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DATE: December 13, 2022

TO: Hearing Attendees and Commenters –
OAR 333-064 - "Oregon Environmental Laboratory Accreditation Program (ORELAP) psilocybin accreditation rules"

FROM: Brittany Hall, Hearing Officer

cc: Melissa Powell, Interim Laboratory Business Director
Oregon State Public Health Laboratory

Travis Bartholomew, ORELAP Manager
Oregon State Public Health Laboratory

SUBJECT: Presiding Hearing Officer's Report on Rulemaking Hearing and Public Comment Period

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Hearing Officer Report

Date of Hearing: November 15, 2022, via Microsoft Teams

Purpose of Hearing: To receive testimony regarding the Oregon Health Authority (Authority), Public Health Division, Oregon State Public Health Laboratory's proposed permanent amendments and adoption of Oregon Administrative Rules in chapter 333, division 64, pertaining to psilocybin accreditation.

The proposed rules are being implemented to comply with provisions in Ballot Measure 109 (passed 2020) and ORS chapter 475A which require the Oregon Environmental Laboratory Accreditation Program (ORELAP) to provide standards for testing and accreditation of psilocybin testing laboratories. The rules include requirements for potency, residual solvents, and speciation testing of psilocybin products. The rules include requirements for sampling psilocybin products and reporting psilocybin product test results. The rules also include enforcement actions for violations of the rules. In addition, these proposed changes will amend several sections to include the correct statutory citations.

Hearing Officer: Brittany Hall

Testimony Received: One individual provided oral testimony on this matter during the hearing. These comments are briefly summarized below.

Anjel Craig, Entheogen Lab start-up

Anjel Craig posed a question about proposed OAR 333-064-0140(11) pertaining to noncompliance testing, quoting from rule text "a laboratory that conducts a quality control or research and development test for a manufacturer may use methods not approved by the Authority, but the laboratory may not identify those test results as accredited results." Their question was "since there is going to be a need for manufacturers to have noncompliance research tests to determine their shelf stability and labeling rules, as well as the possibility of using research samples will the testing laboratories be permitted to grow psilocybin or Psilocybe cubensis on their premises for research purposes on site at the testing lab?"

They further quoted from rule text in OAR 333-064-0140(3)(b)(A) "the laboratory must perform initial method validation to include inclusivity and exclusivity testing using whole tissue or cultured organisms. This is to show the laboratory has proficiency with the DNA extraction, replication, and detection processes and can demonstrate the ability to differentiate between the target organism [which would be Psilocybe cubensis] and other organisms that may be found in samples." They questioned "does that mean that we are going to need to culture possible contaminants that could be found in the sample or could we have, say, oyster mushrooms as the negative control."

They also questioned regarding noncompliance testing "whether or not that is going to include potency labeling."

Agency response:
A laboratory is able to culture *Psilocybe cubensis* spores in grain spawn or agar, as this is considered the pre-production process and not manufacturing psilocybin. To clarify this, ORELAP has added the following language into the draft rules under OAR 333-064-0140(3)(b)(A) “Nothing in these rules prohibits testing laboratories from possessing *Psilocybe cubensis* for purposes of method validation and testing.”

The laboratory must perform initial method validation to include inclusivity and exclusivity. Inclusivity validation must be done on genetic material from *Psilocybe cubensis*. Exclusivity validation and negative control material is recommended to be a fungal tissue or cultured organism. It is up to the laboratory to choose an appropriate negative control used for exclusivity validation and batch quality control.

A laboratory can do non-compliance or research and development testing and it can be done in any manner suitable to the laboratory and client. Non-compliance tests cannot be used for compliance reporting purposes and no compliance claims can be made based on that testing. The ORELAP program and rules are not intended to establish rules for labelling of products.

Other Comments: No written comments were submitted to the Authority within the period allotted for public comment, which closed on November 21, 2022, at 5 P.M. Pacific Time.