State of Connecticut
Regulation of
Department of Consumer Protection
Concerning
Medical Marijuana Laboratory Testing

Section 1. Section 21a-408-60 of the Regulations of Connecticut State Agencies is amended to read as follows:

Sec. 21a-408-60. Laboratory testing

(a) Immediately prior to manufacturing any marijuana product or packaging raw marijuana for sale to a dispensary, a producer shall segregate all harvested marijuana into homogenized batches.

(b) A producer shall make available each such batch at the production facility for a laboratory employee to select a random sample. The laboratory shall test each sample for microbiological contaminants, mycotoxins, heavy metals and pesticide chemical residue, and for purposes of conducting an active ingredient analysis.

(c) From the time that a batch of marijuana has been homogenized for sample testing and eventual packaging and sale to a dispensary facility, until the laboratory provides the results from its tests and analysis, the producer shall segregate and withhold from use the entire batch of marijuana, except the samples that have been removed by the laboratory for testing. During this period of segregation, the producer shall maintain the marijuana batch in a secure, cool and dry location so as to prevent the marijuana from becoming contaminated or losing its efficacy. Under no circumstances shall a producer include marijuana in a marijuana product or sell it to a dispensary facility prior to the time that the laboratory has completed its testing and analysis and provided those results, in writing, to the producer or other designated production facility employee.

(d) A laboratory shall immediately return or dispose of any marijuana upon the completion of any testing, use, or research. If a laboratory disposes of marijuana, the laboratory shall comply with 21a-408-66 of the Regulations of Connecticut State Agencies.

(e) If a sample of marijuana does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical residue test, based on the standards set forth in this subsection, the producer shall dispose of the entire batch from which the sample was taken in accordance with section 21a-408-66 of the Regulations of Connecticut State Agencies.

(1) For the purposes of the microbiological test, a marijuana sample, not less than one gram, shall be deemed satisfactory if [to have passed it satisfies the standards set forth in Section 2023 of]tested using a [validated plating] molecular method that is certified for identifying microbiological DNA and approved by the Association of Official Analytical Collaboration (AOAC) International, which includes quantitative polymerase chain reaction (qPCR), [Federal Food and Drug Association or United States Pharmacopeia,] or tested using an alternative method approved by the [United States Pharmacopeia for all raw products and Section 1111 of the United States Pharmacopeia for all dosage forms other than raw product, which can be obtained at http://www.usp.org.] department [,]. [and] For the purposes of the microbiological test, such samples shall be deemed satisfactory if (i) E. coli, shiga toxin producing E. coli, L. monocytogenes, and salmonella spp. are not detected, (ii) the total aerobic microbial count and total combined yeast and mold count are each equal to or less than 10^5 cfu/g or ml, and (iii)[if the cannabis is intended for inhalation,] the pathogenic *Aspergillus* species *A. fumigatus*, *A. flavus*, *A. niger*, and *A. terreus*

are not detected. Laboratories designated as medical marijuana laboratories as of July 1, 2021 shall have one hundred eighty days from the effective date of this regulation to obtain the necessary equipment and accreditation to comply with the qPCR testing method but shall otherwise meet the standard set forth herein.

(2) For the purposes of the mycotoxin test, a marijuana sample, not less than one half of one gram, shall be deemed [to have passed if it meets] satisfactory if tested using a [validated plating] liquid chromatography- mass spectrometry (LC-MS) or an enzyme-linked immunosorbent assay (ELISA) method approved by the Association of Official Analytical Collaboration (AOAC) International, Federal Food and Drug Association or United States Pharmacopeia, or an alternative method approved by the department, and it contains less than 20 micrograms per kilogram of each of the following [standards:] mycotoxins: aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2, and ochratoxin A. [

Test	**Specification**
Alfatoxin B1	<20 uG/KG of Substance
Alfatoxin B2	<20 uG/KG of Substance
Alfatoxin O1	<20 uG/KG of Substance
Alfatoxin O2	<20 uG/KG of Substance
Ochratoxin A	<20 uG/KG of Substance]

(3) For purposes of the heavy metal test, a marijuana sample shall be deemed to have passed if it meets the following standards:

Metal	**Natural Health Products Acceptable limits uG/KG BW/Day**
Arsenic	<0.14
Cadmium	<0.09
Lead	<0.29
Mercury	<0.29

(4) For purposes of the pesticide chemical residue test, a marijuana sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR 180.

(f) If a sample of marijuana passes the microbiological, mycotoxin, heavy metal and pesticide chemical residue test, the laboratory shall release the entire batch for immediate manufacturing, packaging and labeling for sale to a dispensary facility.

(g) The laboratory shall file with the department an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical

residue test, at the same time that it transmits those results to the producer. In addition, the laboratory shall maintain the laboratory test results and make them available in accordance with section 21a-408-72 of the Regulations of Connecticut State Agencies.

(h) A producer shall provide to a dispensary facility the laboratory test results for each batch of marijuana used in a product purchased by the dispensary facility. Each dispensary facility shall have such laboratory results available upon request to qualifying patients, [primary] caregivers and physicians or APRNs who have certified qualifying patients.

Statement of Purpose

The purpose of this regulation is to update microbial testing standards for medical marijuana to better protect public health and safety. This proposed language creates laboratory testing standards that: (i) prohibit cannabis from entering the market if it has specific microorganisms that are shown to be harmful when inhaled, and (ii) allows for a greater general limit of microorganisms that may be beneficial or not harmful. This proposed change will create clarity and consistency for laboratories and medical marijuana patients.