold testing and is remediated, it should be tested for mycotoxins in addition to the other required testing before being allowed to pass.
6. 11.8.2.1.3: This section is not consistent with previously described testing requirements and regulatory limits. Here total viable aerobic counts are called out, though no limit was given in 11.3.2. Analysis for total anaerobic bacteria is now introduced where it was not mentioned previously. Why would you expect there to be a risk from anaerobic bacteria for these products? Yeast and mold testing is not mentioned here and neither is detection of *Escherichia coli*. The testing requirements should be consistent throughout the document.
7. 11.8.2.1.3: There is no mention of requiring validation of each matrix for which the methods are used. It may be implied by the phrase "...facilities may be approved to conduct testing...", but an explicit statement of method validation including all applicable matrixes conducted either by the laboratory or through a third party such as AOAC INTERNATIONAL would provide clarification.
8. The use of clear terminology is helpful. For example, distinguishing between a 'sample' and a 'test portion'.
9. Table 2: Here the list of microbial tests includes total viable aerobic bacteria, total yeast and mold, and total coliforms. No mention of E. coli (typically evaluated as part of the coliform test) and no mention of anaerobic bacteria as was introduced in 11.8.2.1.3. Only cultural enumeration methods are allowed for the microbial testing. What is the reason for not allowing validated molecular methods or validated rapid

cultural methods? Only FDA BAM and USP methods are listed below in 11.10.1.2.18 – 24. These methods are not validated for use with cannabis flower and cannabis products. There are numerous AOAC PTM and/or OMA methods that have been validated for cannabis matrixes. Should those not be considered?

10. 11.10.1.2.21 – 22: Why are BAM Chapters 4A (STEC) and 5 (Salmonella) listed when there are no requirements for these tests to be conducted?
11. Why is pathogen testing not required for inhalable and edible products? These products should meet FDA standards.
12. 11.10.6: Here only USP methods are called out, where 11.10.1.2.18 – 22 indicate FDA BAM methods can be used. Please fix the discrepancy or simple refer to the above section. Also, what is meant by "raw marijuana"?
13. Table 5: Here the regulatory limits are not wholly consistent with previous sections. For example, here it is the total yeast + mold that has a limit of 400 cfu/g, but in 11.3.2.1 and 11.3.2.2, it is 400 cfu/g of either yeast or mold. Section 11.3.4 indicates no detection of total coliforms or E. coli (see comment 3 above), but Table 5 indicates total coliforms <1 cfu/g. How can you validate a method for quantitation of coliforms down to 1 cfu/g when your test portion is only 1 g? Results will not be reliable at that level. If you tested a second 1 g test portion, you may well get a different result simply due to the distribution of organisms in the bulk sample. What about E. coli? Why are microbial limits presented in more than one section of the regulation? It adds confusion and the risk of inconsistency (which has been realized here).

Thank you for the opportunity to submit comments. Please contact me if you have any questions.

Kind regards,
Sharon

Sharon L. Brunelle, Ph.D.
Principal Consultant, Brunelle Biotech Consulting
AOAC Technical Consultant
Corvallis, OR
[redacted]
Brunelle
Biotech Consulting

Search for PTM certified methods: https://members.aoac.org/AOAC/PTM_Validated_Methods.aspx

Next Method Validation Training Course is in-person on August 24 at the AOAC Annual Meeting in Baltimore, MD: https://www.aoac.org/trainings/ptm-and-oma-technical-requirements-training-course/

Shannon, Taylor (OMC)

From: Novak, Virginia [redacted]
Sent: Thursday, July 25, 2024 1:33 PM
To: OMC
Subject: Comments for Proposed 5001 Rules of the Office of Marijuana

-Providing terpene and cannabinoid content for every product on the product label.
-Including definitions for Azuca oil, ice hash, bubble hash, rosin, and other product types offered via recreational sales.
-holding a certain percentage of product for medical marijuana patients inside the retail space for sale.
-directions on how to use or consume the product safely on the product.
-ensuring online descriptions of products are accurate and match the product/effects.
-information on product regarding "fast acting products" on label
-creating a Delaware Medical and Adult Use Dashboard similar to Maryland's
MCA Medical and Adult-Use Cannabis Data Dashboard (maryland.gov).

VIRGINIA "GINNY" NOVAK

[redacted]