

**4770.3021 MICROBIOLOGICAL AND MYCOTOXINS TESTING OF DRIED RAW CANNABIS.**

Subpart 1. **Testing required.** Before being packaged, a representative sample from each batch of dried raw cannabis must be tested for microbiological contaminants and mycotoxins using an AOAC-approved technology using appropriate aseptic techniques.

Subp. 2. **Microbiological contaminant tests.** A dried raw cannabis sample passes the microbiological contaminant test if it meets the following standards for microbial and fungal limits in colony forming units per gram (CFU/g):

	Standard
Total viable aerobic bacteria	< 10 <sup>5</sup> CFU/g
Total yeast and mold	< 10 <sup>4</sup> CFU/g
Total coliforms	< 10 <sup>3</sup> CFU/g
Bile-tolerant gram-negative bacteria	< 10 <sup>3</sup> CFU/g
Escherichia coli and salmonella species	Not detected in one gram

Subp. 3. **Mycotoxin tests.** For purposes of the mycotoxin test, a dried raw cannabis sample passes if:

- A. the total of aflatoxin B1, B2, G1, and G2 is less than 20 micrograms per kilogram of substance;
- B. aflatoxin B1 does not exceed five micrograms per kilogram of substance; and
- C. ochratoxin A is less than 20 micrograms per kilogram of substance.

Subp. 4. **Remediation.** A manufacturer must comply with the requirements in this subpart when a sample fails to meet the standards for microbiological contaminant or mycotoxin testing.

A. If a sample from a batch of dried raw cannabis fails microbiological contaminant or mycotoxin testing, the manufacturer may attempt to remediate the batch one time and resubmit a batch sample for testing. If a batch of dried raw cannabis fails microbiological contaminant or mycotoxin testing after remediation, the manufacturer may:

- (1) use the batch to make a medical cannabis concentrate if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon-based solvent or a carbon dioxide closed loop system, or the processing method selectively removes the mycotoxins from the batch; or
- (2) dispose of the batch as medical cannabis waste under part 4770.1200, subpart 2, item A.

B. A batch that is remediated in accordance with this subpart must be resampled and tested in accordance with this chapter.

**Statutory Authority:** *MS s 14.389*

**History:** *46 SR 1011*

**Published Electronically:** *June 15, 2022*