

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

MARIJUANA REGULATORY AGENCY

MARIHUANA-INFUSED PRODUCTS AND EDIBLE MARIHUANA PRODUCT

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(6)(9) of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the executive director of the marijuana regulatory agency by section 206 of the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27206, sections 7 and 8 of the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27957 and 333.27958, and Executive Reorganization Order No. 2019-2, MCL 333.27001)

R 420.401, R 420.402, and R 420.403 of the Michigan Administrative Code are amended, ~~to the Michigan Administrative Code~~ as follows:

R 420.401 Definitions.

Rule 1. (1) As used in these rules:

(a) "Acts" refers to the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27101 to 333.27801, and the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27951 to 333.27967, when applicable.

(b) "Agency" means the marijuana regulatory agency.

(c) "Employee" means a person performing work or service for compensation. "Employee" does not include individuals providing trade or professional services who are not normally engaged in the operation of a marihuana establishment.

(d) "Final ~~package~~form" means the form a marihuana product is in when it is available for sale by a marihuana sales location. **For marihuana products intended for inhalation, final form means the marihuana concentrate in the e-cigarette or vaping device.**

(e) "Inactive ingredients" means binding materials, dyes, preservatives, flavoring agents, and any other ingredient that is not derived from the plant *Cannabis Sativa L.*

~~—(f) "Marihuana business" refers to a marihuana facility under the medical marihuana facilities licensing act or a marihuana establishment under the Michigan regulation and taxation of marihuana act, or both.~~

~~—(g) "Marihuana establishment" means a location at which a licensee is licensed to operate a marihuana grower, marihuana safety compliance facility, marihuana processor, marihuana microbusiness, marihuana retailer, marihuana secure transporter, marihuana designated consumption establishment, or any other type of marihuana-related business licensed to operate by the agency under the Michigan regulation and taxation of marihuana act.~~

~~—(h) "Marihuana facility" means a location at which a licensee is licensed to operate under the medical marihuana facilities licensing act.~~

(~~if~~) “Marihuana product” means marihuana or a marihuana-infused product, or both, as those terms are defined in the acts unless otherwise provided for in these rules.

(~~ig~~) “Marihuana sales location” refers to a provisioning center under the medical marihuana facilities licensing act or a marihuana retailer under the Michigan ~~R~~Regulation and ~~T~~Taxation of ~~m~~Marihuana ~~a~~Act, or both.

(~~ih~~) “Marihuana tracking act” means the marihuana tracking act, 2016 PA 282, MCL 333.27901 to 333.27904.

(~~ii~~) “Medical marihuana facilities licensing act” or “MMFLA” means the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27101 to 333.27801.

(~~mj~~) “Michigan ~~R~~Regulation and ~~T~~Taxation of ~~m~~Marihuana ~~a~~Act” or “MRTMA” means the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27951 to 333.27967.

(~~nk~~) “Producer” refers to both a processor under the medical marihuana facilities licensing act and a marihuana processor under the Michigan ~~R~~Regulation and ~~T~~Taxation of ~~m~~Marihuana ~~a~~Act.

~~—(o) “Records of formulation” means the documentation that includes at a minimum: the ingredients, recipe, processing in order to be shelf stable, Certificates of Analysis for any ingredient used, and description of the process in which all ingredients are combined to produce a final package.~~

(~~pl~~) “These rules” means the administrative rules promulgated by the agency under the authority of the medical marihuana facilities licensing act, the marihuana tracking act, the Michigan ~~R~~Regulation and ~~T~~Taxation of ~~m~~Marihuana ~~a~~Act, and Executive Reorganization Order No. 2019-2, MCL 333.27001.

(~~qm~~) “Tag” or “RFID tag” means the unique identification number or Radio Frequency Identification (RFID) issued to a licensee by the ~~agency~~ **statewide monitoring system** for tracking, identifying, and verifying marihuana plants, marihuana products, and packages of marihuana product in the statewide monitoring system.

(2) Terms defined in the acts have the same meanings when used in these rules unless otherwise indicated.

R 420.402 Adoption by reference.

Rule 2. (1) The following codes, standards, or regulations of nationally recognized organizations or associations are adopted by reference in these rules:

(a) National fire protection association (NFPA) standard 1, 201~~8~~**21** edition, entitled “Fire Code,” is adopted by reference as part of these rules. Copies of the adopted provisions are available for inspection and distribution from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, Massachusetts, 02169, telephone number 1-800-344-3555, for the price of ~~\$106.00~~**114.50**.

(b) The International Organization for Standardization (ISO), ISO 22000 / ISO/TS 22002-1:2009,~~—~~ ~~F~~Food ~~s~~Safety ~~b~~Bundle, available for purchase at: <https://webstore.ansi.org/Standards/ISO/ISO22000TS22002FoodSafety>, for the price of \$275.00.

(c) International Organization for Standardization (ISO), ISO/IEC 17025:2017, ~~g~~General ~~r~~Requirements for the ~~e~~Competence of ~~t~~Testing and ~~e~~Calibration ~~H~~Laboratories, available at: <https://webstore.ansi.org/RecordDetail.aspx?sku=ISO%2fIEC+17025%3a2017>, for the price of \$162.00.

(2) The standards adopted in subrule (1)(a) to (c) of this rule are available for inspection and distribution at the agency, located at 2407 North Grand River Avenue, Lansing, **Michigan MI**,

48906. Copies of these standards may be obtained from the agency at the cost indicated in subrule (1)(a) to (c) of this rule, plus shipping and handling.

R 420.403 Requirements and restrictions on marihuana-infused products; edible marihuana product.

Rule 3. (1) A producer shall package and properly label marihuana-infused products before sale or transfer.

(2) Marihuana-infused products processed under these rules must be homogenous. The allowable variation for weight and THC and CBD concentrations between the actual results and the intended serving is to be + or – 15%. The agency shall publish guidelines for a producer to follow to verify the marihuana-infused product is homogeneous.

(3) A producer of marihuana-infused products shall list and record the THC concentration and CBD concentration of marihuana-infused products, as provided in R 420.305 and ~~subrule (4) R 420.404 of this rule~~, in the statewide monitoring system and indicate the THC concentration and CBD concentration on the label along with the tag identification as required under these rules.

(4) Marihuana-infused products that are part of a product recall ~~issued in the statewide monitoring system, or by the agency or other state agency, if applicable,~~ are subject to all of the following requirements:

(a) Must be immediately pulled from production by the producer of the marihuana-infused product.

(b) Must be immediately removed from the sales area of a marihuana sales location.

(c) Must not be sold or transferred.

(5) Marihuana-infused products must be stored and secured as prescribed under these rules.

(6) All non-marihuana inactive ingredients must be clearly listed on the product label. Inactive ingredients must be approved by the FDA for the intended use, and the concentration must be less than the maximum concentration listed in the FDA Inactive Ingredient database for the intended use.

(7) A producer shall label all marihuana-infused product with all of the following:

(a) The name of the marihuana-infused product. **The name of the product must be an appropriately descriptive phrase that accurately describes the basic nature of the product.**

(b) The ingredients, **including component ingredients**, of the marihuana-infused product, in descending order of predominance by weight.

(c) The net weight or net volume of the product.

(d) For an edible marihuana product, ~~the marihuana processor shall comply with subdivisions (a) to (e) of this subrule and all of the~~ **both of the following must be included:**

(i) Allergen labeling as specified by the Food and Drug Administration (FDA), Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), 21 USC 343.

(ii) If any health or nutritional claim is made, appropriate labeling as specified by the federal regulations regarding Food Labeling, 21 CFR part 101.

(e) The date the marihuana product was produced.

(8) A producer of edible marihuana product shall comply with all the following ~~to ensure safe preparation:~~

(a) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, 21 CFR part 117.- Any potentially hazardous ingredients used to

process shelf-stable edible marihuana products must be stored at 40 degrees Fahrenheit, 4.4 degrees Celsius, or below.

~~—(b) Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food, 21 CFR part 110. A marihuana business shall ensure that any handling of marihuana product is compliant.~~

(eb) Keep formulation records for all marihuana products. These records at a minimum must include the recipe, any additional processing **documentation that demonstrates the product in order** to be shelf stable, and test results for ~~any~~ **all** ingredients used.

(ec) Provide annual employee training for all employees on safe food handling and demonstrate an employee's completion of this training by providing proof of food handler certification that includes documentation of employee food handler training, including, but not limited to, allergens and proper sanitation and safe food handling techniques. Any course taken pursuant to this rule must be conducted for not less than 2 hours and cover all of the following subjects:

- (i) Causes of foodborne illness, highly susceptible populations, and worker illness.
- (ii) Personal hygiene and food handling practices.
- (iii) Approved sources of food.
- (iv) Potentially hazardous foods and food temperatures.
- (v) Sanitization and chemical use.
- (vi) Emergency procedures, including, but not limited to, fire, flood, and sewer backup.

(ed) Have an employee **in charge** who is certified as a Food Protection Manager.

(fe) To ensure compliance with the safe preparation standards under this subrule, comply with 1 or more of the following:

(i) ~~The FDA food safety modernization act, 21 USC 2201 to 2252.~~ **Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, 21 CFR part 117.**

(ii) The International Organization for Standardization (ISO), ISO 22000/ISO/TS 22002-1 adopted by reference pursuant to R 420.402.

(gf) -If requested as provided in this subdivision, provide to the agency documentation to verify certifications and compliance with these rules. The agency may request in writing documentation to verify certifications and compliance with these rules.

(9) A producer of edible marihuana product shall comply with all the following:

(a) ~~Edible marihuana product packages shall not be in-~~ **produce an edible marihuana product in a shape or with a labeled in a manner** that would appeal to minors aged 17 years or younger.- ~~Edible marihuana products shall not be associated with or have cartoons, caricatures, toys, designs, shapes, labels, or packaging that would appeal to minors.~~

(b) Not produce an edible marihuana product that is associated with or has cartoons, caricatures, toys, designs, shapes, labels, or packaging that would appeal to minors.

(bc) ~~Edible marihuana products shall not be~~ **that can be** easily confused with a commercially sold ~~candy~~ **available food product**. The use of the word candy or candies on the packaging or labeling is prohibited. ~~Edible marihuana products shall not be in the distinct shape of a human, animal, or fruit, or a shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings. Edible marihuana products that are geometric shapes and simply fruit flavored are permissible.~~

(d) Not produce edible marihuana products in the distinct shape of a human, animal, or fruit, or a shape that bears the likeness or contains characteristics of a realistic or fictional

human, animal, or fruit, including artistic, caricature, or cartoon renderings. Edible marihuana products that are geometric shapes and fruit flavored are permissible.

(e) Not package an edible marihuana product in a package that bears the image, likeness, or contains the characteristics of commercially available food products.

(ef) An edible marihuana product must be in opaque, child-resistant packages or containers that meet the effectiveness specifications outlined in 16 CFR 1700.15. An edible marihuana product containing more than ~~one~~ **1** serving must be in a resealable package or container that meets the effectiveness specifications outlined in 16 CFR 1700.15.

(10) A producer shall not produce an edible marihuana product that requires time and temperature control for safety. The agency may publish validation guidance for shelf stable edible marihuana product. The agency may request to review the validation study for a shelf stable edible marihuana product. The end product must be a shelf stable edible marihuana product and state the following information:

(a) A product expiration date, upon which the marihuana product is no longer fit for consumption **and after which it must be destroyed**. Once a label with an expiration date has been affixed to a marihuana product, a licensee shall not alter that expiration date or affix a new label with a later expiration date. **The expiration date must consider all the following:**

(i) The quality and characteristics of the edible marihuana product.

(ii) The packaging of the edible marihuana product.

(iii) The customary conditions encountered by the edible marihuana product from product to sale.

(b) Any other information requested by the agency that is not inconsistent with the acts and these rules.

(11) As used in this rule, the term “edible marihuana product” means any marihuana-infused product containing marihuana that is intended for human consumption in a manner other than smoke inhalation.

(12) This rule does not affect the application of any applicable local, state, or federal laws or regulations.