Outline Recommendation: Psilocybin Propagation and Production Framework

Adopted: 2-27-26

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.

To be considered by the Board - Initial Ownership/sunset clause proposal from Committee: If the applicant is a corporation, limited liability company, partnership, association, trust, or other legal or commercial entity:

a. Ownership Requirements More than 51% of the ownership interest in the applicant must be held by one or more individuals who have been residents of the State of New Mexico for a minimum of 36 months immediately preceding the date of the application; and

b. Control Requirements The individuals described in Subsection (a) must possess actual authority to direct the management, policies, and operations of the applicant, whether through voting rights, management authority, contractual rights, or other indicia of control, as determined by the New Mexico Department of Health.

Notwithstanding any other provision of law, and until January 1st, 2029, an applicant for a permit subject to this measure must demonstrate compliance with the residency and ownership requirements set forth in this measure.

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, light industrial, and other 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; this is for fruiting bodies from the same inoculation which have been harvested 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:
            - 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

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
- Label
- Ensure the facilitator provides this information for the label and the product information document for the patient.

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 and cultivar 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 traceability 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, 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;
- 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;
    - The New Mexico Suicide crisis hotline number (988);

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 permit suspension or revocation.

X. Transportation

- Needs to be done in safe and secure way. Ensure can meet with others (i.e., contractors) or allow for pick-up so long as there is a chain of custody form (i.e., manifest).

XI. Future Expansion and Review

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