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AND TRIBAL LIAISON



ARCHIVES DIVISION

STEPHANIE CLARK  
DIRECTOR

800 SUMMER STREET NE  
SALEM, OR 97310  
503-373-0701

**TEMPORARY ADMINISTRATIVE ORDER**  
INCLUDING STATEMENT OF NEED & JUSTIFICATION

**PH 43-2023**

CHAPTER 333  
OREGON HEALTH AUTHORITY  
PUBLIC HEALTH DIVISION

**FILED**

09/15/2023 5:01 PM  
ARCHIVES DIVISION  
SECRETARY OF STATE  
& LEGISLATIVE COUNSEL

FILING CAPTION: Standards for Aspergillus Contaminants Compliance Testing on Marijuana Items and Industrial Hemp-Derived Vapor Items

EFFECTIVE DATE: 09/15/2023 THROUGH 03/12/2024

AGENCY APPROVED DATE: 09/15/2023

CONTACT: Oregon Medical Marijuana Program  
971-673-1234  
publichealth.rules@odhsoha.oregon.gov

PO Box 14450  
Portland, OR 97293

Filed By:  
Public Health Division  
Rules Coordinator

NEED FOR THE RULE(S):

The Oregon Health Authority (OHA), Public Health Division, Oregon Medical Marijuana Program (OMMP) is amending OAR 333-007-0390 via temporary rule to remove the requirement for aspergillus testing. OMMP is taking this action in light of a legal challenge to the testing requirement and the issuance of a stay of the requirement on August 25, 2023, by the Oregon Court of Appeals. In addition to removing the testing requirement, the temporary rules make it clear that marijuana items and industrial hemp-derived vapor items that failed for aspergillus and were remediated, or were attempted to be remediated, on or before August 25, 2023, must be resampled and retested for all required tests due to the item either changing forms or undergoing a fundamental change. Retesting an item after remediation ensures the integrity of the item and ensures it meets other testing requirements before being transferred for use by a consumer or patient. Remediated items are not required to be tested for aspergillus. The temporary rules do not affect testing for Shiga toxin-producing Escherichia coli and Salmonella species, and they remain required tests. The temporary rule also specifies that for the purposes of OAR 333-007-0450, any items that were found to contain Aspergillus during testing on or before August 25, 2023, are not considered to have failed a compliance test. It is OHA's intention to enter into rulemaking to make permanent changes prior to the expiration of the temporary rule.

JUSTIFICATION OF TEMPORARY FILING:

In light of the ruling by Court of Appeals staying the aspergillus testing rule, OMMP believes it is necessary to adopt these rules to provide clarity for licensees and registrants in the short term about the status of testing requirements. In addition, with the testing requirement removed, it permits OMMP time, in consultation with the Oregon Liquor and Cannabis Commission and the Oregon Department of Agriculture to reconsider the aspergillus testing requirement. Failure to immediately take rulemaking action may cause cannabis licensees and registrants confusion as to what is required for a compliance test, what testing requirements, if any, remediated products are subject to, and the status of batches where aspergillus was previously detected, potentially leading to unnecessary costs and testing delays. Filing temporary rules immediately will ensure compliance with the testing rules and provide OHA time to do permanent rulemaking.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

ORS chapter 475C: [https://www.oregonlegislature.gov/bills\\_laws/ors/ors475c.html](https://www.oregonlegislature.gov/bills_laws/ors/ors475c.html)

CIAO Order, Court of Appeals No. A181948 (on file with the Agency)

AMEND: 333-007-0390

RULE SUMMARY: OAR 333-007-0390 is being amended to remove the requirement for aspergillus testing. In addition to removing the testing requirement, the rule amendments make it clear that marijuana items and industrial hemp-derived vapor items that failed for aspergillus and were remediated, or were attempted to be remediated, on or before August 25, 2023, must be resampled and retested for all required tests due to the item either changing forms or undergoing a fundamental change. Remediated items are not required to be tested for aspergillus. The rule amendments also specify that for the purposes of OAR 333-007-0450, any items that were found to contain Aspergillus during testing on or before August 25, 2023, are not considered to have failed a compliance test.

CHANGES TO RULE:

333-007-0390

Standards for Microbiological Contaminants Compliance Testing ¶¶

(1) A marijuana item or industrial hemp-derived vapor item required to be tested for microbiological contaminants under OAR 333-007-0320 to 333-007-0342 must be sampled using appropriate aseptic technique and tested by a laboratory for ~~pathogenic Aspergillus flavus, A. fumigatus, A. niger and A. terreus~~, Shiga toxin-producing Escherichia coli and Salmonella species.¶¶

(2) A batch fails microbiological contaminants testing if, during an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1) the laboratory detects:¶¶

(a) ~~The presence of any of the following species of pathogenic molds in one gram of sample: Aspergillus flavus, A. fumigatus, A. niger and A. terreus;~~¶¶

~~(b) Shiga toxin-producing Escherichia coli in one gram; or~~¶¶

~~(c) Salmonella spp. in one gram.~~¶¶

~~(3) Aspergillus speciation testing as required in section (1) of this rule shall be performed using a qPCR analysis or other DNA-based method that has been certified by an independent scientific body.~~¶¶

~~(a) The certification shall show equivalency in terms of fractional recovery with no statistically significant difference between the method and a reference method requiring enrichment such as plate culture. Marijuana items and industrial hemp-derived vapor items tested for Aspergillus on or before August 25, 2023, in accordance with the rules that were in effect at the time, that have a laboratory test report indicating the samples contained pathogenic Aspergillus flavus, A. fumigatus, A. niger and A. terreus that were remediated or were attempted to be remediated must be resampled and retested in accordance with OAR 333-007-0450(6)(c) but are not required to be tested for pathogenic Aspergillus flavus, A. fumigatus, A. niger or A. terreus.~~¶¶

~~(b) Laboratories shall follow the protocol or product instructions provided by the manufacturer, including any enrichment steps. If enrichment is recommended but not required, a marijuana item or industrial hemp-derived vapor item tested for Aspergillus on or before August 25, 2023, in accordance with the rules that were in effect at the time, that have a laboratory test report indicating the samples contained pathogenic Aspergillus flavus, A. fumigatus, A. niger or A. terreus, is not considered to have failed a compliance test for the purposes of OAR 333-007-0450.~~¶¶

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544