



TECHNICAL BULLETIN

April 13, 2022

Supersedes February 16, 2021

Process to Obtain Agency Approval for Production of Marijuana-Infused Beverages

The intent of this technical bulletin is to release guidelines for the safe creation and production of marijuana-infused beverages.

The bulletin details all requirements for the submission and approval of a marijuana-infused beverage, as well as the approval process and expectations for ongoing research and product development related to marijuana-infused beverages.

Rule 3(10) in the Marijuana-Infused Products and Edible Marijuana Product Rule Set- R 420.403(10)

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

- (a) A product expiration date, upon which the marijuana product is no longer fit for consumption. Once a label with an expiration date has been affixed to a marijuana 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.

In accordance with the rules, all marijuana-infused beverages must be shelf-stable and should be produced in such a way as to ensure a product that is safe for ingestion and consistent in production. Below, the steps for submission and approval for the production of marijuana-infused beverages is outlined in detail. If there are any questions regarding the beverage approval process, they should be submitted to CRA-scf@michigan.gov. Please allow 3 business days for review and response to all submissions.

Submission Process

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Licensed producers may submit, in writing, a request to create marijuana-infused beverages to CRA-scf@michigan.gov. This request must include the following components to be considered for approval. When submitting these documents, ensure that they are submitted as a single file, and saved as a PDF with numbered pages and a table of contents to ensure ease of identification and a timely approval process.

General Requirements:

- CRA license number, entity name, and any DBA affiliates / licenses.
- Any person(s) or partner(s) in research, production, or receiving reasonable payment under a licensing agreement or contract concerning the licensing of intellectual property including, but not limited to, brands, recipes, or technology.
- The name(s) and qualifications (CV or resume) of the individual(s) who serve as the Quality Control Manager(s) at the processing facility.
- Confirmation that the processing facility is currently in the process of receiving Good Manufacturing Practices (GMP) certification.
- Written confirmation from the product manufacturer that the beverage production line is hygienically designed, meaning that the production line is cleanable to a microbial level unless the product is pasteurized after filling, in which case, GMP is sufficient.
- Complete environmental sanitation plan.
- Complete Hazard Analysis Critical Control Points (HACCP) plan. This must include all 12 steps as identified by the FDA.
- Complete Standard Operating Procedures (SOPs) for product creation, sanitation protocol, and safety procedures.
- Upon submission of this document, the producer must submit a letter by a recognized process authority that contains all the following.
 - Signature of the process authority.
 - Date.
 - Clear reference to and summary of the microbial prevention policy, include relevant page number(s).
 - Reference to the microbial assessment system and environmental monitoring plan, include relevant page number(s).
 - Reference to the proof of exclusion of microorganisms as evidenced in the plans for operation, SOPs, and QC procedures, include relevant page number(s).

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- Written confirmation that all emulsifiers and preservatives (and their concentrations) are safe for consumption.

Process Requirements:

- The Record(s) of Formulation (ROF) should be submitted in full for every product and should include:
 - Ingredients and source
 - Certificates of analysis (COAs) for all ingredients used, all of which must be obtained from FDA approved sources except for cannabis.
 - Recipe.
 - Processing for shelf-stability.
 - Detailed description of any components used for emulsification.
 - Confirmation of package quality and sterility

Product Requirements:

- All water used for production must be potable, tested, and treated as necessary to ensure safe consumption. The producer will need to provide a passing report from an accredited environmental laboratory confirming that the water is safe for consumption and use in production.
- Any ingredient with a pH of 3 or higher must be pasteurized either by the producer or provider of the ingredient.
- All emulsifiers and preservatives (and their concentrations) must be listed as safe and adhere to requirements outlined in FDA CFR 21. An easy to reference list can be found [here](#).
- Detailed description of the intended product, which must speak to all subjective assessment qualities and include color and appearance of the product.

Research & Product Development:

- Submission of a complete research proposal (detailed

below)

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Research & Ongoing Product Development:

Any producer engaged in the production of marijuana-infused beverages must submit a research proposal that includes ongoing research and product development that will continue until the producer can reasonably ensure product consistency and shelf-stability over time, after which point the producer is expected to maintain product quality through ongoing checks developed with oversight by the process authority, quality control manager, and any parties associated with GMP certification, where appropriate. **The length of this study will directly correspond to the expiration date of the marijuana-infused beverage(s).**

For example, if a producer conducts the study during a 3-month period and determines that the beverage is stable and safe for sale, they will be permitted to produce and sell that product, however, the labeled expiration date may not exceed 3-months. If the licensee has product in the regulated market that has passed the labeled expiration date, the licensee must have the product destroyed in accordance with the administrative rules.

A portion of this study should also be designed to target THC leeching. Producers must assure that the total concentration of THC in a beverage does not degrade by more than the +/- 15% variation allowed for product homogeneity. This study should include both subjective and objective quality checks of the product over time with the goal of providing sufficient data to ensure stability and a variety of environmental conditions and stresses. Quality checks must include but are not limited to the following:

- Potency.
- Stability.
- Phase separation.
- Color changes.
- Clarity.
- pH.
- Microbial contamination.
- Consistency.
- Flavor.
- Visual changes.
- If the product is carbonated, assessment of CO₂ in solution over time.
- Emulsion disability.

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- Turbidity / sedimentation.
- Cloudiness.
- Other deteriorative product quality characteristics to be determined by the processor.

The results of these studies should be submitted to the agency when the producer is ready to launch the infused beverage and quarterly thereafter for a year. The CRA will periodically audit the data from ongoing stability studies after the one-year mark.

On-going submissions

After a producer is approved for the production of marijuana-infused beverages, the producer is required to provide a letter to the Agency attesting that no inconsistencies, irregularities, or contaminants were discovered during production. This letter should be signed and dated by the quality control manager(s). These letters should be submitted to the Agency via email to cra-scf@michigan.gov prior to transfer or sale of any new batch of marijuana-infused beverage to any licensee other than a licensed safety compliance facility. One letter is required per batch. These submissions will be required for one year, initially. This requirement may be relaxed as the producer demonstrates the capability to produce a stable product.

Beverage Compliance Testing

All marijuana-infused beverages must be tested in accordance with the rules and the Sampling and Testing Technical Guidance for Marijuana Products document. Given the nature of marijuana-infused beverages, some additional testing requirements have been added and include:

- Terpene testing.
- Homogeneity (further clarified for marijuana-infused beverages).
- pH.

The safety compliance facility chosen for partnership testing on the research and product development studies, once chosen, must remain consistent. This requirement applies only to the Research and Product Development process and may be reassessed if necessary.

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