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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED

03/31/2022 8:40 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Psilocybin Products, Training Curriculum and Testing Rules

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 04/22/2022 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Oregon Psilocybin Services
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800 NE Oregon St.
Portland, OR 97232

Filed By:
Public Health Division
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 04/18/2022

TIME: 5:00 PM - 7:00 PM

OFFICER: Staff

ADDRESS: Virtual hearing via Zoom

Due to COVID-19 all public meetings are
currently being held virtually

Portland, OR 97232

SPECIAL INSTRUCTIONS:

<https://https://www.zoomgov.com/j/1609448818?pwd=SDJZzJSd1BncmhkazJhWDI3TUJkUT09>

Call in: 1-669-254-5252 US

Meeting ID: 160 944 8818

Passcode: 796908

To sign up to provide oral comments at the hearing, please visit

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/April-2022-Public-Comment-Period.aspx>.

OHA welcomes all participants. A Spanish language interpreter and American Sign Language (ASL) interpreter will provide interpretation at the hearings. Live computer-automated captioning and transcription will also be available. If you have any questions about accommodations or need any assistance to participate please email:

OHA.Psilocybin@dhsosha.state.or.us

DATE: 04/21/2022

TIME: 10:00 AM - 12:00 PM

OFFICER: Staff

ADDRESS: Virtual hearing via Zoom

Due to COVID-19 all public meetings are currently being held virtually

Portland, OR 97232

SPECIAL INSTRUCTIONS:

<https://www.zoomgov.com/j/1613853904?pwd=S2ZINVBpMjBNZTBON082VG5kUzBkUT09>

Call in: 1-669-254-5252 US

Meeting ID: 161 385 3904

Passcode: 506462

To sign up to provide oral comments at the hearing, please visit

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/April-2022-Public-Comment-Period.aspx>.

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NEED FOR THE RULE(S)

The Oregon Health Authority, Oregon Psilocybin Services (OPS) section is proposing to adopt administrative rules in chapter 333, division 333. The rules are needed to implement ORS chapter 475A, the Oregon Psilocybin Services Act. The products rules set forth standards for the types of psilocybin products that may be sold and how psilocybin products must be produced. The products rules protect the health and safety of workers who manufacture psilocybin products and clients who consume these products. The act requires Oregon Health Authority to approve training program curriculum for psilocybin facilitators. The training curriculum rules set forth requirements for approval. The act requires Oregon Health Authority to adopt rules establishing standards for testing psilocybin products. The testing rules specify requirements for testing psilocybin products. The rules protect consumer health and safety by ensuring that psilocybin products are properly tested for psilocybin content and do not contain contaminants.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

ORS 475A https://www.oregonlegislature.gov/bills_laws/ors/ors475a.html

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The rules will impact all psilocybin training programs, psilocybin manufacturers, psilocybin service centers, psilocybin facilitators, psilocybin testing laboratories and clients in Oregon. As part of our government-to-government agreements, OHA Tribal Affairs sent a "Dear Tribal Leader Letter" to Oregon's nine federally recognized tribes on December 22, 2021 to gather feedback on the proposed rules.

The products rules describe allowable cultivation methods for psilocybin and specify the types of psilocybin products that will be permitted. While communities that have historically produced and consumed psilocybin products in a manner inconsistent with the rules could be adversely impacted, the products rules are based on public health and safety recommendations. *Psilocybe Cubensis* has been recommended as a safe species of fungi, and it is the only species allowed under the rules. Certain indigenous communities in Mexico have traditionally consumed *Psilocybe Mexicana* a species of fungi that is prohibited under these rules. Currently, OPS does not have any data that suggest these communities are present in Oregon. There are currently no psilocybin licenses in Oregon and OPS cannot predict whether any of the impacted indigenous communities will apply to be licensed in Oregon. The rules could also impact clients who prefer or require alternate delivery methods, such as topicals or suppositories. ORS chapter 475A

consistently uses the term “consume” when referring to psilocybin services and products. The common meaning of this term is to ingest. Therefore, the rules limit psilocybin products to oral delivery only. Individuals with experience in palliative and hospice care participated in the rule making process. OPS will continue to engage these communities to explore making psilocybin services available to all Oregonians regardless of age, ability, or health status.

The training curriculum rules specify training requirements for licensed psilocybin facilitators. Research suggests that psilocybin can be helpful in addressing mental health issues, including trauma and depression. Because people of color can experience adversity, toxic stress, anxiety and trauma due to historic and present colonialism, genocide, racism and oppression, these communities are likely to be impacted more positively when receiving psilocybin services from licensed facilitators that deliver culturally responsive services. The rules require culturally appropriate training for all licensed psilocybin facilitators. Training requirements include history of indigenous use, health equity, cultural equity, racial justice, intergenerational trauma, and implicit bias. These training requirements are designed to ensure that culturally appropriate psilocybin facilitation is available to people of color in Oregon. As such, OPS hopes that the rules will have a positive impact for these communities. OPS has engaged with impacted communities throughout the rule making process. Additionally, the rules were informed by recommendations from the Equity Subcommittee of the Oregon Psilocybin Advisory Board. The rules may have a negative impact on lower income individuals because the scope and cost of required facilitator training could influence the cost of psilocybin services.

The testing rules are likely to impact lower income clients more acutely because the cost of testing could be passed onto clients receiving psilocybin services. There is no data available to suggest that racial populations will use psilocybin services at different rates. OPS engaged communities through the Rules Advisory Committee held on February 24, 2022 and will continue to engage communities via the public comment which concludes on April 22, 2022.

FISCAL AND ECONOMIC IMPACT:

Businesses and state agencies will incur cost to comply with the psilocybin products rules. However, the overall fiscal and economic impact of the rules cannot be quantified at this time. The products rules are necessary to implement ORS chapter 475A. The statute creates the first regulatory framework for licensed manufacture of psilocybin products. Less restrictive rules could carry a lower cost of compliance for manufacturers. However, this lower cost would be coupled with higher risks of negative outcomes for clients, including health and safety concerns, leading to fiscal and economic impact to individuals. Additionally, an appropriately regulated market creates consumer confidence and encourages members of the public to access psilocybin services through the ORS chapter 475A model rather than purchasing from sources in the unregulated market.

The training curriculum rules specify the requirements for training courses to be approved. Applicants for a psilocybin facilitator license must complete an approved training program as a condition of licensure. These rules will have an impact on psilocybin facilitators and training programs. It's difficult to estimate the impact because training programs will set their own costs. If rules for training curriculum were less comprehensive, psilocybin facilitators could conceivably pay lower training costs.

The testing rules require psilocybin products to undergo certain tests before they may be sold. Licensed psilocybin manufacturers will pay costs to perform the required tests. A portion of these costs could ultimately be passed onto clients. Licensed laboratories may need to purchase additional equipment or hire additional staff to achieve accreditation and perform the tests described in these rules. Laboratory costs will affect fees that labs charge for their services, and, therefore, have an indirect impact on psilocybin manufacturers.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the

rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Oregon Psilocybin Services (OPS) will incur costs to evaluate training programs for approval. This activity is required by statute. The extent to which these rules create costs that are beyond the statutory requirements is unknown. OPS will devote resources to inspecting premises, monitoring compliance with product and manufacturing standards, and educating licensees. Oregon Department of Agriculture will incur cost to inspect and license manufacturers who produce food products containing psilocybin. OPS must devote resources to ensuring compliance with testing requirements. Oregon Environmental Laboratory Accreditation Program (ORELAP) must devote resources to accrediting laboratories that perform psilocybin tests. The proposed rules do not create any cost of compliance for units of local government. To the extent that rules increase the cost of manufacturing and testing psilocybin products, those costs could be passed on to members of the public who purchase psilocybin products.

(2)(a) OPS estimates that many training programs and licensed psilocybin businesses will meet the definition of small businesses. However, at this time OPS cannot accurately predict how many training programs and licensed psilocybin businesses will operate.

(b) The products rules require manufacturers to keep records of certain activities. Because most aspects of psilocybin production will be recorded and tracked pursuant to statutory requirements, the additional requirements of these rule provisions do not present a significant increase in total cost of doing business.

Pursuant to the training curriculum rules, training programs are required to keep records of courses delivered and student completion. It is unclear whether these requirements will result in costs that are beyond what is typical for maintenance of ordinary business records. The testing rules direct laboratories and psilocybin manufacturers to keep records of test results and eventually upload those results into the psilocybin tracking system required by statute and maintained by OPS. Because all aspects of psilocybin production will be tracked, the additional requirement of tracking test results does not present a significant increase in cost.

(c) There are currently no licensed psilocybin manufacturers in Oregon. The requirements of the products rules dictate that manufacturers may only manufacture certain products and may only use certain manufacturing techniques once licensed by OPS. These requirements could lead to increased costs for equipment, supplies, labor, and administration. However, OPS cannot predict what portion, if any, of a manufacturer's overall startup cost will be impacted. There are currently no approved psilocybin training programs. The requirements of these rules dictate that training programs must offer minimum hours of instruction and address certain subjects. These requirements could lead to increased costs for labor. However, OPS cannot predict what portion, if any, of a training program's overall start-up cost may be affected. Licensed laboratories may need to purchase additional equipment or hire additional staff to achieve accreditation and perform the tests described in these rules. Psilocybin manufacturers will not require any additional equipment or supplies to comply with the testing rules. In addition to testing fees, psilocybin manufacturers will incur minimal labor cost to order tests and enter records.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses participated in the rules advisory committee.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

333-333-1010, 333-333-2010, 333-333-2020, 333-333-2030, 333-333-2040, 333-333-2050, 333-333-2060, 333-

333-2070, 333-333-2080, 333-333-2100, 333-333-2110, 333-333-2120, 333-333-3005, 333-333-3010, 333-333-3020, 333-333-3030, 333-333-3035, 333-333-3040, 333-333-3050, 333-333-3060, 333-333-3070, 333-333-3080, 333-333-3090, 333-333-7010, 333-333-7020, 333-333-7030, 333-333-7040, 333-333-7050, 333-333-7060, 333-333-7070, 333-333-7080, 333-333-7090, 333-333-7100, 333-333-7110, 333-333-7120, 333-333-7150

ADOPT: 333-333-1010

RULE SUMMARY: OAR 333-333-1010 - Adopts definitions that will be used throughout psilocybin rules.

CHANGES TO RULE:

333-333-1010

Definitions

For purposes of chapter 333, division 333 the following definitions apply:¶

(1) "Adulterant" means chemicals, drugs, plants or substances that alter the potency, intoxicating effect, duration of effect, toxicity or potential for excessive use when added to psilocybin products. Adulterant does not include naturally occurring substances contained in food items such as, but not limited to chocolate.¶

(2) "Authority" means the Oregon Health Authority.¶

(3) "Batch" means a quantity of whole fungi from a harvest lot, or a quantity of psilocybin product from a process lot. ¶

(4) "Capsule" means a small soluble pill, tablet or container that contains liquid or powdered psilocybin product and is intended for human consumption. ¶

(5) "Chemical synthesis" means the production of psilocybin using precursor ingredients rather than cultivation of fruiting bodies and mycelium. ¶

(6) "Edible psilocybin product" means psilocybin extract or homogenized fungi that has been incorporated into a food item or potable beverage.¶

(7) "Extraction" means: ¶

(a) The process of separating psilocybin from fungi by using a solvent; and ¶

(b) Manufacturing psilocybin extracts. ¶

(8) "Fruiting bodies" means the spore producing organs of the fungi *Psilocybe cubensis*.¶

(9) "Fungi" means the fruiting bodies or mycelium of the fungi *Psilocybe cubensis*¶

(10) "Harvest lot" means a specifically identified quantity of fungi that is cultivated and dried under the same conditions and harvested within a 24-hour period at the same location within the licensed premises. ¶

(11) "Homogenized fungi" means dried fruiting bodies or mycelium that have been mixed by powdering or other techniques which uniformly distribute psilocybin throughout the product. Homogenized products may contain inactive ingredients such as binders, dilutants and carrying agents. ¶

(12) "Laboratory" means a laboratory licensed under ORS 475A.594.¶

(13) "Manufacturer" means a manufacturer licensed under ORS 475A.290.¶

(14) "Manure" means animal excreta, alone or in combinations with litter, such as straw and feathers used for animal bedding, for use as a soil amendment or substrate. Manure does not include stabilized compost produced through a controlled composting process. ¶

(15) "Mycelium" means the fungal threads or hyphae of *Psilocybe cubensis*. ¶

(16) "Pesticide" means any substance or mixture of substances included in ORS 634.006(8).¶

(17) "Process lot" means homogenized fungi, psilocybin extract or edible psilocybin product of the same type that was processed at the same time using the same processing method, ingredients, and standard operating procedures. ¶

(18) "Psilocybin" means psilocybin or psilocin.¶

(19) "Psilocybin extract" means: ¶

(a) A substance consisting entirely of solid or liquid psilocybin and may include other compounds which were simultaneously extracted from fruiting bodies or mycelium of *Psilocybe cubensis*; and ¶

(b) A substance consisting of solid or liquid psilocybin and may include other compounds which were simultaneously extracted from fruiting bodies or mycelium of *Psilocybe cubensis* and inactive ingredients that are used to form capsules, tinctures and other oral preparations.¶

(20) "Psilocybin Tracking System" means the system for tracking psilocybin products required by ORS 475A.400. ¶

(21) "Psilocybin product" means psilocybin-producing fungi, mycelium and mixtures or substances containing a detectable amount of psilocybin, including whole fungi, homogenized fungi, psilocybin extract and edible psilocybin products. ¶

(22) "These rules" mean Oregon Administrative Rules, chapter 333, division 333.¶

(23) "Tincture" means a liquid containing psilocybin that consists of either:¶

(a) A non-potable solution of at least 25 percent non-denatured alcohol, that is exempt from the Liquor Control Act under ORS 471.035; or¶

(b) A non-potable solution comprised of glycerin, plant-based oil, syrup and other ingredients.¶

(24) "Whole fungi" means dried fruiting bodies of Psilocybe cubensis, or portions thereof, that have not been homogenized.¶

(25) "Wood chips" mean substrates consisting primarily of wood products that have not been composted.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-2010

RULE SUMMARY: OAR 333-333-2010-Specifies prohibited cultivation methods and growing medium.

CHANGES TO RULE:

333-333-2010

Psilocybin Production

A manufacturer is prohibited from:

- (1) Using manure in cultivation or production of psilocybin products.
- (2) Using wood chips as a growing medium in cultivation or production of psilocybin products.
- (3) Producing psilocybin by using genetically modified organisms such as bacteria.
- (4) Producing psilocybin by chemical synthesis.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235, ORS 475A.290

ADOPT: 333-333-2020

RULE SUMMARY: OAR 333-333-2020-Specifies general sanitary, storage and tracking requirements for psilocybin manufacturers. Prohibits products that appeal to minors.

CHANGES TO RULE:

333-333-2020

General Manufacturer Requirements

(1) A manufacturer must:

(a) Use equipment, counters and surfaces for processing that are food-grade and do not react adversely with any solvent being used.

(b) Construct and maintain counters and surface areas in a manner that reduces the potential development of microbials, molds and unintended fungi and that can be easily cleaned.

(c) Maintain the licensed premise in a manner that is free from conditions which may result in contamination of psilocybin products and that is suitable for safe and sanitary operations.

(d) Store all psilocybin products in a locked area when not in use, including psilocybin products that require refrigeration.

(e) Assign every process lot and harvest lot a unique identification number and enter this information into the Psilocybin Tracking System.

(2) A manufacturer may not produce, transfer or sell a psilocybin product that appeals to minors, including but not limited to:

(a) Products that are modeled after non-psilocybin products primarily consumed by and marketed to children; or

(b) Products in the shape of an animal, vehicle, person or character.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235, ORS 475A.290

ADOPT: 333-333-2030

RULE SUMMARY: OAR 333-333-2030-Specifies types on manufacturer endorsements and application process for endorsements.

CHANGES TO RULE:

333-333-2030

Manufacturer Endorsements

(1) A manufacturer may only produce and sell psilocybin products if the manufacturer has received an endorsement from the Authority for that type of product. Endorsement types are:

(a) Fungi cultivation;

(b) Psilocybin extraction; and

(c) Edible psilocybin production.

(2) An applicant for a manufacturer license must request an endorsement upon submission of an initial application but may also request to add or remove an endorsement at any time following licensure.

(3) To apply for an endorsement, an applicant or licensee must submit a form prescribed by the Authority that identifies the proposed endorsement.

(4) Only one application and license fee are required regardless of how many endorsements an applicant or licensee requests or when the request is made.

(5) An individual manufacturer may hold multiple endorsements.

(6) The Authority may deny a manufacturer's request for an endorsement or revoke an existing endorsement if the manufacturer cannot or does not meet the requirements of these rules. If the Authority denies or revokes approval, the processor has a right to a hearing under ORS chapter 183.

Statutory/Other Authority: ORS 475A.235, ORS 475A.295

Statutes/Other Implemented: ORS 475A.235, ORS 475A.295

ADOPT: 333-333-2040

RULE SUMMARY: OAR 333-333-2040-Prohibits the use of pesticides.

CHANGES TO RULE:

333-333-2040

Pesticides

Manufacturers are prohibited from applying pesticides to fungi or growing medium.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235, ORS 475A.290

ADOPT: 333-333-2050

RULE SUMMARY: OAR 333-333-2050-Prohibits adulterating products with substances that alter potency or duration of effect. Sets standards for products.

CHANGES TO RULE:

333-333-2050

Adulterants

(1) A licensee may not add to psilocybin products any chemical, drug, plant, or substance that has the effect of altering potency, intoxicating effect, duration of effect, toxicity or potential for excessive use, including but not limited to monoamine oxidase inhibitors (MAOI's), beverage alcohol or cannabis. A psilocybin product that has added chemicals, drugs, plants or substances that alter the potency, intoxicating effect, duration of effect, toxicity or addictiveness is considered adulterated.¶

(2) A licensee may not produce, store or transfer adulterated psilocybin products. In addition to the provisions of section (1) of this rule, a psilocybin product may be considered adulterated if:¶

(a) It bears or contains any poisonous or deleterious substance in a quantity rendering the psilocybin product a risk to human health;¶

(b) It bears or contains any added poisonous or deleterious substance exceeding a safe tolerance if such tolerance has been established;¶

(c) It consists in whole or in part of any unsanitary, putrid, or decomposed substance, or is otherwise unfit for human consumption;¶

(d) It is processed, prepared, packaged or held under improper time-temperature conditions or under conditions increasing the probability of contamination with excessive microorganisms or physical contaminants; ¶

(e) It is processed, prepared, packaged, or held under unsanitary conditions increasing the probability of contamination or cross-contamination;¶

(f) It is held or packaged in containers composed, in whole or in part of any poisonous or deleterious substance rendering the contents potentially injurious to health;¶

(g) Any substance has been substituted wholly or in part; ¶

(h) Damage or inferiority has been concealed in any manner; or¶

(i) Any substance has been added, mixed or packaged to make it appear a better or of greater value than it is. ¶

(3) Psilocybin products that are intended for research and development and will not be made available for consumption may be stored in states that are unfit for human consumption.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-2060

RULE SUMMARY: OAR 333-333-2060-Specifies requirements for manufacturing psilocybin extracts, including allowable solvents and production methods. Requires food ingredients to be manufactured at a facility with an appropriate ODA license.

CHANGES TO RULE:

333-333-2060

Psilocybin Extract Manufacturing Requirements

(1) A manufacturer with a psilocybin extraction endorsement may use only water, vegetable glycerin, acetic acids, ethanol and methanol as solvents in extraction. All other solvents are prohibited. ¶

(2) A manufacturer with a psilocybin extraction endorsement may not use denatured alcohol. ¶

(3) A manufacturer with a psilocybin extraction endorsement may not apply pressure or heat over 140 degrees Fahrenheit when manufacturing psilocybin extracts. ¶

(4) If using methanol or ethanol, a manufacturer must process psilocybin extracts in a room with equipment, including all electrical installations that meet the requirements of the Oregon Structural Specialty Code, related Oregon Specialty Codes and the Oregon Fire Code. ¶

(5) If a manufacturer with a psilocybin extraction endorsement produces a psilocybin extract that will be used in an edible psilocybin product, the manufacturer's licensed premises must be licensed by the Oregon Department of Agriculture as a food establishment and must comply with applicable provisions of OAR chapter 603, division 21, division 24, division 25 and division 28.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-2070

RULE SUMMARY: OAR 333-333-2070-Specifies safety requirements for extract manufacturing.

CHANGES TO RULE:

333-333-2070

Psilocybin Extract Manufacturing Safety Procedures

(1) A manufacturer with an extraction endorsement must:

(a) Work in an environment with proper ventilation, controlling all sources of ignition where flammable vapors may be present;

(b) Use only potable water in processing;

(c) Have an emergency eye-wash station, rinse kit and emergency shower in any room in which solvents other than water are used; and

(d) Make appropriate personal protective equipment available to employees.

(2) A manufacturer with a psilocybin extraction endorsement must create and maintain a comprehensive training program that includes the hazards presented by all solvents used at the licensed premises as described in the material safety data sheet for each solvent.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-2080

RULE SUMMARY: OAR 333-333-2080-Specifies requirements for manufacturing edible psilocybin products. Requires food items to be manufactured at a facility with an appropriate ODA license.

CHANGES TO RULE:

333-333-2080

Psilocybin Edible Manufacturing Requirements

(1) A manufacturer with an edible psilocybin production endorsement may only process in a food establishment licensed by the Oregon Department of Agriculture (ODA) and must comply with the applicable provisions of OAR chapter 603, division 21, division 24, division 25 and division 28. ¶

(2) A manufacturer with an edible psilocybin production endorsement may not use a psilocybin product to produce edible psilocybin products unless that psilocybin product was processed or cultivated in a food establishment licensed by the ODA in compliance with the applicable provisions of OAR chapter 603, division 21, division 24, division 25 and division 28.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-2100

RULE SUMMARY: OAR 333-333-2100-Specifies requirements for manufacturer record keeping.

CHANGES TO RULE:

333-333-2100

Psilocybin Manufacturing Records

A manufacturer with a psilocybin extraction, or edible psilocybin production endorsement must create and maintain standard policies and procedures that include but are not limited to: ¶

- (1) Instructions and ingredients for making each psilocybin product;¶
- (2) The procedure for making each process lot homogenous;¶
- (3) If applicable, the procedure for purging and disposing of any solvent or other unwanted product from a psilocybin extract; ¶
- (4) Procedures for conducting necessary safety checks prior to commencing production of psilocybin products;¶
- (5) Procedures for cleaning all equipment, counters and surfaces;¶
- (6) Procedures for preventing growth of pathogenic organisms and toxin formations;¶
- (7) Proper handling and storage of any solvent or other chemical used in processing in accordance with material safety data sheets and other applicable laws;¶
- (8) Proper disposal of any waste produced during processing in accordance with applicable laws, rules and regulations; ¶
- (9) Appropriate use of any necessary safety or sanitary equipment; and ¶
- (10) Emergency procedures to be followed in case of fire, chemical spill or other emergencies.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-2110

RULE SUMMARY: OAR 333-333-2110-Describes allowable and prohibited psilocybin product types.

CHANGES TO RULE:

333-333-2110

Allowable Psilocybin Product Types

(1) A manufacturer with a fungi cultivation endorsement may produce and dry whole fungi, mycelium and homogenized fungi. A manufacturer with a fungi cultivation endorsement may produce fungi in aquatic environments in addition to any substrates and growing mediums allowed by these rules.¶

(2) A manufacturer with a psilocybin extraction endorsement may produce psilocybin extract.¶

(3) A manufacturer with an edible psilocybin production endorsement product may produce edible psilocybin products.¶

(4) A manufacturer may only produce those psilocybin products for which they hold an endorsement.¶

(5) Psilocybin products not included in this rule are prohibited and may not be manufactured, nor possessed by any licensee.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-2120

RULE SUMMARY: OAR 333-333-2120-Requires that psilocybin products must be consumed orally.

CHANGES TO RULE:

333-333-2120

Psilocybin Product Delivery Methods

(1) All psilocybin products must be designed to be consumed by a client orally or delivered via another enteral method. ¶

(2) Psilocybin products designed to be delivered to clients through any method other than orally, including but not limited to, transdermal patches, inhalers, nasal sprays, suppositories and injections, are prohibited.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235

ADOPT: 333-333-3005

RULE SUMMARY: OAR 333-333-3005-Adopts definitions that will be used in psilocybin training rules.

CHANGES TO RULE:

333-333-3005

Psilocybin Training Definitions

As used in OAR 333-333-3010 through OAR 333-333-3090 the following definitions apply: ¶

- (1) "Adverse behavioral reaction" means client behavior that a facilitator reasonably believes may endanger the safety of the client, facilitator, or others. ¶
- (2) "Adverse medical reaction" means a client's physiological reaction occurring during an administration session that a facilitator reasonably believes may lead to medical harm. For example, a cardiac event or other health emergency. ¶
- (3) "Client information form" means the form required by ORS 475A.350. ¶
- (4) "Cultural equity" means values, policies, and practices that ensure all people, especially those who have been historically marginalized based on race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances are considered in the development of social pathways to health equity. ¶
- (5) "Curriculum" means the topics, subjects, and activities that make up courses taught by a training program. ¶
- (6) "Facilitation" means the provision of services to clients by a licensed facilitator during preparation, administration, and integration sessions. ¶
- (7) "Health equity" means opportunity for all people to reach their full health potential and well-being without being disadvantaged by their race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities or other socially determined circumstances. ¶
- (8) "Intervention" means taking proactive steps to respond to the client's behavior, experience, or condition during an administration session. ¶
- (9) "Lead educator" means a person affiliated with a training program who is responsible for tracking the progress of students throughout the program. ¶
- (10) "Nondirective facilitation" means an approach to facilitation in which the facilitator maintains a consistent disposition with a client, while avoiding giving the client direct advice or directly interpreting a client's statements or behaviors. ¶
- (11) "Oregon Psilocybin Services Act" means ORS 475A.210 to ORS 475A.722. ¶
- (12) "Practicum site" means a designated service center that provides practicum training. ¶
- (13) "Practicum site supervisor" means an onsite practicum supervisor of assigned trainees, affiliated with a practicum site. ¶
- (14) "Responsible referral and support" means supporting the personal needs, growth, and wellbeing of others, particularly those going through temporal crises such as houselessness, illness or marginalization. ¶
- (15) "Service Center" means a premises licensed under ORS 475A.305. ¶
- (16) "Scope of practice" means practice boundaries related to psilocybin facilitation and avoiding the unlicensed practice of other disciplines including but not limited to medicine or psychotherapy. ¶
- (17) "Synchronous learning" means that students learn from their instructor at the same time as their fellow students. ¶
- (18) "Training program applicant" means a program that has applied to offer training to psilocybin facilitators as described in ORS 475A.380. ¶
- (19) "Training program" means a program that has been approved to offer training to psilocybin facilitators as described in ORS 475A.380.

Statutory/Other Authority: ORS 475A.235

Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

ADOPT: 333-333-3010

RULE SUMMARY: OAR 333-333-3010-Specifies application process for training programs applying for OHA approval.

CHANGES TO RULE:

333-333-3010

Psilocybin Training Program Approval Process

(1) A training program applicant must submit the following to the Authority to be considered for approval to train psilocybin facilitators:¶

(a) A completed application package, including a description of the proposed curriculum that shows the applicant meets the requirements of OAR 333-333-3050, OAR 333-333-3060, OAR 333-333-3070 and OAR 333-333-3090; and¶

(b) A \$500 non-refundable application evaluation fee paid in the form and manner specified by the Authority.¶

(2) The Authority will notify a training program applicant if their application is incomplete. The training program applicant will have 90 days from the date the notification is issued to submit a complete application. If the training program applicant does not complete their application within 90 days, the Authority will refuse to process the application. If the Authority refuses an application, the applicant may submit a new application, including a non-refundable application evaluation fee, for the program to be considered for approval. ¶

(3) The Authority will evaluate training program applications to determine if the course meets the standards in OAR 333-333-3060 and OAR 333-333-3070.¶

(4) The Authority will notify the training program applicants in writing if the application is approved or denied. ¶

(5) The Authority may deny a training program application for approval or revoke approval of a previously approved training program if:¶

(a) The training program application does not meet the requirements of OAR 333-333-3050, OAR 333-333-3060 and OAR 333-333-3070; or¶

(b) The program instructors, staff or representatives have made false or misleading statements to the Authority, students or the public. ¶

(6) If the Authority denies an application or revokes an approval, the Authority will provide notice of the denial and the training program has a right to a hearing under ORS chapter 183. ¶

(7) Training program approval has a term of five years from the date of initial approval. If the requirements for training program approval change substantively during the term, the Authority may require training programs to resubmit an application for approval.

Statutory/Other Authority: ORS 475A.235, ORS 475A.380

Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

ADOPT: 333-333-3020

RULE SUMMARY: OAR 333-333-3020-Specifies application requirements for training programs applying for OHA approval.

CHANGES TO RULE:

333-333-3020

Psilocybin Training Program Application Requirements

To be approved, training program applicants must:

(1) Demonstrate that its proposed course modules contain the content required by OAR 333-333-3060;

(2) Demonstrate that its proposed hours of instruction meet the requirements of OAR 333-333-3050;

(3) Demonstrate that its proposed practicum meets the requirements of OAR 333-333-3070;

(4) Identify all instructors, including at least two lead educators and list the instructors' qualifications to teach curriculum modules identified in these rules;

(5) Identify a program director who is responsible for tracking student progress and has authority to confer student enrollment and program completion; and

(6) Be located within the United States of America or U.S Territories.

Statutory/Other Authority: ORS 475A.235, ORS 475A.380

Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

ADOPT: 333-333-3030

RULE SUMMARY: OAR 333-333-3030-Specifies requirements for training program instructors.

CHANGES TO RULE:

333-333-3030

Psilocybin Training Instructor Qualifications and Program Performance

(1) In order to be approved, a training program must demonstrate that each instructor and person who trains instructors at a training program must have sufficient experience, knowledge, skills and ability to competently train students in their assigned subject matter. ¶

(2) Sufficient experience, knowledge, skills and ability can be demonstrated via education, certifications, professional experience, personal narratives and references. ¶

(3) Personal narratives and references must be treated as confidential unless an instructor has consented to their publication. ¶

(4) Each instructor at a training program must:¶

(a) Understand the objectives of the training program and be able to communicate effectively with students; and¶

(b) Demonstrate skill in instruction and student supervision.¶

(5) Training programs must notify the Authority of any material changes to the curriculum and staff identified in their application in a form and manner prescribed by the Authority.

Statutory/Other Authority: ORS 475A.235, ORS 475A.380

Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

ADOPT: 333-333-3035

RULE SUMMARY: OAR 333-333-3035-Specifies requirements and application process for training program re-approval.

CHANGES TO RULE:

333-333-3035

Psilocybin Training Reapproval

(1) A training program that wishes to be reapproved upon expiration of their initial approval term must submit a completed reapproval application and a non-refundable \$500 reapproval fee. ¶

(2) The Authority must receive the reapproval application and fee at least 30 days prior to the date that the training program's approval is set to expire. ¶

(3) If the Authority approves reapproval, the reapproval is valid for five years. ¶

(4) The Authority may deny the application for reapproval if:¶

(a) The training program has not complied with these rules; or¶

(b) The training program instructors, staff or representatives have made false or misleading statements to the Authority, students or the public. ¶

(5) If the Authority denies reapproval, the Authority will provide notice of the denial and the program has a right to a hearing under ORS chapter 183.

Statutory/Other Authority: ORS 475A.235, ORS 475A.380

Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

ADOPT: 333-333-3040

RULE SUMMARY: OAR 333-333-3040-Specifies requirements for training program record keeping. Requires that student records are kept confidential and provided to students upon request.

CHANGES TO RULE:

333-333-3040

Psilocybin Training Program Record Keeping

(1) Training programs shall maintain records for each class, including course curriculum, location, date and student attendance for every online and in-person class. These records must be maintained for five years. Training programs shall provide these records to current and former students upon request. Training programs shall provide these records to the Authority upon request. ¶

(2) Training programs shall maintain enrollment records, including the name of each student enrolled, their date of completion and examination results. These records must be maintained for five years. ¶

(3) Training programs shall provide records required to be maintained under this rule to the Authority upon request, and in the manner requested. ¶

(4) Except as required by sections (1) and (3) of this rule, student records shall not be released without the student's written consent.

Statutory/Other Authority: ORS 475A.235, ORS 475A.380

Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

ADOPT: 333-333-3050

RULE SUMMARY: OAR 333-333-3050-Identifies subject matter for core training modules and specifies minimum hours of instruction for each module.

CHANGES TO RULE:

333-333-3050

Psilocybin Training Program Core Requirements

(1) Programs shall provide core training that consists of at least 120 hours of instruction. At least 25 percent of core training hours shall take place in an in-person teaching format. ¶

(2) For training that is not conducted in person, at least 50 percent of the training shall be conveyed through online synchronous learning. ¶

(3) The in-person teaching requirements in section (1) of this rule may be waived by the Authority during a Governor declared emergency or Governor declared public health emergency. ¶

(4) Applicants for training programs must demonstrate that their curriculum consists of the following minimum hours of instruction, in the following areas consistent with the requirements of OAR 333-333-3060: ¶

(a) Historical, Traditional, and Contemporary Practices and Applications: 12 hours. ¶

(b) Cultural Equity in relation to Psilocybin Services: 12 hours. ¶

(c) Safety, Ethics and Responsibilities: 12 hours. ¶

(d) Psilocybin Pharmacology, Neuroscience, and Clinical Research: 8 hours. ¶

(e) Core Facilitation Skills: 16 hours. ¶

(f) Preparation and Orientation: 16 hours. ¶

(g) Administration: 20 hours. ¶

(h) Integration: 12 hours. ¶

(i) Group Facilitation: 12 hours. ¶

(5) Training programs must comply with the requirements specified in these rules to maintain approved status. ¶

(6) The requirements listed in these rules are minimum requirements. Nothing in these rules prevents a training program from offering additional modules or hours of instruction.

Statutory/Other Authority: ORS 475A.235, ORS 475A.380

Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

RULE SUMMARY: OAR 333-333-3060-Identifies detail topics that must be delivered in each core training module.

CHANGES TO RULE:

333-333-3060

Psilocybin Training Curriculum Modules

(1) "Historical, Traditional, and Contemporary Practices and Applications" module shall include:¶

(a) Current and historical use of plant and fungal medicines in indigenous and western cultures;¶

(b) The Controlled Substances Act and its effect on psilocybin research and drug policy; and¶

(c) Overview of historical and recent academic research.¶

(2) "Cultural Equity in relation to Psilocybin Services" module shall include the following subjects and their application during preparation, administration, and integration sessions:¶

(a) Cultural equity, its relationship to health equity and social determinants of health;¶

(b) Racial justice, including the impact of race and privilege on health outcomes and the impact of systemic racism on individuals and communities; ¶

(c) The impact of drug policy on individuals and communities;¶

(d) History of systemic inequity, including systemic inequity in delivery of healthcare, mental health and behavioral health services;¶

(e) Intergenerational trauma; and¶

(f) Responsible Referral and Support¶

(3) "Safety, Ethics, Law and Responsibilities" module shall include the following subjects and their application during preparation, administration, and integration sessions:¶

(a) Awareness of facilitator's personal bias, including examination of facilitator's motives;¶

(b) Training on the Oregon Psilocybin Services Act and related laws, regulations, and professional standards for facilitators; including facilitator scope of practice and expectation of referral when scope of practice is exceeded.¶

¶

(c) Training in ethical issues related to psilocybin facilitation, including: ¶

(A) Oregon's Facilitator Code of Ethics;¶

(B) Ethical considerations relating to equity, privilege, bias and power;¶

(C) Awareness of increased vulnerability associated with altered states of consciousness; ¶

(D) Appropriate use of touch and client consent to physical contact; ¶

(E) Appropriate emotional and sexual boundaries between facilitators and clients both during provision of psilocybin services and at other times, potential harm to clients and consequences for facilitators of breaching those boundaries; ¶

(F) History of abuse of power associated with psychedelics;¶

(G) Financial conflicts of interest and duties to clients; and¶

(H) Reasonable expectations regarding client outcomes.¶

(d) Accurate record keeping and client confidentiality.¶

(e) Awareness of new research related to safety and ethics of providing psilocybin services and resources for professional development following program completion. ¶

(f) Appropriate measures to mitigate risks associated with psilocybin services, including harm reduction, de-escalation, and conflict resolution.¶

(4) "Psilocybin Pharmacology, Neuroscience, and Clinical Research" module shall include:¶

(a) Pharmacodynamics and pharmacokinetics of psilocybin;¶

(b) Drug and supplement interaction;¶

(c) The metabolism of psilocybin and psilocybin products including concentration of psilocybin and psilocin in available psilocybin products; ¶

(d) The primary effects and mechanisms of action of psilocybin on the brain, including connectivity in the brain and activation of serotonin receptors; ¶

(e) Key areas of psilocybin research; and¶

(f) Models of substance use, addiction, and recovery.¶

(5) "Core Facilitation Skills" module shall include the following subjects and their application during preparation, administration, and integration sessions:¶

(a) Client communication, empathy and rapport, including a nondirective facilitation approach, cultural attunement and a nonjudgmental disposition;¶

(b) Response to psychological distress and creating a safe space for difficult emotional experiences;¶

(c) Physical reactions and side effects of psilocybin;¶

(d) Trauma informed care, including physiology of trauma, vicarious trauma, empathic stress and compassion

fatigue;¶

(e) Active monitoring of client-facilitator boundaries specifically boundaries related to consent and touch;¶

(f) Identification and facilitation of a variety of subjective psilocybin experiences, including experiences relating to physiological sensations, cognitive, emotional and mystical states, and traumatic memories;¶

(g) Appropriate modes of intervention, understanding when intervention is necessary, and when a client may need a higher level of care; ¶

(h) Recognizing and addressing adverse behavioral reactions and adverse medical reactions; and¶

(i) Identification of the unique health, psychological and socio-cultural presented by persons with terminal illness; and awareness of the appropriate knowledge, skills and approach needed to provide safe facilitation to such persons in a manner consistent with client goals, values, heritage, and spiritual practices. ¶

(6) "Preparation and Orientation" module shall include: ¶

(a) Informed consent; ¶

(b) Client information form and intake interview, including discussion of client's reasons for seeking psilocybin services;¶

(c) Scope of practice, including using the client Information form to identify clients in need of referral to specialized treatment services;¶

(d) Facilitator role and the limits of facilitator's scope of practice; ¶

(e) Trauma informed interview techniques;¶

(f) Evaluation of client safety concerns, including medical history, contra-indicated medication and psychological instability;¶

(g) Appropriate mitigation strategies to address client safety concerns, including but limited to assessment of client's support system;¶

(h) Client's suitability for psilocybin services; ¶

(i) Safety planning to address client safety concerns;¶

(j) Boundaries between the facilitator and the client including use of touch; ¶

(k) Understanding of how racial and cultural dynamics affect interactions between client and facilitator; and¶

(l) Historical and indigenous modalities of preparation.¶

(7) "Administration" module shall include:¶

(a) Dosing strategies and considerations, including:¶

(A) Experiential differences relating to differing dosages;¶

(B) Physiological considerations in relation to dosage; ¶

(C) Delivery mechanisms of psilocybin;¶

(D) Use of secondary doses.¶

(b) Effectively working with challenging behaviors during session, including:¶

(A) Unexpected client disclosures;¶

(B) Substance-induced psychosis;¶

(C) Suicidality.¶

(c) Traumatic stress and its manifestation during a psilocybin experience and appropriate facilitator response, including:¶

(A) Trauma's relationship to the body;¶

(B) Repressed trauma emerging during a psilocybin experience;¶

(C) Trauma and traumatic stress resulting from systemic oppression;¶

(D) Safety for trauma resolution and risks associated with re-traumatization;¶

(E) Protocols for ensuring facilitator safety and responding to emergencies.¶

(d) "Set and Setting" including environmental considerations for administration session such as lighting sound and temperature; and¶

(e) Completion of administrative session. ¶

(8) "Integration" module shall include: ¶

(a) Identification of appropriate resources and referrals to assist client with integration, including:¶

(A) Interpreting feelings and emotions experienced during administration session;¶

(B) Facilitation of positive internal and external changes;¶

(C) Enhancement of existing supportive relationship. ¶

(b) Identification of client safety concerns;¶

(c) Facilitator scope of practice; and¶

(d) Discussion of appropriate intervals between administration sessions and related safety concerns. ¶

(9) "Group Facilitation" module shall include: ¶

(a) Skills required to facilitate psilocybin group sessions, including, but not limited to:¶

(A) Assessing client's compatibility with group format;¶

(B) Facilitating group communications and dynamics;¶

(C) Group agreements, including confidentiality and safety; and¶¶

(D) Identifying when a client within a group requires individual support, removal from a group, or additional intervention.¶¶

(b) Group Preparation Sessions;¶¶

(c) Group Integration Sessions; and¶¶

(d) Regulatory requirements for group facilitation.

Statutory/Other Authority: ORS 475A.235, ORS 475A.380

Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

ADOPT: 333-333-3070

RULE SUMMARY: OAR 333-333-3070-Specifies training requirements for student practicum.

CHANGES TO RULE:

333-333-3070

Psilocybin Facilitator Practicum Requirements

- (1) Programs shall require students to complete practicum training that provides an opportunity to facilitate and observe the facilitation of non-ordinary states of consciousness.¶
- (2) If a practicum site is available, practicum training shall include placement at a practicum site where students can observe and facilitate psilocybin services under the supervision of a practicum site supervisor. ¶
- (3) Any licensed Service Center can function as practicum site. If a training program uses practicum sites to satisfy the requirements of this rule, the training program shall notify the Authority in a form and manner proscribed by the Authority. ¶
- (4) A practicum site must obtain written client consent prior to allowing a client to be observed by practicum students and prior to sharing any client information with practicum students or a training program. ¶
- (5) The practicum site administrator is primarily responsible for developing students' practicum skills and evaluating students' practicum performance, focusing on direct services with clients.¶
- (6) If a practicum site is not reasonably available or accessible to students, a training program may identify alternative practicum in their application for approval that reasonably approximates training at a practicum site. ¶
- (7) Alternative practicum may include but is not limited to observation of taped facilitation sessions that were recorded with participants' consent, participating in psychedelic peer support organization, role playing, and experience with altered states of consciousness that are not drug-induced, for example breath work, meditation or spiritual journeys. ¶
- (8) Students shall complete a minimum of 40 hours of practicum training, including at least 30 hours of direct practice, and at least 10 hours of consultation relating to the student's direct practice.¶
- (9) Practicum may not include participating in unregulated administration of psilocybin or other unregulated substances where it is unlawful to do so.

Statutory/Other Authority: ORS 475A.235, ORS 475A.380

Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

ADOPT: 333-333-3080

RULE SUMMARY: OAR 333-333-3080-Allows training programs to grant credit for prior training and experience.

CHANGES TO RULE:

333-333-3080

Accelerated Training Hours

(1) Programs may confer upon qualified students accelerated training hours not to exceed 40 percent of the total number of core training hours required by OAR 333-333-3050. ¶

(2) Accelerated training hours may be awarded based on students' professional credentialing, prior training and education, or relevant experiences such as practicing in established plant or fungi-based healing traditions. ¶

(3) Training programs that offer accelerated training hours must establish and document criteria for conferring accelerated hours to qualifying students. ¶

(4) Student transcripts and other records shall document the number and type of accelerated training hours conferred to each student. ¶

(5) Training programs may not offer accelerated training for the following modules: ¶

(a) "Cultural Equity in relation to Psilocybin Services;" ¶

(b) "Safety, Ethics and Responsibilities;" or ¶

(c) "Preparation and Orientation."

Statutory/Other Authority: ORS 475A.235, ORS 475A.380

Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

ADOPT: 333-333-3090

RULE SUMMARY: OAR 333-333-3090-Specifies requirements for training program completion. Requires programs to administer a comprehensive exam for students to complete the program.

CHANGES TO RULE:

333-333-3090

Training Program Completion and Exams

(1) Training programs shall maintain a level of training for students such that students who successfully complete the program's training could reasonably expect to possess the knowledge and skills required to practice as a facilitator.¶

(2) Training programs must administer a comprehensive skills-based exam and every student must receive a passing score, established by the training program, as a condition of completing the training program.¶

(3) The exam required by section (2) of this rule is in addition to the exam required by ORS 475A.330.¶

(4) Training programs shall provide every student written confirmation of program completion signed by a lead educator upon the student's successful completion of the program, including:¶

(a) Student's full name;¶

(b) Date of completion; and¶

(c) Name and location of the training program.

Statutory/Other Authority: ORS 475A.235, ORS 475A.380

Statutes/Other Implemented: ORS 475A.235, ORS 475A.380

ADOPT: 333-333-7010

RULE SUMMARY: OAR 333-333-7010-Describes purpose of psilocybin testing rules.

CHANGES TO RULE:

333-333-7010

Psilocybin Testing: Purpose

(1) The purpose of these rules is to establish minimum compliance testing standards for psilocybin products. ¶

(2) A person licensed under ORS 475A.290, 475A.305, or 475A.325 may not transfer, accept or provide a psilocybin product unless it has been sampled and tested in accordance with these rules.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

ADOPT: 333-333-7020

RULE SUMMARY: OAR 333-333-7020-Describes process for ordering required tests.

CHANGES TO RULE:

333-333-7020

Ordering Tests

(1) A manufacturer must provide to a laboratory, prior to the laboratory taking samples, the following information:¶

(a) The manufacturer's license number and endorsement type;¶

(b) The manufacturer's name, address and contact information;¶

(c) Type of psilocybin product;¶

(d) Batch numbers to be sampled;¶

(e) Harvest lot number associated with the batch number, if applicable;¶

(f) Process lot number associated with the batch number, if applicable;¶

(g) Total mass or volume of each batch to be sampled; and¶

(h) Identification of tests requested.¶

(2) If the manufacturer informs a laboratory that a psilocybin product is being re-sampled after a failed test, the manufacturer must provide the laboratory with documentation of the failed test.¶

(3) A manufacturer is responsible for ordering the compliance tests necessary to comply with these rules.¶

(4) A manufacturer may not order more than one compliance test for the same harvest lot, process lot or psilocybin product except as allowed under OAR 333-333-7120.¶

(5) A manufacturer violates these rules if they:¶

(a) Fail to provide information required in these rules to a laboratory.¶

(b) Submit false or misleading information to a laboratory.¶

(6) Tests ordered under these rules expire after one year. If a test has expired, the psilocybin product must be tested again before it can be sold to a client, transferred to another licensee, or converted to another product type.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

ADOPT: 333-333-7030

RULE SUMMARY: OAR 333-333-7030-Describes testing required to ensure that psilocybin products consist only of the species Psilocybe Cubensis.

CHANGES TO RULE:

333-333-7030

Speciation Testing

(1) A manufacturer must order a test for a batch taken from the first harvest lot recorded in a calendar year to ensure that the lot consists only of Psilocybe cubensis. This test must be performed prior to transferring the harvest lot to another licensee or converting the harvest lot to another product type. ¶

(2) Following the test described in section (1) of this rule, a manufacturer must order tests for one batch harvested in each month that a harvest lot is recorded to ensure that the lot consists only of Psilocybe cubensis. ¶

(3) A batch fails speciation testing if the test demonstrates that the fungi is a species other than Psilocybe cubensis. ¶

(4) If a batch fails speciation testing, a manufacturer must order tests for every harvest lot for a period of 12 months following the failed test to ensure that batches consist only of Psilocybe cubensis. This test must be performed prior to transferring the harvest lot to another licensee or converting the harvest lot to another product type. ¶

(5) In addition to the requirements of section (1) of this rule, a manufacturer must submit one or more batches from a harvest lot or process lot for speciation testing upon written request by the Authority.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

ADOPT: 333-333-7040

RULE SUMMARY: OAR 333-333-7040-Describes testing required to measure product potency, i.e., amount of psilocybin and psilocin.

CHANGES TO RULE:

333-333-7040

Potency Testing

(1) A manufacturer must order tests for every batch of finished psilocybin product from a harvest lot or process lot to determine the concentration (potency) of psilocybin and psilocin in the product.¶

(2) A process lot of homogenized fungi, psilocybin extract or edible psilocybin product fails potency testing if the amount of psilocybin or psilocin between samples taken from the batch exceeds 20 percent relative standard deviation between sample increments.¶

(3) In addition to the requirements of section (1) of this rule, a manufacturer must submit one or more batches from a harvest lot or process lot for potency testing upon written request by the Authority.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

ADOPT: 333-333-7050

RULE SUMMARY: OAR 333-333-7050-Describes testing required to ensure that psilocybin products do not contain dangerous levels of residual solvents.

CHANGES TO RULE:

333-333-7050

Solvent Testing

(1) If methanol or acetic acid are used to manufacture psilocybin extract, a manufacturer must order tests for methanol or acetic acid for every process lot of psilocybin extract prior to selling or transferring the psilocybin extract or converting to another product type. ¶

(2) A batch fails solvent testing if a laboratory detects the presence of methanol above 3000 µg/g or acetic acid above 5000 µg/g in any sample. ¶

(3) If a sample from a batch fails solvent testing, the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level. ¶

(4) A batch that is remediated in accordance with section (3) of this rule, must be re-sampled and re-tested for solvents in accordance with these rules. ¶

(5) In addition to the requirements of section (1) of this rule, a manufacturer must submit one or more batches from a process lot for solvent testing upon written request by the Authority.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

ADOPT: 333-333-7060

RULE SUMMARY: OAR 333-333-7060-Describes requirements and process for pesticide testing.

CHANGES TO RULE:

333-333-7060

Pesticide Testing

(1) A manufacturer must submit one or more batches from a harvest lot or process lot for pesticide testing upon written request by the Authority. ¶

(2) A batch fails pesticide testing if the test detects the presence of a pesticide above action levels in any sample, including a field duplicate:¶

(a) During an initial test where no reanalysis is requested; or¶

(b) Upon reanalysis as described in OAR 333-333-7120.¶

(3) If a sample from a harvest lot or process lot fails pesticide testing, the batch may not be remediated and must be destroyed.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

ADOPT: 333-333-7070

RULE SUMMARY: OAR 33-333-7070-Describes requirements and process for microbial contaminant testing

CHANGES TO RULE:

333-333-7070

Contaminant Testing

- (1) A manufacturer must submit one or more batches from a harvest lot or process lot for contaminant testing upon written request by the Authority. ¶
- (2) A psilocybin product required to be tested for contaminants under these rules must be sampled using appropriate aseptic technique and tested for total coliform count. ¶
- (3) If the presence of any fecal coliforms is detected the sample must be assessed for Escherichia coli (E. Coli) ¶
- (4) A batch fails microbial contaminant testing if the presence of E. Coli at more than 100 colony forming units per gram is detected in a sample. ¶
- (5) A psilocybin product required to be tested for contaminants may also be tested for aflatoxins and other harmful mycotoxins. ¶
- (6) A psilocybin product fails testing for aflatoxins and other harmful mycotoxins if the tests detect mycotoxins at levels that are unsafe for human consumption. ¶
- (7) If a sample from a batch of psilocybin product fails contaminant testing, the batch may not be remediated and must be destroyed.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

ADOPT: 333-333-7080

RULE SUMMARY: OAR 333-333-7080-Describes requirements and process for testing for heavy metals in psilocybin products.

CHANGES TO RULE:

333-333-7080

Heavy Metals Testing

(1) A manufacturer must submit one or more batches from a harvest lot or process lot for heavy metal testing upon written request by the Authority. ¶

(2) A harvest lot or process lot required to be tested for heavy metals may be tested for lead, cadmium, mercury and arsenic. ¶

(3) A batch fails heavy metal testing if the presence of metals above the limits in section (4) of this rule are detected in any sample, including a field duplicate:¶

(a) During an initial test where no reanalysis is requested; or¶

(b) Upon reanalysis as described in OAR 333-333-7120.¶

(4) The limits for heavy metal testing are:¶

(a) Lead (Pb) above .5 ¶g/g.¶

(b) Cadmium (Cd) above .2 ¶g/g.¶

(c) Arsenic (As) above .2 ¶g/g.¶

(d) Mercury (Hg) above .1 ¶g/g.¶

(5) If a sample from a batch of psilocybin product fails heavy metal testing, the batch may not be remediated and must be destroyed.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

ADOPT: 333-333-7090

RULE SUMMARY: OAR 333-333-7090-Specifies requirements for identifying and documents testing batches.

CHANGES TO RULE:

333-333-7090

Psilocybin Batch Requirements

(1) A manufacturer must separate each harvest lot of dried whole fungi into batches no larger than one kilogram.¶

(2) A process lot for psilocybin extracts, homogenized fungi or edible psilocybin products is considered a batch.¶

(3) A manufacturer must assign each batch a unique batch number and that unique batch number must be:¶

(a) Documented and maintained in the manufacturer's records for at least three years and available to the Authority upon request;¶

(b) Provided to the individual responsible for taking samples; and¶

(c) Included in the batch labels required by OAR 333-333-7110.¶

(4) A manufacturer may not reuse a unique batch number.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

ADOPT: 333-333-7100

RULE SUMMARY: OAR 333-333-7100-Specifies requirements for sampling psilocybin products for testing.

CHANGES TO RULE:

333-333-7100

Psilocybin Product Sampling Requirements

(1) Whole fungi.¶

(a) Whole fungi may only be sampled after it is dried, regardless of whether the whole fungi will be processed into another product type. ¶

(b) Sample increments taken must in total represent a minimum of 2.0 percent of the batch, consistent with the laboratory's accredited sampling policies and procedures. ¶

(2) Other product types.¶

(a) Samples of psilocybin extracts, homogenized fungi, and edible psilocybin products intended for use by a client must be taken from the finished product. ¶

(b) Sufficient sample increments from a batch must be taken to determine whether the batch is homogenous and must be taken in a manner consistent with the laboratories sampling policies and procedures. ¶

(c) A sufficient sample size must be taken for analysis of all requested tests and the quality control performed by the testing laboratory for these tests. ¶

(3) Sufficient sample increments must be taken for analysis of all required tests and the quality control performed by the testing laboratory for these tests. ¶

(4) Only individuals employed by a laboratory with an ORELAP accredited scope item for sampling under these rules may take samples. ¶

(5) Sampling may be conducted at a manufacturer's licensed premises, or the manufacturer may transport the batch to a laboratory with an ORELAP accredited scope item for sampling under these rules.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

ADOPT: 333-333-7110

RULE SUMMARY: OAR 333-333-7110-Specifies requirements for labeling and storage of psilocybin products that have not been tested.

CHANGES TO RULE:

333-333-7110

Requirements for Pre-Tested Psilocybin Products

(1) Following samples being taken from a harvest or process lot a manufacturer must:

(a) Label the batch with the following information:

(A) The harvest or process lot unique identification number;

(B) The name of the laboratory that took samples and the name of the laboratory responsible for testing, if different;

(C) The test batch or sample unique identification numbers supplied by the laboratory;

(D) The date the samples were taken; and

(E) In bold, capital letters, no smaller than 12-point font, "PRODUCT NOT TESTED."

(b) Store and secure the batch in a manner that prevents the product from being tampered with or transferred prior to test results being reported; and

(c) Be able to easily locate a batch stored and secured under subsection (1)(b) of this rule and provide that location to the Authority or a laboratory upon request.

(2) If the samples pass testing, the product may be sold or transferred in accordance with applicable rules.

(3) If the samples do not pass testing, the manufacturer must comply with OAR 333-333-7120.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

RULE SUMMARY: OAR 333-333-7120-Describes process and required actions for failed product tests. Allows for retesting in some circumstances.

CHANGES TO RULE:

333-333-7120

Failed Test Samples

(1) If a sample or a field duplicate sample (collectively referred to as "sample" for purposes of this rule) fails any initial test, the laboratory that did the testing may reanalyze the sample. The laboratory that did the initial test may not subcontract the reanalysis. If a primary sample or a field duplicate sample fails, both must be reanalyzed. If the sample passes, another laboratory must resample the batch and confirm that result for the batch to pass testing.

(a) If a manufacturer wishes to have a sample reanalyzed, the manufacturer must request a reanalysis within seven calendar days from the date the laboratory sent notice of the failed test to the manufacturer. The reanalysis must be completed by the laboratory within 30 days from the date the reanalysis was requested.

(b) If a manufacturer has requested a reanalysis in accordance with subsection (1)(a) of this rule and the sample passes, the manufacturer has seven calendar days from the date the laboratory sent notice of the passed test to request that another laboratory resample the batch and confirm the passed test result. The retesting must be completed by the second laboratory within 30 days from the date the retesting was requested.

(c) A manufacturer must inform the Authority immediately, of the following, in a manner prescribed by the Authority:

(A) A request for reanalysis of a sample;

(B) The testing results of the reanalysis;

(C) A request for retesting; and

(D) The results of retesting.

(2) If a sample fails a test or a reanalysis under section (1) of this rule the batch:

(a) May be remediated in accordance with these rules; or

(b) If it is not or cannot be remediated under this rule, must be destroyed in a manner specified by the Authority.

(3) If a manufacturer is permitted to remediate under this rule, the manufacturer must provide notice to the Authority of the registrant's intent to remediate.

(4) A psilocybin extract that is permitted to undergo remediation cannot be further processed into a psilocybin product during the remediation process.

(5) Failed microbiological contaminant testing. If a sample from a batch psilocybin product fails microbial contaminant testing the batch may not be remediated and must be destroyed as ordered by the Authority.

(6) Failed solvent testing.

(a) If a sample from a batch fails solvent testing the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level.

(b) A batch that is remediated in accordance with subsection (a) of this section must be re-sampled and re-tested in accordance with these rules and must be tested if not otherwise required for that product under these rules, for solvents and pesticides.

(c) A batch that fails solvent testing that is not remediated or that if remediated fails testing must be destroyed in a manner specified by the Authority.

(7) Failed pesticide testing. If a sample from a batch of psilocybin product fails pesticide testing the batch may not be remediated and must be destroyed as ordered by the Authority.

(8) Failed heavy metal testing. If a sample from a batch of psilocybin product fails heavy metal testing the batch may not be remediated and must be destroyed as ordered by the Authority.

(9) Failed potency testing. A psilocybin product that fails potency testing under OAR 333-333-7040 may be re-mixed in an effort to meet the standards in OAR 333-333-7040. A psilocybin product that is re-mixed must be re-sampled and re-tested in accordance with these rules.

(10) If a sample fails a test after undergoing remediation as permitted under this rule the batch must be destroyed in a manner approved by the Authority.

(11) A manufacturer must inform a laboratory prior to samples being taken that the batch has failed a test and is being retested after undergoing remediation.

(12) A manufacturer must document all sampling, testing, remediation and destruction that are a result of failing a test under these rules.

(13) If a batch fails a test under these rules a manufacturer:

(a) Must store and segregate the batch in a secure area and label the batch clearly to indicate it has failed a test and the label must include a test batch number.

(b) May not remove the batch from the registered premises without permission from the Authority.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590

ADOPT: 333-333-7150

RULE SUMMARY: OAR 333-333-7150-Specifies process for quality control testing, i.e., tests that are not required by rule.

CHANGES TO RULE:

333-333-7150

Quality Control and Research and Development Testing

(1) A manufacturer may request that a laboratory conduct testing for the purpose of assuring quality control or research and development, except as provided in section (2) of this rule.¶

(2) A manufacturer may not request that a laboratory conduct pesticide testing on psilocybin products for the purpose quality control or for research and development. A pesticide test is always a compliance test. ¶

(3) A manufacturer that submits a psilocybin product for quality control or research and development testing is not subject to OAR 333-333-7010 to OAR 333-333-7120.¶

(4) A laboratory result from a quality control or research and development test cannot be used as a compliance test result. A psilocybin product that has undergone a quality control or research and development test may not be transferred or sold. ¶

(5) Manufacturers must retain all quality control and research and development test results for at least two years and provide copies of such results upon request to the Authority.

Statutory/Other Authority: ORS 475A.235, ORS 475A.590

Statutes/Other Implemented: ORS 475A.235, ORS 475A.590