



TECHNICAL BULLETIN

Supersedes November 27, 2019
February 4, 2020

Requirements for Marijuana Products Intended for Inhalation

The intent of this technical bulletin is to publish information in accordance with the Emergency Rules for Manufacturing of Marijuana Products Intended for Inhalation filed on November 22, 2019.

Rule 3. Ingredients.

(1) All inactive ingredients shall be clearly listed on the product label for any marijuana product intended for inhalation produced after the effective date of these rules.

(2) A licensee is prohibited from adding an inactive ingredient to a marijuana product intended for inhalation unless it has been approved by the FDA for inhalation. The concentration of any inactive ingredient in a marijuana product intended for inhalation shall not exceed the maximum concentration listed in the [FDA Inactive Ingredient database](#).

(3) Processors and marijuana processors shall keep records of formulation for a minimum of two years after the use of the formulation is discontinued for all marijuana products intended for inhalation.

(4) All records of formulation and changes to formulations must be submitted to the agency for all marijuana products intended for inhalation.

Any product created after November 22, 2019, must be accompanied by the [Record of Formulation for Marijuana Products Intended for Inhalation](#).

Please see the proceeding pages for additional information on how to compliantly submit documentation to the agency.

Acceptable Ingredients:

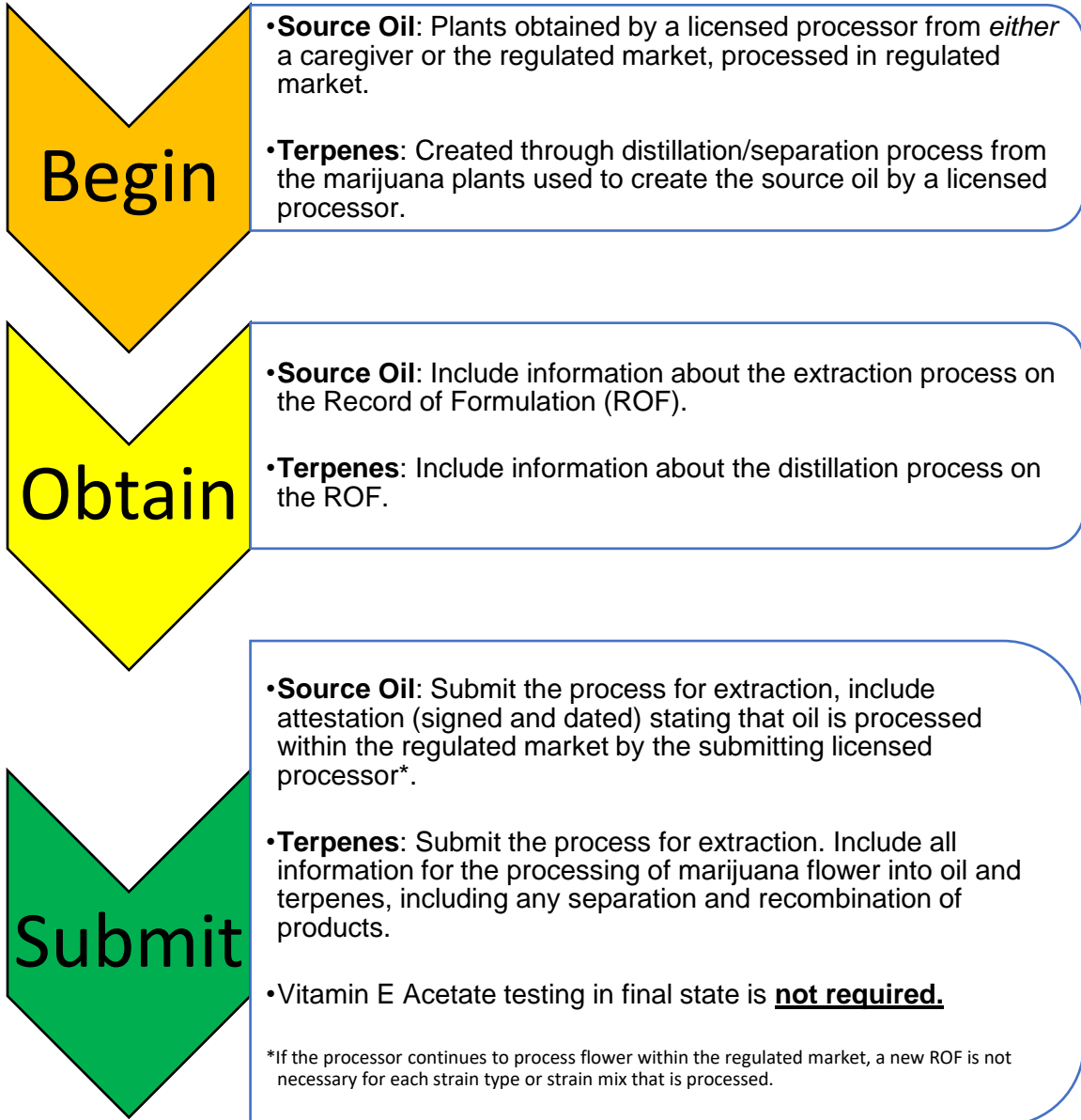
Formulations for marijuana vape cartridges may include distillate and terpenes processed within the regulated market by licensed processors or distillate and terpenes (**including botanically derived terpenes**) brought in from the external market. The process and procedures for which those products move through the Record of Formulation process are outlined in the flow charts below.



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Source Oil (Regulated Market), Terpenes (Regulated Market)

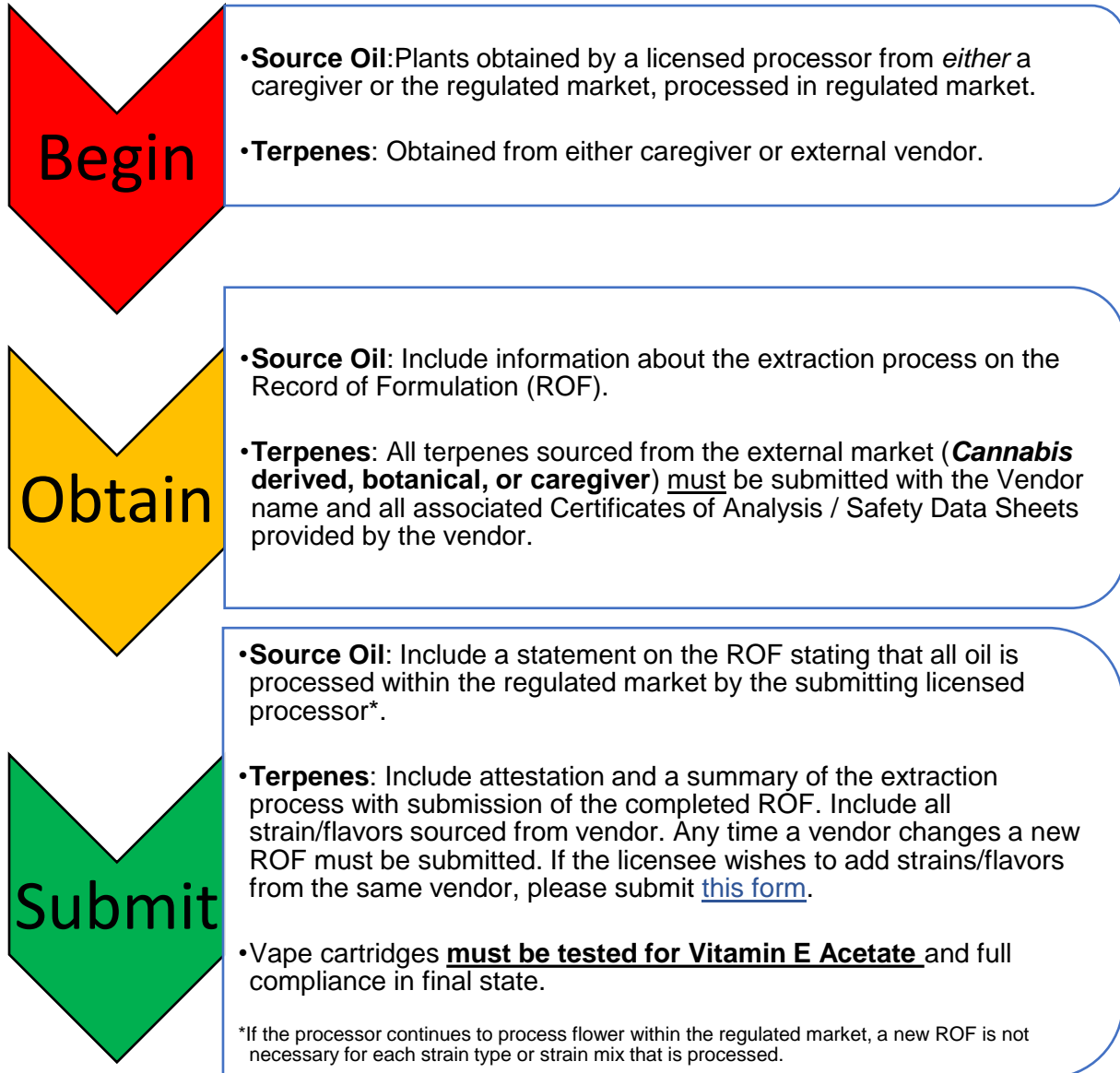




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Source Oil (Regulated Market), Terpenes (External Market)

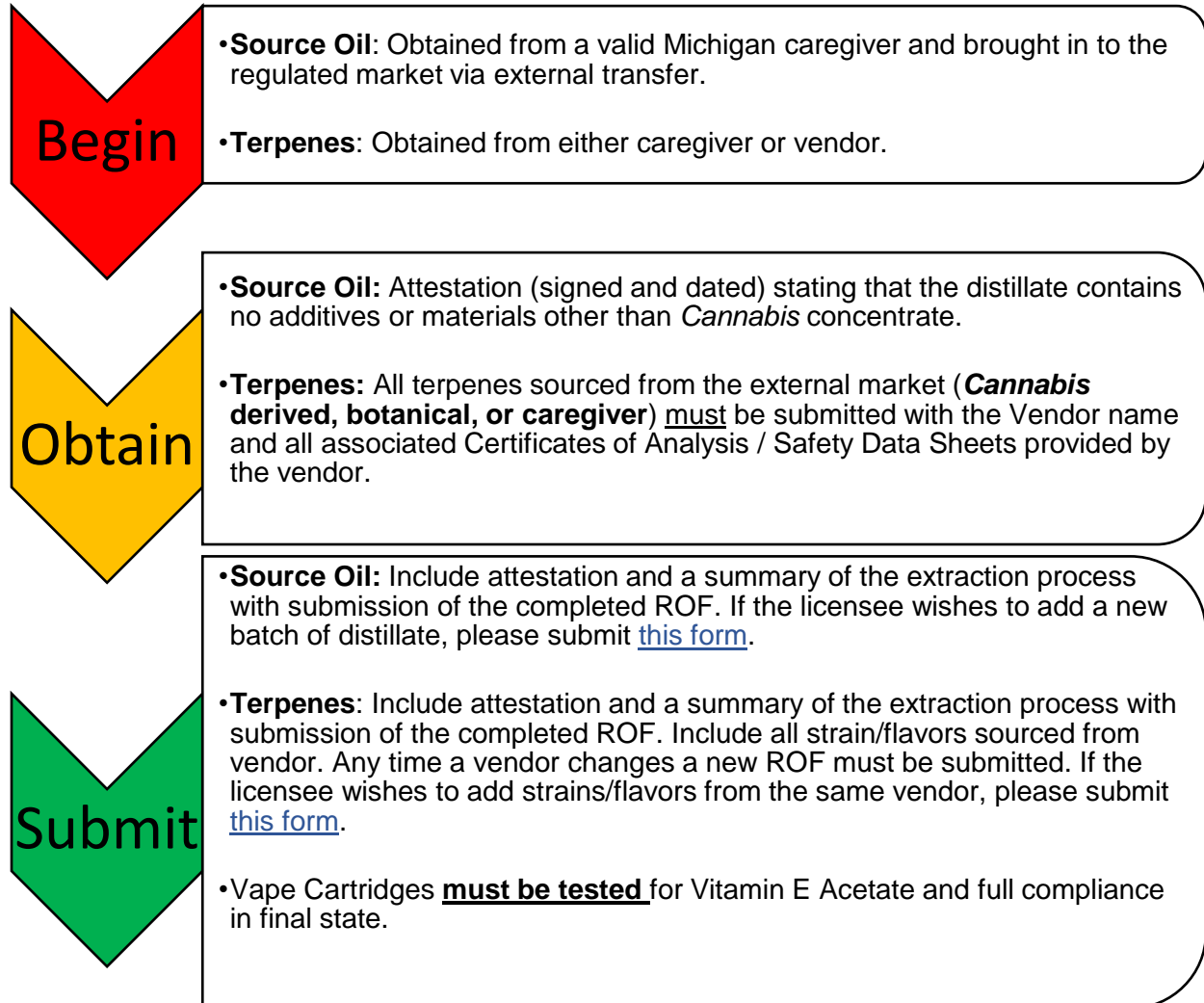




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Source Oil (External Market), Terpenes (External Market)





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FREQUENTLY ASKED QUESTIONS

Where is the Record of Formulation (ROF) form?

You can find the form [here](#). Please fill it out in its entirety before submission or the request is subject to denial.

Where do we submit our Record of Formulation request?

Please send an email to: MRA-compliance@michigan.gov

When submitting, please make sure that all sections are completed. In the submission email, please include the facility name and license number in the subject line of the email along with the phrase "Submission of Record Formulation".

When submitting an update to an approved ROF, in the subject line of the email please include the following:

"Update- AXXXX – Name of Licensee and License number"

What documents are required for approval?

All relevant documents listed in the ROF form must be submitted with the ROF request. Please refer to the previous pages and the information below to ensure that the ROF request is complete before submission.

Can we use terpenes and what kind of terpenes may we use?

Licensees may use terpenes that are botanically derived from *Cannabis* or other plants.

Terpenes from a vendor:

All terpenes and terpene blends submitted as part of a record of formulation must be submitted along with the associated Certificate of Analysis and Safety Data Sheets from the vendor as an attachment. If you use multiple vendors for the procurement of terpenes/blends, you will need to submit ROF for each vendor with their respective terpene products.

My formulation process didn't change, but I want to add additional terpenes or distillate to my record, how do I do this?

Please submit an ROF Update Form which can be found [here](#). On the form, you will need to include the name, date of request, and the full Metrc number. When submitting an update to an approved ROF, in the subject line of the email please include the following:

"Update- AXXXX – Name of Licensee and License number."