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PERMANENT ADMINISTRATIVE ORDER

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CHAPTER 333

OREGON HEALTH AUTHORITY

PUBLIC HEALTH DIVISION

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ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

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

EFFECTIVE DATE: 12/20/2023

AGENCY APPROVED DATE: 12/07/2023

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AMEND: 333-007-0390

REPEAL: Temporary 333-007-0390 from PH 43-2023

NOTICE FILED DATE: 10/27/2023

RULE SUMMARY: OAR 333-007-0390 is being permanently amended to adopt changes from a temporary rule that was filed and effective on September 15, 2023 (Temporary Administrative Order PH 43-2023), 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 on Marijuana items and industrial hemp-derived vapor items tested for Aspergillus on or before August 25, 2023, using a qPCR analysis or~~

other DNA-based method that has been certified by an independent scientific body.¶

~~(a) The certificate of compliance with the rules that were in effect at the time, that have a laboratory test report indicating the samples contained method 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. pathogenic Aspergillus flavus, A. fumigatus, A. niger or 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; the enrichment shall be performed. do 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