

## **Outline: Psilocybin Propagation and Production Framework**

### **I. Purpose and Scope**

- Establish a regulated framework for the lawful propagation, production, testing, and preparation of psilocybin products in New Mexico.
- Emphasize public health, safety, consistency, and traceability.
- Minimize duplication by utilizing existing state, county, and municipal licensing and inspection authorities.

### **II. Authorized Species**

- Whole mushroom fruiting bodies shall be harvested for use in this program. Mycelial biomass products are prohibited.

### **III. Permit Structure**

#### **A. Primary Psilocybin Production Permit**

- Permits Issued by the Department
- Required for production, which includes:
  - Cultivation
  - Harvesting
  - Processing (i.e., homogenizing)
  - Packaging
- Applying persons can apply for one or any aspects of the permit
- Demonstrate psilocybin containing mushrooms/products are kept in a secure location; i.e.
  - Double locks
  - Video surveillance
  - Alarm system
  - Commercial grade locks
  - Keypad entry?

#### **B. Business, Facility, and Occupancy Compliance**

- Proof of ownership of the land/facility or written approval from the owner (i.e., lease specifying use to include psilocybin cultivation/production)
- Business License in the State of New Mexico
- Proof of Registration with NM Secretary of State
- Registration with NM Tax and Revenue
- Local Building and Safety Authorities

- Certificate of Occupancy
- Fire code compliance
- Electrical and HVAC inspection
- \*No new psilocybin-specific building standards unless explicitly necessary.

### **C. Zoning and Municipal Permits**

- Must be within the geographical boundaries of New Mexico
- City and County Planning / Zoning Departments
  - Land use approval
  - Conditional use permits where applicable – i.e., City of Albuquerque raw food permit
- Food safety training certification for employees
- Note: Local governments retain zoning authority consistent with existing agricultural or light industrial classifications.

### **D. Agricultural:**

- New Mexico Department of Agriculture (NMDA)
  - Utilize Pest and contamination mitigation guidance
- Production is treated analogously to controlled-environment agriculture

## **IV. Cultivation Standards**

### **A. Growth Medium**

- Growth medium is not restricted
  - All substrates and inputs must be:
    - Documented
    - Tracked
    - Fully disclosed on final product labeling

### **B. Environmental Controls**

- Indoor or controlled-environment cultivation required
- No pesticides utilized
- Other substances determined harmful by the Department

## **V. Harvesting, Processing, and Homogenization**

### **A. Batch Definition**

- A “batch” is defined as harvested and homogenized under uniform conditions utilizing best practices at no more than 1 kilogram after drying over a 4-week period.
- Batches must be fully homogenized prior to testing.

## **B. Homogenization Requirements**

- Physical homogenization is required to ensure consistent potency across the batch.
- Purpose:
  - Accurate potency testing
  - Reduction of dose variability

## **VI. Testing and Quality Assurance**

### **• A. Testing Authority**

- Testing is performed by Department permitted laboratories
- Requirements for laboratories to be permitted
  - Cannabis testing laboratories which have been approved (submit SOP/IDCs and process for extraction) and similar pathway for those who are not a cannabis testing laboratory; or,
  - ISO/IEC 17025 or NELAC/TNI (<https://nelac-institute.org/index.php>) accredited labs; or,
  - Labs approved or overseen by the Department i.e., State Lab Division
- Ensure proficiency and verification testing annually
- The Department can require samples to be conducted by additional labs for validation purposes

### **B. Required Testing Panels**

- Testing occurs once the batch is homogenized
- Cultivators must submit a sample of each homogenized batch and may be between 2-5 grams as required by the testing laboratory sampling procedures
- Product will need to be re-tested one year after the initial test date
- The Department can require additional tests if there are complaints, concerns, or at random;
- No cultivation or processing facility will be asked to test more than 4 times a year with regard to the random testing; except if there are contaminants or false statements made by the organization/facility or on the labels
- Potency Testing
  - Psilocin

- Psilocybin
    - Baeocystin, norbaeocystin and aeruginascin
- Contaminant Testing
  - Microbial contamination (examples)
    - E. coli
    - Salmonella
  - Heavy metals (this is an example)
    - The limits for heavy metal testing are:
      - Arsenic (As) above .2 µg/g.
      - Cadmium (Cd) above .2 µg/g.
      - Lead (Pb) above .5 µg/g.
      - Mercury (Hg) above .1 µg/g.
  - Pesticides/fungicides
  - Synthetic tryptamine screening - upon request of the department in the event there is suspicion of it having been added.
- The department can stagger the implementation of testing as laboratories are permitted and are able to provide validation of testing.

### **C. Batch Release**

- Only batches that pass all required testing may be released for use

**Note: the next sections are to be reviewed during the 2/18 committee meeting and are not yet recommendations (to be updated after review).**

## **VII. Food Preparation and Product Handling**

### **A. Applicability**

- Any conversion of raw material into ingestible or prepared products subject to food safety oversight.
- Environmental Health / Food Safety Divisions
  - Food safety and handling training/certification
- No exemption from standard food safety requirements.

## **VIII. Labeling, Packaging, and Traceability (tracking)**

### **A. Packaging**

- Sealed
- Labeled

## **B. Required Label Elements**

- The label must be printed or affixed on the product package and must include:
  - Contain all required information in a legible font at least eight points.
  - Be in English, though it may also be provided in other languages.
  - Be unobstructed and clearly visible.
- The producer's business name and permit number.
- The type of product (ie, homogenized fungi)
- The species name of the fungi
- The net quantity of contents using the metric system of measurement
- The potency of psilocybin analytes contained in the product, expressed in milligrams, and calculated using laboratory test results.
- Total Potential Psilocyn (report both or one of TPP or TPE)
- Total Psilocybin Equivalent
- A logo designed and provided by the department that notifies a reasonable person that the product contains psilocybin that is no smaller than 1/2 inch by 1/2 inch.
- A unique identification number of the product lot, and the state track and trace system number or identifier associated with the product;
- The expiration date; and,
- The statement: "The risks, benefits, drug interactions, and effects of psilocybin are not fully understood. Individual results may vary."
- The statement "Keep out of the reach of children.
- The statement "Do not drive a motor vehicle or operate machinery while under the use of psilocybin."

## **C. Product Information Document**

- A product information document must be available that lists the following information in English on a printed or electronic document in 12-point font or larger: All of the requirements for the product label;
- A statement regarding the number of years the business has been established in New Mexico and a statement declaring the state and country of residency, including length of time, of their primary investors; Results of all laboratory tests conducted on the homogenized batch; Date of homogenization;
- The type and composition of the growth medium used, including type of grain, soil, compost, pesticides, and other inputs;
- Date of manufacture or processing of the final product;
- List of all active and inactive ingredients in descending order of predominance by weight or volume;
- Growth medium used;

- List of potential major food allergens which might be contained in the product or in the growth medium;
- Identify the intended use and directions for use; and,
- A description of how the product should be stored;
- The following statement: “This product is not approved by the FDA to treat, cure, or prevent any disease. FDA has not evaluated this product for safety, effectiveness, and quality. There may be long term adverse health effects from consumption of psilocybin, including additional risks for women who are or may become pregnant or are breastfeeding.”
- The New Mexico poison and drug information center phone number;

#### **D. Traceability (tracking)**

- Utilize online tracking system as required by the Department
- End-to-end batch tracking from cultivation through final product
  - Steps for grow, harvest, processing, testing, transport/sale.
- Records retained for a defined regulatory period (5 years)

#### **IX. Compliance**

- Compliance authority:
  - The Department
  - NMDA for applicable permits
  - Local building and health departments/inspectors for local permits
- Clear corrective action pathways prior to license suspension or revocation.

#### **X. Future Expansion and Review**

- Framework designed to be scalable.
- Periodic review for:
  - Scientific developments
  - Public health data
  - Operational performance

#### **XI. Definitions**

**“Contamination”.** means the presence of microbial, chemical, or physical substances not intended to be part of a psilocybin product and that may pose a risk to patient safety or product integrity, including but not limited to pathogenic microorganisms, mycotoxins, heavy metals, pesticides, solvents, or foreign matter.

**“Facility”**. means any building, space, or grounds licensed for the cultivation, harvesting, drying, storage, or preparation of psilocybin-producing fungi or psilocybin products, and subject to inspection and regulation by the Department.

**"Harvest"**. means the act of removing psilocybin-producing fungi from a production environment for drying, processing, or storage.

**“Lot”**. means an identified portion of a batch that is uniform and intended to meet specifications for identity, strength, purity, and composition, and that may be subject to testing, quarantine, or recall.

**“Licensed premises”**. means the specific facility or facilities identified in a producer’s license application and approved by the Department, within which the producer is authorized to conduct regulated activities.

**“Producer”**. means a person or entity licensed by the Department to cultivate, harvest, dry, store, and prepare psilocybin-producing fungi or psilocybin products for authorized transfer within the Medical Psilocybin Program.

**“Produce” or “Production”**. means to engage in any activity related to the cultivation, harvesting, drying, storage, or preparation of psilocybin-producing fungi or psilocybin products.

**“Psilocybin product”**. means psilocybin-producing fungi, mycelium, or preparations derived therefrom that are intended for patient use and contain a detectable amount of psilocybin or psilocin.

**“Recall”**. means an action taken to remove a psilocybin product from distribution or use after the discovery of a contamination, mislabeling, or other condition that may pose a risk to patient safety.

**"Release for transfer"** means the point at which a psilocybin product has satisfied applicable testing and quality assurance requirements and may be transferred to another licensed entity.

**“Segregate”**. means to separate and withhold from transfer or use a batch or lot of psilocybin-producing fungi or psilocybin products pending testing, investigation, or corrective action.

**“Testing”**. means laboratory analysis of psilocybin-producing fungi or psilocybin products for potency, identity, and the presence of contaminants, conducted by a laboratory approved or licensed by the Department.

**“Waste” or “Wastage”**. means psilocybin-producing fungi, psilocybin products, or related material that is destroyed, discarded, or otherwise rendered unusable in accordance with Department rules.