



ADVISORY BULLETIN

May 15, 2019

Homogeneity Testing for Processors

According to Administrative Rule 61(2), processed marijuana-infused products must be homogenous. The allowable variation for weight and delta-9 tetrahydrocannabinol (THC) potency between the actual results and the intended dose is to be +/- 15%. This is the Marijuana Regulatory Agency's (MRA) guidelines for a processor to follow to verify the marijuana-infused product is homogeneous.

Ensuring that delta-9 THC concentration and weight are distributed uniformly throughout a batch of a marijuana-infused product provides patients with the assurance that the dose of medication is accurate and consistent. A patient who is accustomed to a gummy containing a specific amount of delta-9 THC knows what effect to expect from that dose. When products are not homogenous, the delta-9 THC concentration varies and could result in the patient being either underdosed or overdosed.

A packaged unit of marijuana-infused product cannot contain more than the published [THC Limit](#) and must be divided into distinct and easily identifiable dosages. Each dose must not contain more than the maximum published [THC Limit](#).

Testing for homogeneity is not required on every batch of marijuana-infused product. The testing is required on the initial batch and every six months, as verification, if the manufacturing process does not change. The processor should attest that there are no changes to the manufacturing process prior to the Safety Compliance Facility (SCF) taking a sample. The SCF should include this attestation on the chain of custody form.

To perform homogeneity testing, each dose shall be treated as a separate sample. The weight and concentration of delta-9 THC must be recorded and the variation must only be +/- 15% amongst all samples.



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Example:

A processor who produces a batch of 50 capsules would need to have all three units tested for potency and the weight must be documented. The difference between the weight and delta-9 THC amongst the three units must be within +/- 15%.

	Weight	delta-9 THC
Sample 1	163 mg	100 mg/g
Sample 2	165 mg	50 mg/g
Sample 3	188 mg	103 mg/g

- The weight in sample 3 exceeds the 15% variance for weight.
- The delta-9 THC concentration in sample 2 exceeds the 15% variance for potency.

This can be determined by calculating the median for the sample results and comparing the median value to the other sample values. Any comparison where the sample value exceeds 15% variance would indicate the samples are not homogenous. The failed sample results will be entered into the statewide monitoring system as a percentage (example: variance= 21%).

Although processors are not required to have homogeneity testing completed on cannabinoids aside from delta-9 THC, accurate dosing is important and the processor may request this additional testing. Homogeneity testing only applies to marijuana-infused products in accordance with Administrative Rule 61.

Questions can be sent to the Marijuana Regulatory Agency Enforcement Section via email at MRA-Enforcement@michigan.gov

For more information about the Marijuana Regulatory Agency, please visit www.michigan.gov/MRA