

## Discussion Draft, Prepared for February 2022 RAC Meetings

### **Psilocybin Testing: Purpose (333-333-7010)**

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

(2) A person licensed under Ballot Measure 109 (2020) Section 23, 26 or 30 may not transfer, accept or provide a psilocybin product unless it has been sampled and tested according to these rules.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96

Statutes Implemented: Ballot Measure 109 (2020), Section 96

### **Ordering Tests (333-333-7020)**

(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 tests necessary to comply with these rules.

(4) A manufacturer may only order tests for psilocybin products that the manufacturer has produced.

(5) A manufacturer may not order more than one test for the same psilocybin item except as allowed under OAR 333-333-7120.

(6) 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.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96

Statutes Implemented: Ballot Measure 109 (2020), Section 96

### **Speciation Testing (333-333-7030)**

(1) A manufacturer must order tests for every harvest lot to ensure that the lot consists only of *Psilocybe cubensis* prior to transferring the harvest lot to another licensee or converting the harvest lot to another product type.

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

(3) In addition to the requirements of (1), 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 Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96

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Statutes Implemented: Ballot Measure 109 (2020), Section 96

### **Potency Testing (333-333-7040)**

- (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.
- (3)** In addition to the requirements of (1), 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 Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96

Statutes Implemented: Ballot Measure 109 (2020), Section 96

### **Solvent Testing (333-333-7050)**

- (1)** If methanol is used to manufacture psilocybin extract, a manufacturer must order tests for methanol 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 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 (1), a manufacturer must submit one or more batches from a harvest lot or process lot for solvent testing upon written request by the Authority.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96

Statutes Implemented: Ballot Measure 109 (2020), Section 96

### **Pesticide Testing (333-333-7060)**

- (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 batch of psilocybin product fails pesticide testing, the batch may not be remediated and must be destroyed.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96

Statutes Implemented: Ballot Measure 109 (2020), Section 96

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### **Microbiological Contaminant Testing (333-333-7070)**

- (1) A manufacturer must submit one or more batches from a harvest lot or process lot for microbiological contaminant testing upon written request by the Authority.
- (2) A psilocybin product required to be tested for microbiological contaminants under these rules will be sampled using appropriate aseptic technique and tested for total coliform count.
- (3) If the presence of any coliforms is detected the sample will 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) If a sample from a batch of psilocybin product fails microbial contaminant testing, the batch may not be remediated and must be destroyed.

Statutory Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96

Statutes Implemented: Ballot Measure 109 (2020), Section 96

### **Heavy Metals Testing (333-333-7080)**

- (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 will be tested for lead, cadmium, mercury and arsenic.
- (3) A batch fails heavy metal testing if the presence of metals above the limits in (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 3.0 µg/g;
  - (b) Cadmium (Cd) above .2 µg/g;
  - (c) Arsenic (As) above .2 µg/g;
  - (d) Mercury (Hg) above .1 µg/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 Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96

Statutes Implemented: Ballot Measure 109 (2020), Section 96

### **Psilocybin Batch Requirements (333-333-7090)**

- (1) A manufacturer must separate each harvest lot of dried whole fungi into batches no larger than five pounds.
- (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 two years and available to the Authority upon request;

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- (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 Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96  
Statutes Implemented: Ballot Measure 109 (2020), Section 96

### **Psilocybin Product Sampling Requirements (333-333-7100)**

#### **(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 Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96  
Statutes Implemented: Ballot Measure 109 (2020), Section 96

### **Requirements for Pre-Tested Psilocybin Products (333-333-7110)**

- (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

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(c) Be able to easily locate a batch stored and secured under section (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 Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96

Statutes Implemented: Ballot Measure 109 (2020), Section 96

### Failed Test Samples (333-333-7120)

(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.

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- (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 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.
- (9)** 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.
- (10)** 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.
- (11)** A manufacturer must document all sampling, testing, remediation and destruction that are a result of failing a test under these rules.
- (12)** 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 Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96

Statutes Implemented: Ballot Measure 109 (2020), Section 96

### **Quality Control and Research and Development Testing (OAR 333-333-7150)**

- (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 Authority: Ballot Measure 109 (2020), Section 8(2)(c) and Section 96

Statutes Implemented: Ballot Measure 109 (2020), Section 96