

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

MARIJUANA REGULATORY AGENCY

MARIHUANA-INFUSED PRODUCTS AND EDIBLE MARIHUANA PRODUCT

Filed with the secretary of state on June 22, 2020

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a(6) 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, R 420.403, R 420.404, and R 420.405 are added 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" means the form a marihuana product is in when it is available for sale by a marihuana sales location.

(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.

(i) "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.

(j) “Marihuana sales location” refers to a provisioning center under the medical marihuana facilities licensing act or a marihuana retailer under the Michigan regulation and taxation of marihuana act, or both.

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

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

(m) “Michigan regulation and taxation of marihuana act” or “MRTMA” means the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27951 to 333.27967.

(n) “Producer” refers to both a processor under the medical marihuana facilities licensing act and a marihuana processor under the Michigan regulation and taxation of marihuana 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.

(p) “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 regulation and taxation of marihuana act, and Executive Reorganization Order No. 2019-2, MCL 333.27001.

(q) “Tag” or “RFID tag” means the unique identification number or Radio Frequency Identification (RFID) issued to a licensee by the agency 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, 2018 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.

(b) The International Organization for Standardization (ISO), ISO 22000 / ISO/TS 22002-1:2009 - food safety 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, general requirements for the competence of testing and calibration 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, 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 Rule 420.305 and subrule (4) 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.

(b) The 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 (c) of this subrule and all of the following:

(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.

(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.

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

(d) 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.

(e) Have an employee who is certified as a Food Protection Manager.

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

(g) 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 a shape or 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) Edible marihuana products shall not be easily confused with commercially sold candy. 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.

(c) 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 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. 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.

(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.

R 420.404 Maximum THC concentration for marihuana-infused products.

Rule 4. A marihuana sales location shall not sell or transfer marihuana-infused products that exceed the maximum THC concentrations established by the agency by more than 10%. For the purposes of maximum THC concentrations for marihuana-infused products, the agency shall publish a list of maximum THC concentrations and serving size limits.

R 420. 405 Severability.

Rule 5. If any rule or subrule of these rules, in whole or in part, is found to be invalid by a court of competent jurisdiction, such decision will not affect the validity of the remaining portion of these rules.