



## ADVISORY BULLETIN

April 13, 2022

Supersedes March 7, 2022

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### **Homogeneity Requirements for Processors**

#### **Rule 3(2) in the Marihuana-Infused Products and Edible Marihuana Product Rule Set – R. 420.403(2)**

Marihuana-infused products processed under these rules must be homogenous.

Homogeneity testing only applies to marijuana-infused products in accordance with the administrative rules. However, to ensure that the final product is homogenous, it is a good manufacturing process to ensure that the source oil used to make products is homogeneous.

#### **Rule 3(2) in the Marihuana-Infused Products and Edible Marihuana Product Rule Set – R. 420.403(2)**

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.

There are several practices processors can employ to ensure homogenous product including:

- Using homogenous ingredients when producing products, it is critical that the oil or distillate used has been thoroughly mixed and tested.
- Ensuring the scales and measuring instruments are calibrated and the calibrations are verified daily.
- Sourcing non-marijuana ingredients from reputable companies who are GMP certified.

Testing for homogeneity is not required on every batch of marijuana-infused product. Homogeneity testing is required on the initial batch and every six months thereafter, as verification, if the manufacturing process does not change.

To perform homogeneity testing each dose or serving shall be treated as a separate individual sample and a total of 10 doses or servings shall be sampled at random. The weight and concentration of Delta-9 THC must be recorded and the variability of weight and concentration of Delta-9 THC among servings in a single package may not exceed +/- 15%.



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This can be determined by first calculating the Standard Deviation (SD) among samples and subsequently calculating the Relative Standard Deviation (RSD) for both weight and concentration of Delta-9 THC.

The SD is calculated using the following formula:

$$SD = \sqrt{\frac{(sample1 - mean)^2 + (sample2 - mean)^2, \dots, (sample10 - mean)^2}{total\ number\ of\ samples - 1}}$$

The RSD is calculated using the following formula:

$$RSD = \frac{SD}{mean} \times 100$$

The CRA has determined that the laboratories should complete potency testing based on the information provided by the processors at the time of the sampling event.

- If a product is sampled as an individual serving/dosage, the facility will report total THC by serving/dose.
- If the product is sampled in final package, total THC content for the package will be reported.

It is not incumbent on the laboratory to determine if the product will meet the package labeling requirements. The laboratory testing results provided on the package will report the calculated THC as the product was submitted for testing and is not required to replicate the processor designated package label for THC content. The processor designated package label will be considered the target THC.

Questions can be sent to the Cannabis Regulatory Agency, Scientific Section via email at [CRA-scf@michigan.gov](mailto:CRA-scf@michigan.gov)