

August 11, 2020

Under the current regulations, marijuana and marijuana products are required to be tested for certain contaminants before being sold on the market. The Cannabis Control Commission (Commission) has received this petition, *Formal Petition to the Massachusetts Cannabis Control Commission for Amendment to 935 CMR 500.160 “Testing of Marijuana and Marijuana Products,”* pursuant to 935 CMR 500.830, to amend the testing requirements for adult-use cannabis by modifying the current microbe thresholds under 935 CMR 500.160: *Testing of Marijuana and Marijuana Products*. The petition sets forth proposed changes to the regulations and to the testing protocol. During this regulatory public comment period, ending at 5:00 PM on Friday, August 14, the Commission seeks public comment on the petition for its consideration of the proposed changes.



Formal Petition to the Massachusetts Cannabis Control Commission for Amendment to 935 CMR 500.160 “Testing of Marijuana and Marijuana Products”

We, the undersigned, are submitting a formal Petition pursuant to 935 CMR 500.830: “Petitions for the Adoption, Amendment or Repeal of Regulations.” We are petitioning to amend the microbe thresholds under 935 CMR 500.160 “Testing of Marijuana and Marijuana Products” paragraph (1). This petition sets forth two lines of reasoning for the proposed changes: (1) the science does not support the current microbe thresholds, which, as currently set forth, are not necessary for the health and safety of the public or consumer of Adult Use Cannabis; and (2) the microbe thresholds create a direct conflict with the energy reduction requirements in the Adult Use Regulations and create an unreasonable barrier to entry for small farmers and sustainable, ecological, biologically-based outdoor cultivation.

Section 935 CMR 500.830 sets forth the following:

- (1) Any interested Person may file a petition with the Commission pursuant to M.G.L. c. 30A, § 4, for the adoption, amendment or repeal of any regulation. Such petition shall be submitted in written and electronic form, be signed by the petitioner or petitioner's representative, and include the following information:
 - (a) The name, address, and relevant contact information for the petitioner or the petitioner’s representative;
 - (b) The petitioner’s specific interest in the regulation;
 - (c) The petitioner’s request for the adoption, amendment or repeal of a regulation, including proposed regulatory language;
 - (d) If the request is to amend an existing regulation, a copy of the existing regulation with changes clearly marked on paper and electronic copies; and
 - (e) The reasons for the request, including, but not limited to citation to any relevant legal authority, arguments and evidence, including data, that supports the request.

Pursuant to the requirement set forth under 935 CMR 500.830(1)(a) I, Suehiko Ono, am preparing and submitting this petition on behalf of EOS-Bittersweet LLC, which is a provisionally licensed (MC281338) outdoor cultivator to be located at 1107 Barker Road (formerly 973 Barker Road) in Pittsfield, MA, and the undersigned below. I am co-founder and COO of EOS Farm LLC, which is a majority member of EOS-Bittersweet LLC. I can be reached at:

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Pursuant to the requirement set forth under 935 CMR 500.830(1)(b), EOS-Bittersweet LLC is specifically interested in this provision because EOS-Bittersweet LLC shall be a licensed cultivator subject to the testing requirements under 935 CMR 500.160. These standards make ecological, outdoor growing practices impractical and unreasonably costly, and they are not necessary for the health and safety of the public or consumer of Adult Use Cannabis. The additional undersigned are licensees, license applicants, and consumers of MA Adult Use marijuana who wish to see these regulations amended in order to allow outdoor farmers to grow MA Adult Use cannabis sustainably under the sunshine and in the earth.

Pursuant to the condition set forth under 935 CMR 500.830(1)(c) & (d), on behalf of EOS-Bittersweet LLC and the undersigned, I am proposing the following regulatory amendment:

935 CMR 500.160(1) currently reads:

No Marijuana Product, including Marijuana, may be sold or otherwise marketed for adult use that is not capable of being tested by Independent Testing Laboratories, except as allowed under 935 CMR 500.000: Adult Use of Marijuana. Testing of Marijuana Products shall be performed by an Independent Testing Laboratory in compliance with a protocol(s) established in accordance with M.G.L. c. 94G, § 15 and in a form and manner determined by the Commission including, but not limited to, the Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-infused Products. Testing of environmental media (e.g., soils, solid growing media, and water) shall be performed in compliance with the Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Medical Marijuana Dispensaries published by the Commission.

I am setting forth two alternative proposed changes for the Massachusetts Cannabis Control Commission to consider in the alternative. Either alternative, or one substantially the same as either alternative, will suffice to address the issue(s) currently present in 935 CMR 500.160(1).

1. The first alternative proposed change would read as follows (changes **emphasized in red**):

No Marijuana Product, including Marijuana, may be sold or otherwise marketed for adult use that is not capable of being tested by Independent Testing Laboratories, except as allowed under 935 CMR 500.000: Adult Use of Marijuana. Testing of Marijuana Products shall be performed by an Independent Testing Laboratory in compliance with a protocol(s) established in accordance with M.G.L. c. 94G, § 15 and in a form and manner determined by the Commission. ~~including, but not limited to, the Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-infused Products.~~ Testing of environmental media (e.g., soils, solid growing media, and water) shall be performed in compliance with the Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Medical Marijuana Dispensaries published by the Commission. **Any Marijuana Products, including Marijuana, to be sold or otherwise marketed for adult use shall be tested for the following:**

- (a) Four species of Aspergillus: A. flavus, A. fumigatus, A. niger, and A. terreus <20 µg of any mycotoxin per kg of material;
- (b) Total generic E. Coli. above 100 CFU/gram;
- (c) Any detectable Salmonella;
- (d) Products made from fresh raw marijuana for ingestion without any form of heating or combustion shall, in addition to the pathogens described in (a) through (c) above, be tested for Pseudomonas aeruginosa, Clostridium botulinum, and toxigenic E. coli.

2. The second alternative proposed change would read as follows (changes **emphasized in red**):

No Marijuana Product, including Marijuana, may be sold or otherwise marketed for adult use that is not capable of being tested by Independent Testing Laboratories, except as allowed under 935 CMR 500.000: Adult Use of Marijuana. Testing of Marijuana Products shall be performed by an Independent Testing Laboratory in compliance with a protocol(s) established in accordance with M.G.L. c. 94G, § 15 and in a form and manner determined by the Commission. **including, but not limited to, the Protocol for Sampling and Analysis of Finished Medical Adult Use Marijuana Products and Marijuana-infused Products.** Testing of environmental media (e.g., soils, solid growing media, and

water) shall be performed in compliance with the Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Medical Marijuana Dispensaries published by the Commission.

Under this alternative, the CCC would publish separately the “Protocol for Sampling and Analysis of Finished *Adult Use* Marijuana Products and Marijuana-infused Products.”

These would set thresholds the same as the “Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-infused Products,” *but would eliminate the “Total Viable Aerobic Bacteria (CFU/g)” and “Total Yeast and Mold (CFU/g).”*

Cannabis Material	Total Viable Aerobic Bacteria (CFU/g)	Total Yeast and Mold (CFU/g)	Total Coliforms (CFU/g)	Bile-tolerant Gram-negative Bacteria (CFU/g)	E Coli (pathogenic strains) and Salmonella spp.	Mycotoxins ^c
Unprocessed Materials ^b	10⁵	10⁴	10³	10 ³	Not detected in 1 g	<20 µg of any mycotoxin per kg of material
Processed Materials ^b	10⁵	10⁴	10³	10 ³		
CO ₂ and Solvent-based Extracts	10⁴	10³	10²	10 ²		

Example Protocol Table.

Either of the two proposed changes in the alternative would suffice to alleviate the undue burden and hardship caused by the current microbe thresholds provision.

Reasons for the Requested Amendment

Pursuant to 935 CMR 500.830(1)(e), we present the following two arguments for the proposed changes: (1) The science does not support the current microbe thresholds; and (2) the microbe thresholds create a direct conflict with the energy reduction requirements in the Adult Use

Regulations and create an unreasonable barrier to entry for small farmers and sustainable, ecological, biologically-based outdoor cultivation. I will discuss both in further detail below.

Argument 1: The Science Does not Support the Current Microbe Thresholds

The science does not support the current microbe thresholds, which, as set forth, are not necessary for the health and safety of the public or consumer of Adult Use Cannabis. The Adult Use regulations require testing of marijuana to be sold to the market according to "the Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-infused Products."¹ This testing protocol can be found on the Medical Use of Marijuana website.² In particular, "Exhibit 6. Analysis Requirements for Microbiological Contaminants and Mycotoxins in Medical Marijuana Products," sets the microbe testing thresholds.

Specifically, the thresholds for "Total Viable Aerobic Bacteria (CFU/g)" is set at 100,000 and "Total Yeast and Mold (CFU/g)" is set at 10,000 CFU/g for processed and unprocessed materials.

There is no scientific basis to have such strict thresholds. In 2015, four authors, including Harvard Immunology Faculty, Jatin M. Vyas, MD, PhD, published "Microbiological Safety Testing of Cannabis."³

Under the "Recommendations" section (pp 29-34), the paper states the following (*emphasis added*):

4. *Cannabis should be tested for four species of Aspergillus: A. flavus, A. fumigatus, A. niger, and A. terreus.* Together these species are responsible for the vast majority of cases of invasive pulmonary aspergillosis, and they are the only pathogens that represent a clear and certain danger on Cannabis.

5. *Cannabis should be tested for total generic E. Coli. Samples with levels above 100 CFU/gram should be rejected.* This is the one indicator test that we recommend. Detection of significant levels of E.Coli are

¹935 CMR 500.160(1).

²<https://www.mass.gov/info-details/medical-use-of-marijuana-program-product-testing>

³Holmes, Mowgli, Jatin M. Vyas, William Steinbach, and John McPartland. "Microbiological Safety Testing of Cannabis." <https://cdn.technologynetworks.com/tn/Resources/pdf/microbiological-safety-testing-of-cannabis.pdf> Cannabis Safety Institute, May 2015.

strong evidence of problems during growing or processing, including contaminated soil or water, or improper handling. E. Coli is now accepted to be the optimal indicator organism for the identification of possible fecal contamination. Were pathogenic bacteria such as E.Coli or Salmonella to be present, they would likely have arrived through this type of pathway, therefore samples positive for E.Coli are both higher risk and indicative of general production problems that need to be addressed. E. Coli is usually not pathogenic, and many food-safety protocols do not require it to be entirely absent. A general guideline for E. Coli testing, and one which fits well with existing Cannabis testing data, is that no product should have over 100 CFU/gram (or equivalent) of generic E. Coli.

6. *Cannabis should be tested for Salmonella.* Samples with detectable Salmonella should be rejected. The odds of Salmonella infection from Cannabis are very low. Nonetheless, it is the one bacterial pathogen that poses a potential threat to Cannabis smokers. There is precedent for Salmonella association with Cannabis in both this early epidemic, and in very recent microbial sequencing data. It is highly infectious and can cause disease with as low a dose as one single cell. It is hardy and highly resistant to desiccation. And it has a mortality rate that is significant, and significantly higher in older or immunocompromised patients that are likely to be exposed through the use of medical Cannabis.

All Cannabis flower material should be tested for Salmonella, with close attention paid to the statistical sampling methods discussed below. Batches with any detectable Salmonella should be failed.

7. *There is no need to test Cannabis for Pseudomonas aeruginosa, Listeria, toxigenic E. Coli (e.g., H7:0157), or other bacterial pathogens besides Salmonella.* Cannabis is not a potential delivery vehicle for these organisms, or for most bacterial pathogens. Because it is both dried and heated before use, it has undergone two highly effective sterilization steps, and none of these pathogens can survive both of these. All of them

will die if exposed to the heat of smoking or decarboxylation, and all of them will generally be rendered noninfectious by the curing process. This does not mean that mis-handled or improperly cured Cannabis could not be a vehicle for these organisms. As with any agricultural or food product, it can be a source of increased hazard if it is maintained at high water activity levels, if typical decontamination steps are not performed, or if it is consumed fresh.

8. *There is no need to test Cannabis for “total yeast and mold”.* Total yeast and mold tests detect only a small fraction of the fungal species in the environment, and do not correlate with the presence of pathogenic species. The only pathogenic mold species on Cannabis are types of *Aspergillus* that must be tested for separately in any case. Molds can potentially be a cause of allergic hypersensitivity reactions, but there is no evidence that these are mediated by smoking. Molds can also be a source of plant spoilage, but these processes can be monitored appropriately by testing for water activity levels, and by visual or microscopic inspection.

9. *There is no need to test Cannabis for aflatoxins.* These would be at least partly degraded by the heat of smoking or decarboxylation, if they were present. But seedless Cannabis plants are not capable of supporting aflatoxin production, because they lack the high oil content necessary for *A. flavus* replication.

California is an example of a state that tests for specific pathogens in medicinal and recreational marijuana. Section 5720 of Title 16 of the California Code of Regulations sets the testing requirements for legal cannabis sold in California. California specifically tests marijuana and marijuana products for Shiga toxin-producing *Escherichia coli*, *Salmonella* spp., and Pathogenic *Aspergillus* species *A. fumigatus*, *A. flavus*, *A. niger*, and *A. terreus*. Washington and Oregon Adult Use commercial markets follow suit.⁴

⁴WA (WAC 314-55-102) and OR (OAR 333-007-0390). Colorado (CCR R712) and Nevada (NAC 453D.780) similarly test for specific bacteria (but they test for total yeast and mold the same way as MA currently does).

Argument 2: The Microbe Thresholds Create a Direct Conflict with the Energy Reduction Requirements in the Adult Use Regulations and Create an Unreasonable Barrier to Entry for Small Farmers and Sustainable, Ecological, Biologically-Based Outdoor Cultivation.

In short, this simple regulatory amendment will eliminate a significant barrier to entry for growing cannabis ecologically outdoors, which will address many of the concerns about the sustainability and energy efficiency of cannabis production, while including the small farmers in the Commonwealth.

Simply put, growing outdoors under the sunshine uses approximately 1% of the electricity used to grow in controlled, indoor environments. Outdoor environments are naturally rich in microbial life (bacteria and fungi). Most bacteria and fungi are beneficial to plant (including cannabis) health. The current testing thresholds do not differentiate between microbes that are beneficial and microbes that are harmful to humans.

The Massachusetts legislators and the Massachusetts Adult Use Regulations are clear about the preference toward sustainability and energy efficiency. For example, 935 CMR 500.105(q) requires:

Policies and procedures for energy efficiency and conservation that shall include: 1. Identification of potential energy use reduction opportunities (including, but not limited to, natural lighting, heat recovery ventilation and energy efficiency measures), and a plan for implementation of such opportunities; [...].

935 CMR 500.120: Additional Operational Requirements for Indoor and Outdoor Marijuana Cultivators, paragraph (11) states:

A Marijuana Cultivator shall adopt and use additional best management practices as determined by the Commission [...] to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts [...].

The simplest, best, most effective way to “to reduce energy and water usage, engage in energy conservation and mitigate other environmental impacts” is by growing outdoors in the sunshine in a biologically rich environment.

The current, extremely strict microbe testing protocols set forth under 935 CMR 500.160, which do not differentiate species of bacteria and fungi, contradict the ability of the farmer to grow in a

biologically active environment. This, in effect, selects away from outdoor growing and the best sustainable cannabis cultivation solutions that are available.

The sustainable agricultural movement has long championed farming practices that minimize the impact on the natural environment and contribute to biodiversity, conserve natural resources, and do not cause harm to human health. As cannabis becomes legal across the United States, this discussion has entered into the center of the cannabis industry.

Over-simplifying, there are currently two dominant, competing philosophies with respect to agriculture. The predominant agricultural model is based on careful management of chemicals and sterilization and elimination of biology. In contrast, the sustainable approaches are based on integration and synergy with complex biodiversity and ecosystems. In terms of the strategies of Integrated Pest Management, these are the Cultural and Biological solutions. Taken together, these strategies can be called a “biodiverse ecosystem.” This means promoting and encouraging an immeasurable diversity of plant species, animal species, insects, and microbes, including millions of species of bacteria and fungi.

Sustainable farming practices without the use of harmful pesticides rely on a rich, biologically diverse environment in the soil and in the plant foliage. Much like the human microbiome, which is largely responsible for human health, the soil and foliage microbiome are crucial to healthy plant biology. To quote the USDA website:

An incredible diversity of organisms make up the soil food web. They range in size from the tiniest one-celled bacteria, algae, fungi, and protozoa, to the more complex nematodes and micro-arthropods, to the visible earthworms, insects, small vertebrates, and plants.

As these organisms eat, grow, and move through the soil, they make it possible to have clean water, clean air, healthy plants, and moderated water flow.⁵

The same microbial diversity is necessary above the soil. For example, in a recent study published in the journal *Nature*, Michigan State University scientists demonstrate a causal relationship between plant health and the microbial life in the foliage and above ground portions of the plant.⁶ The work provides further evidence that plants share a similar strategy to animals to control their microbiomes in order to maintain health.

⁵https://www.nrcs.usda.gov/wps/portal/nrcs/detailfull/soils/health/biology/?cid=nrcs142p2_053868

⁶Michigan State University. "Plants control microbiome diversity inside leaves to promote health." ScienceDaily. ScienceDaily, 13 April 2020. <www.sciencedaily.com/releases/2020/04/200413103534.htm>.

The Commission’s “Guidance on Integrated Pest Management,” published on April 4, 2019,⁷ provides the definition, “Integrated pest management (IPM) is an approach to pest control that applies a combination of methods to manage pest problems.” The Guidance goes on to provide the four primary strategies available in a pest management program: 1. Cultural Controls; 2. Mechanical Controls; 3. Biological Controls; and 4. Chemical Controls. The Guidance explains each method:

1. Cultural Controls: Cultural controls modify the environment to make the cultivation operation an unaccommodating habitat for pests. They involve practices such as adjusting the irrigation schedule to combat root disease, reducing humidity to make the environment less hospitable to pathogenic fungus and shaping the canopy to facilitate superior airflow, or companion plantings to boost the populations of beneficial insects.
2. Mechanical Controls: mechanical controls use physical methods to trap, exclude, and remove pests, such as putting filters on air intakes, placing sticky traps in strategic locations to trap flying pests, removal of diseased plant material, or removal of weeds.
3. Biological Controls: biological controls utilize natural enemies (predators and parasites that deplete the health of a pest population) to directly attack pests. Biological control organisms can be extremely effective at maintaining pest populations below economic thresholds, and preventing infestations from reaching damaging levels.
4. Chemical Controls: chemical controls should be used judiciously in any IPM program. *Cannabis cultivators are limited in their options for chemical controls since Massachusetts prohibits the use of any pesticide with an EPA registration number. While there are minimum-risk (25(b)) pesticides available for use in cannabis cultivation, pesticides in general should not be used as a primary pest control method in cannabis.*⁸

⁷<https://mass-cannabis-control.com/wp-content/uploads/2019/04/Guidance-on-Integrated-Pest-Management.pdf>

⁸ibid. (*Emphasis added.*)

Strategy 4. Chemical Controls, except the limited minimum risk 25(b) pesticides, is not possible for the cultivation of recreational cannabis in the Commonwealth. The Massachusetts Department of Agricultural Resources (“MDAR”), which is responsible for oversight of all pesticide use in the Commonwealth, published on October 16, 2018, the “Pesticide Use on Cannabis Advisory.”⁹ In it, MDAR effectively prohibits the use of all pesticides except those with the active ingredients the Federal EPA designated as exempt “Minimum Risk Pesticides.”¹⁰

This leaves the other three strategies, Cultural, Mechanical, and Biological, available to the MA cannabis cultivator. Of these, it is crucial that a grower using sustainable, biologically rich practices, in particular an outdoor grower in a natural environment, can rely on a robust, diverse microbial community.

Massachusetts is the first recreational market on the East Coast, and it is unique from most other legal recreational markets in the U.S. because, unlike the Pacific Northwest, for example, Massachusetts did not have a large, existing, illegal marijuana cultivation infrastructure to the degree these other states did. Massachusetts is building from the ground up. It is at a crossroads, and has the possibility to lead the country in sustainable cannabis production.

There are 7,241 farms in Massachusetts according to MDAR.¹¹ Over 79% of those are family owned small farms (USDA defined as less than \$250,000 gross annual revenues). The average farm in MA brings in \$65,624 gross revenues per year. These farms provide the foundation for a vibrant, outdoor, sustainable cultivation infrastructure in Massachusetts. As it currently stands, the small farmer has been effectively excluded from the Adult Use market. This is in large part due to the technical difficulty of producing outdoor flower that is compliant under the microbe testing thresholds currently set forth in 935 CMR 500.160.

In closing, to repeat the statements above, the current, extremely strict microbe testing protocols set forth under 935 CMR 500.160 contradict the ability of the farmer to grow in a biologically active environment. This, in effect, selects away from the best sustainable cannabis cultivation solutions that are available.

The simple regulatory amendment proposed herein will eliminate a significant barrier to entry for growing cannabis outdoors, which will address many of the concerns about the sustainability of cannabis production, while including the small farmers in the Commonwealth Adult Use market.

⁹<https://www.mass.gov/files/documents/2018/10/19/Pesticide%20Advisory.pdf>

¹⁰<https://www.epa.gov/sites/production/files/2018-01/documents/minrisk-active-ingredients-tolerances-jan-2018.pdf>

¹¹<https://www.mass.gov/info-details/agricultural-resources-facts-and-statistics#current-statistics->

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