PUBLIC HEALTH DIVISION Office of the State Public Health Director

Tina Kotek, Governor



800 NE Oregon Street Portland, OR 97232 Voice: (971) 673-1222 FAX: (971) 673-1299 TTY: 711

Date: December 4, 2023

TO: Rulemaking Commenters – OAR 333-007-0390, "Standards for

Aspergillus contaminant compliance testing on marijuana items and

industrial hemp-derived vapor items"

FROM: Brittany Hall, Administrative Rules Coordinator

cc: Megan Lockwood, Section Manager

Oregon Medical Marijuana Program

SUBJECT: Report on Rulemaking Comment Period

Comment Deadline: November 21, 2023 at 5:00 PM

Purpose of Comment Period: The purpose of this comment period was to receive public comments regarding the Oregon Health Authority (OHA), Public Health Division, Oregon Medical Marijuana Program's proposed permanent amendment of OAR 333-007-0390 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.

Comments Received: Five individuals or organizations submitted written comments to OHA within the period allotted for public comment. These comments are briefly summarized as follows and attached to this report as **Exhibit 1**.

Written comments expressed both concern and support for the removal of the requirement for Aspergillus testing on marijuana items and industrial hemp-derived vapor items.

Written comments requested that Aspergillus testing not be eliminated completely and that a "tolerable" limit be established.

Written comments requested that the rules be further amended to "eliminate requirements for Salmonella and E. coli testing since the significant expense v. limited public safety benefit does not pass muster." Comments further opined that "recent research casts doubt on the need for mycotoxin testing, as well" and "there is now growing evidence that mycotxins [sic] are not a concern in cannabis."

Agency response:

The agency thanks those that provided comment. The Oregon Health Authority (OHA) 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 Appellate Commissioner of the Oregon Court of Appeals. OHA recommends that anyone who has health concerns due to a suspected exposure to aspergillus mold species consult their doctor.

This rulemaking focused solely on the removal of Aspergillus from the testing rules. The rules advisory committee did not discuss nor consider any other changes to the testing rules; therefore, no changes will be made in response to comments received around Salmonella, E. coli, and mycotoxin testing at this time. The agency appreciates these comments. OHA will continue to evaluate regulations to ensure that cannabis products are reasonably safe.

EXHIBIT 1



The Cannabis Industry Alliance of Oregon jesse@ciaoforegon.org

OHA, Public Health Division Brittany Hall, Administrative Rules Coordinator 800 NE Oregon Street, Suite 930 Portland, Oregon 97232

RE Oregon Administrative Rule 333-007-0390

Ms. Hall And the OHA Team,

I am writing to you on behalf of the CIAO Board and our 500+ Member businesses. The CIAO is supportive of the proposed rule to amend OAR 333-007-0390. We strongly support eliminating the Aspergillus testing requirement. In-light-of the lack of scientific justification for QPCR Aspergillus testing, we applaud the proposed rule language.

I want to thank the OHA staff for working with and listening to the cannabis industry and our concerns. We hope to continue working collaboratively to protect consumer safety while ensuring Oregon has a thriving industry providing the highest quality cannabis in the country.

All the best,

Jesse Bontecou Executive Director | Cannabis Industry Alliance of Oregon jesse@ciaoforegon.org | 503-381-7173



Les Helgeson Owner/ Cultivation Manager Green Hills LLC

11/20/2023

OHA, Public Health Division Brittany Hall, Administrative Rules Coordinator 800 NE Oregon Street, Suite 930 Portland, Oregon 97232

RE Oregon Administrative Rule 333-007-0390

Ms. Hall.

I am supportive of the proposed rule to amend OAR 333-007-0390 eliminating the Aspergillus testing requirement. There is currently no scientific justification for the existing rule and the Oregon Court of Appeals found the rule did not meet legal scrutiny, as well.

I would ask that OHA further amend the rule(s) to eliminate requirements for Salmonella and E. coli testing since the significant expense v. limited public safety benefit does not pass muster, as well. These organisms do not occur naturally on cannabis inflorescence and are not transmitted by personnel who follow required management protocols. Nor is there a convincing record of public safety concerns documented in Oregon.

Recent research casts doubt on the need for mycotoxin testing, as well. Required moisture levels absolutely prevent the growth of responsible organisms. There is a substantial body of evidence showing a need for oil rich seeds, etc. as a prerequisite for mycotoxin production in food crops (corn, peanuts, sunflower, etc.). There is now growing evidence that mycotxins are not a concern in cannabis (Bluhm, et al, University of Arkansas, in publication).

In lieu of saddling struggling producers - and ultimately consumers - with unnecessary costs, OLCC/OHA should instead incorporate testing requirements imposed since 2022 into their Reference Lab protocols and base future rule making decisions on concerns identified as such.

From: Michael McKinney
To: Public Health Rules
Subject: Rules Coordinator

Date: Wednesday, November 1, 2023 8:20:57 AM

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Notice of proposed permanent rulemaking – OAR 333-007-0390 Standards for *Aspergillus* contaminant compliance testing on marijuana items and industrial hemp-derived vapor items.

Hopefully, all products that are to be sold should be given the same processes - mould conditions are a problem for many humans of all ages groups.

Yes, this should be changed as the proposition to permanently amend Oregon Administrative Rule 333-007-0390 to adopt changes from a temporary rule that was filed and effective on the date recommendation set within communications

Aspergillus - Genus of fungi

Aspergillus is a genus consisting of several hundred mould species found in various climates worldwide. Aspergillus was first catalogued in 1729 by the Italian priest and biologist Pier Antonio Micheli. Viewing the fungi under a microscope, Micheli was reminded of the shape of an aspergillum, from Latin spargere and named the genus accordingly. Aspergillum is an asexual spore-forming structure common to all Aspergillus species; around one-third of species are also known to have a sexual stage. While some species of Aspergillus are known to cause <u>fungal infections</u>, others are of commercial importance.

OHA, Public Health Division

Brittany Hall, Administrative Rules Coordinator

800 NE Oregon Street, Suite 930

Portland, Oregon 97232

E-mail comments to: publichealth.rules@odhsoha.oregon.gov.

You may also send comments by fax to (971) 673-1299.

Michael McKinney

From: PN Macdhubhsidhe
To: Public Health Rules

Subject: Public comment from Dr. Paula Macfie - OCC subcommittee member - Research + Patient Care

Date: Monday, November 6, 2023 11:27:39 AM

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Permantenly remove aspergilius? No

Creating a reasonable limit with scientific and research advisory. Aspergilius is in our environment and around us every day. For cannabis medical or recreational standards - there needs to be a "tolerable" limit. There will always be "some" aspergillius because it lives all around us in our environment in Oregon. Create an accepted limit. But do NOT completely eliminate it. These August 25th dates, etc..... these are people who want to not lose money. I am so tired of the business/recreational side of cannabis always going after money instead of logical thinking and medical consideration.

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