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

- Psilocybe Cubensis shall be the authorized species for cultivation and production;
- Other species or cultivars may be considered for approval upon submission to the Department with evidence (recommend at least three peer-reviewed studies) demonstrating safety and potency.
- The exception to this is for research proposals which will be determined once the Medical Psilocybin Research Fund process and protocols are promulgated and based on funding capacity.

III. Permit Structure

A. Primary Psilocybin Production Permit

- Issued by the Department
- Required for:
    - Cultivation
    - Harvest
    - Processing
    - Packaging
- Applying persons can apply for one or any aspects of the permit
- Demonstrate psilocybin containing mushrooms/products are kept in a secure location
    - Double locks
    - Video surveillance
    - Alarm system
    - Keypad entry

B. Business, Facility, and Occupancy Compliance

- Proof of ownership of the land/facility or written approval from the owner (ie, lease specifying use to include psilocybin cultivation/production)

- Business License in the State of New Mexico
- Proof of Registration with NM Secretary of State
- Local Building and Safety Authorities
    - Certificate of Occupancy
    - Fire code compliance
        - Electrical and HVAC inspection
- *No new psilocybin-specific building standards unless explicitly necessary.
- Language for New Mexico focused business

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 – Note: still seeking more information.

- 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 by batch
        - Fully disclosed on final product labeling

B. Environmental Controls

- Indoor or controlled-environment cultivation required.
- Biosecurity measures to prevent cross-contamination.
- No pesticides utilized

V. Harvesting, Processing, and Homogenization

A. Batch Definition

- A “batch” defined as a single harvest lot processed under uniform conditions (no regulated size requirement).what would be standard language to define this regarding harvesting and size of the “lot”.
- 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 approved laboratories.
    - Requirements for laboratories to be approved
        - Existing cannabis testing laboratories (submit SOPs and process for extraction)
        - ISO/IEC 17025 accredited labs
        - Labs approved or overseen by the Department

B. Required Testing Panels

- Testing occurs once the batch is homogenized and end products
- If the product is older than 6 months, it needs to be re-tested
- 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
    - Psilocybin and Psilocin concentration equivalency
        - psilocybin, psilocin, baeocystin, norbaeocystin and aeruginascin
- Contaminant Testing
    - Microbial contamination
    - Heavy metals (this is an example)
        - The limits for heavy metal testing are:
            - (a) Lead (Pb) above .5 µg/g.
            - (b) Cadmium (Cd) above .2 µg/g.
            - (c) Arsenic (As) above .2 µg/g.
            - (d) Mercury (Hg) above .1 µg/g.
    - Pesticides/fungicides
    - Residual solvents

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
- Labeled

B. Required Label Elements

- Authorized species name; ie, Psilocybe cubensis
- Batch identification number
- Potency results (as tested)
- Growth medium disclosure
- Testing laboratory and date of test
- Packaging Date
- Require re-test at 6 months – add re-test date)
- Required health or regulatory statements (ie, this is not evaluated by the FDA for efficacy and safety)

C. 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
- Species expansion or process changes require formal rulemaking.