# Licensing Analytical Laboratories for Sampling and Testing Cannabis

Sherman Hom <sherman.hom@medicinalgenomics.com> Thu 7/6/2023 1:20 PM To:Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

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Mr. Garceau I am referencing the following proposed rulemaking: <u>https://risos-apa-production-</u> <u>public.s3.amazonaws.com/DOH/12981/PBN\_12981\_20230626152123337.pdf [risos-apa-production-public.s3.amazonaws.com]</u>

I would appreciate it very much if you could provide me with the text of the proposed amendments.

Do any of the proposed amendments impact the present rules concerning cannabis microbial testing?

Thanks. Respectfully Sherman

Sherman Hom, PhD Director of Regulatory Affairs Sherman.hom<u>@medicinalgenomics.com</u> 862-588-9898 www.medicinalgenomics.com [medicinalgenomics.com]

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### COMMENTS ON PROPOSED AMENDMENTS TO DEPARTMENT OF HEALTH RULES AND REGULATIONS ON LICENSING ANALYTICAL LABORATORIES FOR SAMPLING AND TESTING CANNABIS 216-RICR-60-05-6 July 2023

The ACLU of Rhode Island appreciates the opportunity to comment on these draft regulations which make a number of changes to licensing analytical laboratories for sampling and testing cannabis. While we do not have a position on the comprehensive set of amendments being made to these regulations, we would like to voice our support for one specific change.

Specifically, these regulations remove the requirement under Section 6.9.2 that a laboratory director "be a person of good moral character." The ACLU has long argued that using such broad and vague language as a professional licensing standard has the potential to invite intrusive invasions of privacy, arbitrary decision-making, and unduly expansive background checks for the purpose of determining whether an individual meets this imprecise and subjective qualification.

In addition, the application of such an amorphous standard creates the possibility of being used to circumvent laws like the Fair Chance Licensing Act, designed to limit the use of criminal record histories to deny employment or licensing. Especially given the disproportionate impact that the prior criminalization of marijuana had on BIPOC and lower-income communities, we are pleased to see the deletion of language that could invite disqualification from this role on the basis of prior offenses which have now been decriminalized.

Because this amendment advances equity as Rhode Island's sale of recreational marijuana expands, we support its inclusion in these proposed revisions. Thank you for your consideration of our views.



July 24, 2023

Zachary J. Garceau, M.A. Chief Program Development Rhode Island Department of Health

### Dear Mr. Garceau

As industry leaders in cannabis and pathogen genomics, we have spent decades working with quantitative polymerase chain reaction (qPCR) and culture-based methods for the detection of microorganisms. We are experts in the field with over 40 patents related to PCR and DNA sequencing based methods for detecting microorganisms. Kevin McKernan, Chief Scientific Officer at Medicinal Genomics Corporation (MGC) managed the Research and Development team for the Human Genome Project at the Whitehead Institute of MIT. He has over 58,328 citations related to his work in this field. Our scientists recommend microbial testing specifications that will ensure that adult-use and medical cannabis plant material and manufactured products are safe for consumers and patients. Due to concerns for public health, the Rhode Island Department of Health should consider having a single set of required microbial testing rules for both cannabis programs by modifying the present medical cannabis microbial testing rules to reflect ongoing efforts at AOAC International, ASTM International, the United States Pharmacopeia (USP), the Centers of Disease Control and Prevention (CDC), and the United States Food and Drug Administration (FDA) that are consistent with our findings at MGC.

The presence of microorganisms is common on plants, such as cannabis. One must be able to differentiate between harmless and/or beneficial microbes (bacteria, yeasts, and fungi) ubiquitous in nature and those that are human pathogens that have contaminated the cannabis plant material and/or manufactured products. Examples of pathogens that have caused human illness affiliated with cannabis use are *Salmonella* species, Shiga toxin producing *E. coli* (STEC), *Aspergillus flavus, A. niger*, and *A. terreus* [1-25].

Current required tests for microbial contamination in states that have medical cannabis programs vary among the states. Some states require different combinations of total count tests, such as Total Aerobic Microbial (TAM), Total Yeast & Mold (TYM), Total Bile-Tolerant Gram-Negative Bacteria Count, and Total Coliforms; as well as the six human pathogens listed above with various action levels for each test and each cannabis product type. On the other hand, some states, such as California, Oregon, Montana, and Vermont only require tests for detecting the human pathogens *Salmonella* spp., STEC, and *Aspergillus flavus*, *A. fumigatus*, *A. niger*, & *A. terreus* for inhalable products.

**NOTE:** Total count tests have action levels as colony forming units (cfu/g), which is the number of colonies that grow on the surface of an agar medium plate. Specific pathogen tests have an action level of "None detected per gram".

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In TITLE 216 – DEPARTMENT OF HEALTH CHAPTER 60 – LABORATORIES AND MEDICAL EXAMINER SUBCHAPTER 05 – STATE LABORATORY PART 6 – Licensing Analytical Laboratories for Sampling and Testing Medical Marijuana [26], it states "Section 6.21 Sample Analysis,

B. Approved Methods

1. Methods approved by RIDOH for the analysis of ... contaminants in cannabis products are listed in Table 1. Equivalent test procedures may be followed if the laboratory has demonstrated the analysis is an acceptable alternative to normally used reference methods to the satisfaction of RIDOH.

Microbiological					
Total Viable Aerobic Bacteria	Culture and enumeration	(r)		(w), (x), (y)	(z)
Total Yeast and Mold	Culture and enumeration	(s)		(w), (x), (y)	(z)
Total Coliforms	Culture and enumeration	(t)			
Bile-tolerant Gram-negative Bacteria	Culture and enumeration			(w), (x)	(z)
<i>E. coli</i> (Pathogenic)	Culture	(u)			(z)
Salmonella	Culture	(v)			(z)

2. Table 1: List of Approved Methods for the Analysis of Cannabinoids and Contaminants.

3. Procedures and Notes for Table 1:

p. FDA. 2001. Biological Analytical Manual. Chapter 3 Total Viable Aerobic Bacteria.

q. FDA. 2015. Biological Analytical Manual. Chapter 18 Total Yeast and Mold.

r. FDA. 2013. Biological Analytical Manual, Chapter 4 Enumeration of E. coli and Coliform.

s. FDA. 2016. Biological Analytical Manual, Chapter 4A Diarrheagenic Escherichia coli.

t. FDA. 2016. Biological Analytical Manual, Chapter 5 Salmonella.

u. USP. 2008. "Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests." USP 31, Chapter 61.

v. USP. 2008. "Microbiological Examination of Nonsterile Products: Tests for specified Microorganisms." USP 31, Chapter 62.

w. USP. Undated-b. "Articles of Botanical Origin." USP 36, chapter 561.



x. WHO 2007 guidelines for assessing quality of herbal medicines regarding contaminants and residues. Annex 5"

Our first concern is the allowed methods for cannabis testing. We do not recommend plating methods for required cannabis microbial testing. The reasons are outlined below.

Concerning the procedures listed underneath Table 1 above in "3. Procedure", there are **no** FDA, USP, or WHO approved methods using any microbiological procedures that have been validated using cannabis as the sample type. **In all regulated industries, allowable methods should be validated using the cannabis sample type that will be tested on a daily basis.** 

Additional disadvantages of using plating methods to detect bacterial and fungal (mold) pathogens are:

- The cannabinoids, which usually represent 10-20% of the cannabis flower by weight, have been shown to have antibiotic activity. Antibiotics inhibit the growth of bacteria in plating methods. *Salmonella* and *E. coli* bacteria; especially shiga-toxin producing *E. coli* (STEC) are very sensitive to antibiotics, which may lead to a false negative result. [27-28]
- Plating methods cannot detect endophytes [29-30], which are molds that live a part or all of their life cycle <u>inside</u> a plant. Examples of endophytes are the species specific *Aspergillus* pathogens. Methods to break open the plant cells to access these endophytes for plating methods also lyses these mold cells (killing these cells in the process). Therefore, these endophytes will not be able to form colonies in a plating method.
- Selective media for mold plating methods, such as Dichloran Rose-Bengal Chloramphenicol (DRBC) reduces mold growth; especially *Aspergillus* by 5-fold. This may lead to a false negative result for this human pathogen. In other words, although DRBC medium is typically used to reduce bacteria; it comes at the cost of missing 5 fold more yeast and molds than Potato Dextrose Agar (PDA) + Chloramphenicol or molecular methods. These observations were derived from study results of the AOAC emergency response validation [31].

We recommend molecular methods, such as qPCR. The primary advantage of using qPCR detection assays are that they are designed to identify unique short DNA sequences either shared by a "group" of bacteria, such as all *Salmonella* species and STEC subtypes or a specific genus and specie, such as the 4 different pathogenic *Aspergillus* species. If the unique sequences are present, then the qPCR test will detect it. Therefore, a qPCR test is very specific, very sensitive, and possesses a rapid turnaround time (12-36 hours) *vs.* plating methods that are less specific, less sensitive, and has a very slow turnaround time of multiple days for colonies to form on a plate. Moreover, MGC has developed a method to remove the DNA from dead cells by using a DNA nuclease enzyme, incubation, & nuclease inactivation step before amplification to detect only the DNA from live pathogens [32].

AOAC has released 3 Standard Method Performance Requirements (SMPRs) for the species specific pathogens listed above (see #1-3 below) so that method developers can validate procedures using different cannabis sample types.

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- 1. Detection of *Aspergillus* in Cannabis and Cannabis Products https://www.aoac.org/wp-content/uploads/2019/10/SMPR-2019\_001.pdf
- 2. Detection of *Salmonella* species in Cannabis and Cannabis Products <u>https://www.aoac.org/wp-content/uploads/2020/07/SMPR-2020\_002.pdf</u>
- 3. Detection of Shiga toxin-producing *Escherihia coli* in Cannabis and Cannabis Products https://www.aoac.org/wp-content/uploads/2021/02/SMPR-2020\_012.pdf

Medicinal Genomics is a member of AOAC's Cannabis Analytical Science Program (CASP) Microbial Contaminants Working Group. The goal and objectives of this working group are to

- Develop Standard Method Performance Requirements (SMPR) for cannabis and hemp
- Extend a Call for Methods for each of the completed SMPRs
- Empanel an Expert Review Panel to review candidate methods
- Deliver consensus-based validated Performance Test Methods (PTMs) & Final Action Official Methods for the cannabis industry

**NOTE:** Medicinal Genomics have an AOAC Certified qPCR PTM for the detection of the 4 *Aspergillus* species, which was approved on August 10, 2021 and an AOAC Certified qPCR PTM for the detection of *Salmonella* spp. & STEC, which was approved in March 2022. The sample types for the multiplex qPCR tests are cannabis flower, concentrates, & infused products.

Therefore, we strongly recommend that all the FDA, USP, and WHO methods in "3. Procedures and Notes for Table 1: p-x" be removed and replaced with:

"3. Procedures and Notes for Table 1:

p. AOAC International certified Performance Test Methods (PTM) or an alternative method approved by the Office of Cannabis Regulation, which may include molecular methods, such as a qPCR method"

Our second concern is that total count tests, such as Total Viable Aerobic Bacteria, Total Yeast and Mold, Total Coliforms, and Bile-tolerant Gram Negative Bacteria **do not** test directly for the presence of any human pathogens that may cause illness to individuals handling or inhaling cannabis. The American Herbal Pharmacopoeia's *Cannabis* Inflorescence *Cannabis* spp. monograph [33] states that total microbial counts **must never** be used to pass or fail a cannabis sample. In other words, total count results **do not** provide any information about the presence of any pathogenic microorganisms in the cannabis sample, which may cause harm to patients. Moreover, approximately 25 pest control agents that contain either non-pathogenic bacterial or fungal strains are available to prevent infection that could lead to reduction of cannabinoid yield or total crop loss. Required total count tests may cause cultivators to use toxic chemical pesticides instead of harmless biological agents.

Concerning the list of required microbial tests for finished cannabis plant material in Table 1 above, therefore we recommend:

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- 1. Removing Total Viable Aerobic Bacteria, Total Yeast and Mold, Total Coliforms, and Bile-tolerant Gram Negative Bacteria
- 2. Replacing E. coli (pathogenic) with Shiga-toxin producing E. coli (STEC), because
  - a. STEC is the most pathogenic of the 6 *E. coli* pathotypes
  - b. STEC has the lowest minimum infection rate (<10 cells) of the 6 *E. coli* pathotypes
  - c. There is **no** single procedure using any method that can detect all 6 *E. coli* pathotypes
- 3. Adding the 4 pathogenic *Aspergillus* species (*A. flavus, A. fumigatus, A. niger,* and *A. terreus*)

**NOTE:** Since some medical cannabis consuming patients are very ill; especially those that are immunocompromised, the action levels for detecting *Salmonella* species, STEC, and the 4 pathogenic *Aspergillus* species should be "Not detected/gram".

Concerning testing for *Aspergillus* species, the United States Pharmacopeia stated that "Many states with legalized cannabis markets now require that all cannabis goods intended for consumption by inhalation be tested for the four pathogenic *Aspergillus* species (*A. flavus, A. fumigatus, A. niger*; and *A. terreus*). When inhaled, all four of these species are known to cause a variety of immune lung disorders, ranging from asthma, allergic bronchopulmonary aspergillosis, and hypersensitivity pneumonitis to invasive and life-threatening systemic fungal infections in immunocompromised hosts." [34]

The number of states and territories that require microbial testing rules for inhaled cannabis products (flower, pre-rolls, *etc*) was 26 in 2019 [35] and 39 in 2023 [36]. A comparative analysis of the required microbial testing rules for all jurisdictions with legal cannabis programs in 2019 and in 2023 showed that the percentage of states and territories that require the detection of the pathogens listed above has increased during this 3+ year period (see the following table).

Microorganism ('19)	# (%)	Microorganism ('22)	# (%)	% Increase	
Salmonella species	22 (85%)	Salmonella species	37 (95%)	10%	
STEC	4 (15%)	STEC	17 (44%)	29%	
4 Aspergillus species	8 (31%)	4 Aspergillus species	24 (62%)	31%	
NOTE #1: States & territory that require STEC testing are AK, CA, CO, CT, FL, IA, MI, MS,					
MT, NM, NY, OK, OR, SD, VT, WA, and Guam					
NOTE #2: States & territory that require pathogenic Aspergillus species testing are AK, AL, AZ,					
CA, CO, CT, DE, FL, HI, IA, MI, MO, MS, MT, NM, NJ, NV, NY, OK, OR, SD, UT, VT, and					
Guam					

Since other states and territories with legal cannabis programs are in the process of modifying or drafting their microbial testing rules and new states & territories will legalize medical cannabis



in the future, we predict that the percentage of jurisdictions requiring the detection of microbial pathogens for cannabis products will continue to increase.

I thank you for your time and consideration. If you have any questions, please feel free to contact me.

Respectfully,

Sherman Hom, PhD Director of Regulatory Affairs Medicinal Genomics Corporation



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### Dr. Sherman Hom, Director of Regulatory Affairs, Medicinal Genomics Corporation

Dr. Hom has a B.A. in Biology from the University of California at San Diego, a Ph.D. in Microbiology from University of California at Davis, and was a Postdoctoral Fellow in Molecular Genetics at Department of Biology, The John Hopkins University (Baltimore, MD).

In 2012 at the New Jersey Department of Health Public Health and Environmental Laboratories, Sherman was the Project Manager that led a team of chemists that started the first Cannabis Testing Laboratory in support of the Division of Medicinal Marijuana. The team validated methods for the quantitation of 8 cannabinoids using HPLC UV-DAD, of various heavy metals using ICP-MS, and of aflatoxins & ochratoxin A using affinity chromatography & HPLC MS.

From 2019 to 2021, he was the Project Manager that led the team that built out the Cannabis Microbial Testing Lab and was about to validate qPCR methods to detect shiga toxin producing *E. coli, Salmonella* spp., and the four pathogenic species of *Aspergillus (flavus, fumigatus, niger,* and *terreus)*. Unfortunately, the SARS-CoV-2 pandemic caused the Cannabis Microbial Testing Lab staff to be diverted to pandemic testing and supply chain activities.

From 2017 to 2021, Dr. Hom led a team that created the first and updated (5X) the Compendium of the All States Medical Cannabis Program Required Testing of all analytes with their corresponding action levels. Comparative analyses were performed to make general observations and identify trends & gaps in the required testing rules. In 2019, 25 chemical pesticides were detected in a cannabis marketed product. Nine pesticides were not tested by any state, while the other sixteen pesticides were tested by various fractions of the states. Moreover in 2019, there were 16 distinct microbial test combinations amonst the 27 states that required microbial testing.

Sherman is presently the Director of Regulatory Affairs at Medicinal Genomics Corporation (MGC), which markets genetics-based cannabis tests and breeding technologies. His primary responsibility is to make recommendations to state, territory, and country regulatory officials that are tasked with either drafting and/or modifying cannabis, hemp, and psychedelic mushroom required microbial testing regulations to ensure safe products for patients and consumers. Another major task is to update MGC's Compendium of the All States Cannabis Microbial Testing Rules in real time (updated to December 2022)

[https://www.medicinalgenomics.com/cannabis-microbial-testing-regulations-by-state/]. Comparative analyses of the microbial testing rules for the cannabis product types (plant material, concentrates, edibles, and infused-products non-edible) by state are being conducted to provide information concerning historical trends and identify potential gaps. We hope that these analyses will support regulatory agencies to create a consensus set of microbial testing rules.

TO:	Zachary Garceau Rhode Island Department of Health 3 Capitol Hill Providence, RI 02908 zachary.garceau@health.ri.gov
FROM:	Jeffrey Padwa, Esq. Padwa Law LLC
RE:	Rules and Regulations Related to Licensing for Sampling and Testing Medical Cannabis including Marijuana and Industrial Hemp [216-RICR-60-05-6]
DATE:	July 26, 2023

#### Public Comment - Marijuana Testing Regulations

Dear Mr. Garceau:

I represent Sensible Cultivators for Intelligent Reform Inc. ("SCIR"), which is an organization comprised of Rhode Island's top licensed marijuana cultivators. Each of these cultivators has employed 10 or more employees and invested hundreds of thousands of dollars in their businesses.

While we support wholeheartedly robust testing of marijuana to protect consumers, this written testimony is submitted to express our specific concerns with the Rules and Regulations Related to Licensing for Sampling and Testing Medical Cannabis including Marijuana and Industrial Hemp [216-RICR-60-05-6].

The purpose of testing is to ensure the quality and safety of cannabis products, and to provide information needed for product labeling requirements so users are fully aware of what they are consuming. The comments proposed below would reduce or eliminate unnecessary costs while having no impact on the important purposes for testing.

 Pesticides – the proposed regulations requiring testing for additional pesticides will require the licensed testing labs to purchase expensive equipment. It is highly probable and foreseeable that only one (1) lab testing company will have the necessary equipment and capacity to perform the required testing, which will create significant challenges to the cannabis industry. The sole lab testing company will not have adequate capacity to perform the tests for the entire Rhode Island cannabis industry, which will cause a bottleneck in cannabis products being tested, and cause delays in getting the products to retail stores. In addition, the monopoly created circumstances will undoubtedly result in the cost of testing for pesticides to increase significantly. We urge the Department of Health to drop the additional pesticide testing, or alternatively suspend the testing of additional pesticides until more than one (1) licensed testing lab has the necessary equipment.

- 2. Microbial the upper Limits for Yeast and Mold should be increased from 10,000 (CFU/g) to 100,000 (CFU/g). Rhode Island is in the small minority of states (i.e. 2 states) in the United States that sets the upper limits for Yeast and Mildew at the 10,000 level, while all other states set the upper limits at the 100,000 level.
- 3. Batch Size the Batch size for testing cannabis flower should be 15 pounds rather than 10 pounds. Because of the number of plants that most cultivators grow and harvest at one time, the average harvest of cannabis flower is typically between ten (10) and fifteen (15) pounds. Requiring testing of 10-pound batch sizes requires the performance of double testing at twice the cost. Increasing the Batch size to up to 15 pounds will eliminate double testing and reduce operational costs for cultivators and consumers.
- 4. Testing Batch Products Currently a 10-pound batch of flower that will be made into flower and pre-rolls require two separate tests. Testing requires that the laboratory grind the product prior to testing for both flower and pre-roll material, therefore testing ground and flower separately is redundant. This doubles the testing cost for the same product. Allowing one test to be used for both flower and pre-rolls would eliminate the double testing and reduce the operational costs for cultivators and consumers.
- 5. Post Testing Remediation cannabis products that are tested, determined to be out of compliance and which undergo subsequent remediation should only be required to undergo the tests for which the products were out of compliance and not the full panel of tests. Requiring a full panel of testing for post-remedial products is redundant, and expensive and does not add any value to consumers. Post-remedial testing should only pertain to the tests for which the products were originally found to be out of compliance.
- 6. Retesting Potency in the event retesting of potency is required the testing regulations should allow the lab that performed the initial potency test to conduct the potency re-test.

Thank you for your consideration of these issues.

Very truly yours,

Kardwa

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Zachary Garceau Department of Health 3 Capitol Hill Providence, RI 02908

July 25th, 2023

Dear Mr. Garceau,

Please find here below some comments and suggestions concerning the proposed amendment of Licensing for Sampling and Testing Medical Cannabis including Marijuana and Industrial Hemp [216-RICR-60-05-6]. They are presented by the three accredited cannabis testing laboratories in Rhode Island, *i.e.*, Cannalytics, Pura Vita and Lifted Testing Laboratories.

The undersigned would like to suggest three revisions of the present draft. For your convenience, they are labelled according to the code followed in the original.

#### Concerning Section 6.21.C.1 "Cannabinoid Profile Analysis- Additional Information/Requirements"

The quantitative analysis of cannabinoids, *i.e.*, Total THC, Total CBD and Total Cannabinoids, requires of defined equations for its reporting. We recommend the following equations to be included in PART 6 – Licensing Analytical Laboratories for Sampling and Testing:

- Total THC = [Δ9-THC] + 0.877\*[THCA]; being 0.877 the remaining mass fraction of Δ9-THC after the total decarboxylation of THCA
- Total CBD = [CBD] + 0.877\*[CBDA]; being 0.877 the remaining mass fraction of CBD after the total decarboxylation of CBDA
- Total Cannabinoids = [Δ9-THC] + [THCA] + [Δ8-THC] + [CBD] + [CBDA] + [CBN] + [CBC] + [CBCA] + [CBL] + [CBDV] + [CBDVA] + [CBG] + [CBGA]; being these components the most abundant in cannabis

These definitions/equations would facilitate the common understanding of requirements and their implementation.

We also suggest the implementation of Total Cannabinoids results, as above calculated, as part of the labelling information on cannabis products, as it is a trendy concept between consumers. Introducing Total Active Cannabinoids, another trending topic, is controversial and therefore discourage, as it requires a deeper knowledge of the physiological response of each of those components.

### Concerning Section 6.21.E.1.a "Pesticides Residues Analysis- Additional Information/Requirements"

Some of the additional pesticides added to the previous list have practical analytical implications that will require significant capital investment for labs, hindering the rapid implementation of the proposed changes.

The following pesticides require an additional ionization methodology, atmospheric pressure chemical ionization (APCI), or the purchasing of an instrument with GC-MS/MS capability. Unfortunately, the analytical testing market in RI is not sufficient to support such expenditure, as the recent closure of Green Peaks Analytical have demonstrated. The commented pesticides are:

Chlorpyrifos (2921-88-2), Cypermethrin (52315-07-8), Flonicamid (158062-67-0), Naled (300-76-5), Permethrin (52645-53-1), Prallethrin (23031-36-9), Pyrethrins (8003-34-7), Chlorfenpyl (122453-73-0), Methly Parathion (298-00-0), and Pentachloronitobenzene (PCNB, 82-68-8)

Furthermore, the required additional methodologies will not only grant the detection of those compounds at the desired level but will force the labs to add multiple steps in the test, making it convoluted and prompt to errors.

The three labs would strongly recommend an incremental expansion of the list that would make economic and practical sense. Removing from the list the pesticides mentioned above for this iteration of the regulations would allow the testing labs to successfully implement the testing of the remaining 57 pesticides in a rapid time frame, with the view of future expansion to the list when there is improved economic viability.

Finally, it would make sense to apply immediately the new action limit thresholds of the 17 pesticides residues that are currently being tested for by all three labs, as it will provide the necessary relief to the market where cultivators are unnecessarily being penalized.

Concerning Section 6.7.1.G.4.b "Test categories and descriptions"

Stray

We discourage the inclusion of a waiver of potency testing on infused cannabis products if the manufacturing of remains consistent from batch to batch in this amendment. The process followed in the preparation of these infused edibles lacks the rigor desired for the waiver, as most manufactures cannot guarantee the reproducibility and accuracy capacity needed to grant the suggested consistency. The testing of psychotropic active ingredients should be treated as close as possible to any pharmaceutical active ingredient for public safety concerns. Only if the producer of said product can generate their own QC data for each batch supporting the label claim using a validated method should they be able to get a wavier to test externally periodically.

A careful revision of the testing performed in those products will reveal examples of batches with double and or half the target potency, or products were the infusion process failed completely. There have been cases where incorrect starting materials have been used for infusion, *e.g.*, CBD instead of THC and vice versa.

Dosage and the labeling of Infused products remains an industry problem at the national level, this waiver, would be large step in the wrong direction. Continued analysis of infused products would confirm and grant the correct dosages on these labels. Afterall, we are responsible of quality and safety of medical and recreational cannabis products and the consumers' overall health protection.

Please do not hesitate in contacting any of the labs if you require further explanations of clarifications.

Kindly,

Tanya Luongo

Laboratory Director Cannalytics RI

Stuart Procter

Dr. Cesar A. Marquez

Cias Heijer

Laboratory Director Lifted Testing Labs

Lab Director & Co-Founder PurrVita Labs

# ONLINE PUBLIC COMMENTS FOR REVIEW Date: 07/27/2023

Regulation: 216-RICR-60-05-6

Title: Licensing Analytical Laboratories for Sampling and Testing Cannabis

No online public comments found