9810.3100 PRODUCT TESTING AND PRODUCT SAMPLING PROTOCOLS.

Subpart 1. **Office authority.** To ensure public health and safety, the office may, at any time, require immediate testing of a regulated product suspected to be a potential human health hazard or threat to public safety.

Subp. 2. **Prohibited actions.** A person must not offer any regulated product in the product's final packaging for wholesale distribution or retail sale if the product:

A. has not undergone testing required by this chapter and Minnesota Statutes, chapter 342; or

B. does not meet the acceptance criteria established by the office for the regulated product.

Subp. 3. **Standard operating procedures.**

A. A testing facility must maintain written standard operating procedures describing how to collect all representative samples for each regulated product that the facility handles. Standard operating procedures must:

(1) address all requirements for sample and data collection and laboratory analysis;

(2) contain detail necessary for accurate and consistent actions by assigned staff; and

(3) contain the process for supervisors to verify that sample collection procedures are completed accurately by assigned staff.

B. Staff conducting sampling activities or sample testing must be knowledgeable in standard operating procedures necessary to perform actions accurately and consistently. Training records of staff conducting sampling activities or sample testing must be maintained for three years.

Subp. 4. **Testing methods.**

A. A testing facility must grind a representative sample to create a homogeneous composite batch sample for testing, except a testing facility is not required to create a homogeneous composite batch sample when the facility is performing gross foreign matter, microbiological, or homogeneity testing. When a testing facility is performing gross foreign matter, microbiological, or homogeneity testing, the testing facility must take a representative sample before creating a homogeneous composite batch sample for other mandatory testing.

B. A testing facility must grind a raw cannabis sample and may also use a paddle blender on all or part of a representative sample to produce a homogeneous composite batch sample.

C. A testing facility must perform required testing on a homogeneous composite batch sample.

Subp. 5. **Mandatory testing.**

A. A testing facility must test a batch of regulated products to verify:

(1) the potency and stability of the cannabinoids in the products for accurate labeling; and

(2) the homogeneity of the cannabinoids in each serving in the batch to meet the acceptance criteria established by the office and for accurate labeling.

B. If a testing facility finds any of the following contaminants in a batch of regulated products, the batch does not meet the acceptance criteria established by the office:

(1) foreign material;

(2) heavy metals;

(3) microbiological contaminants;

(4) mycotoxins;

(5) pesticide residue; or

(6) residual solvents.

C. A cannabis-derived ingredient testing report or hemp-derived ingredient testing report meets the testing requirement in this subpart if:

(1) the production process of the cannabis consumer product does not introduce a contaminant or increase the potential for introducing a contaminant into the regulated product; or

(2) handling the product has not altered the stability, potency, or homogeneity of the regulated product.

D. A product offered for sale is not required to be tested for a contaminant when the contaminant is not hazardous and the cannabis business provides supporting written documentation to the office that the contaminant is not hazardous.

E. A testing facility must test a batch for stability and homogeneity after the batch has been packaged as a regulated product. A testing facility may test a batch for contaminants and potency before the batch has been packaged as a regulated product.

F. A testing facility must test a batch of a regulated product for stability, except that the first batch of a regulated product may have a six-month expiration date.

G. A testing facility must maintain a testing report produced by the facility for at least three years from the date of the report. A testing facility must make all testing reports available for inspection by the office upon request.

Subp. 6. **Annual report for testing thresholds.**

A. No later than July 1 each year, the office must publish on the office's website an annual report for testing thresholds that identifies:

(1) approved analytical methods for contaminant tests under each category in subpart 5, item B;

(2) the specific contaminants listed in subpart 5, item B, required to be tested for each product type in part 9810.2100;

(3) the acceptance criteria by product category and contaminant type;

(4) analytical methods and acceptance criteria for homogeneity; and

(5) reporting requirements for the analytical test labs for each analyte and product category.

B. A licensed testing facility must ensure that the facility's testing protocols and standard operating procedures are updated to reflect any changes in the annual report no later than August 1 each year.

C. The office must only amend the annual report for testing thresholds outside the schedule in item A if the office determines an addition or revision is necessary to protect public health and safety.

Subp. 7. **Sample collection methods.**

A. A cannabis or hemp business must use methods of sample collection that ensure the accurate representation of the batch. Representation of the batch must be based upon established criteria such as random sampling and must consider:

(1) the statistical criteria for component variability, confidence levels, and degree of precision desired;

(2) the inherent characteristics of the regulated product that may impact batch consistency; and

(3) the quantity needed for specific laboratory analysis.

B. A cannabis or hemp business must design methods of sample collection that maintain the integrity of the sample. A cannabis or hemp business must:

(1) ensure that sample containers, collection tools, and supplies do not alter the accuracy of the sample analysis;

(2) clean sample containers, collection tools, and supplies and handle sample containers, collection tools, and supplies in a manner to prevent contaminants from being introduced into the sample;

(3) perform sample collection in a manner visible to mandatory recording devices;

(4) open, fill, and reseal a sample container in a manner designed to prevent the contamination of the container's contents and contamination of other samples;

(5) use sterile equipment, utensils, and aseptic sampling techniques for the sample analysis;

(6) identify collected samples with the product's name, the product batch number, the date on which the sample was taken, and the identity of the person who collected the sample; and

(7) seal sample containers immediately after collecting the sample in a manner to indicate when tampering has occurred or when the integrity of the sample has been compromised.

Subp. 8. **Responsibilities of license holder.** A license holder is responsible for ensuring that:

A. workers responsible for sample collection have been properly trained on sampling procedures;

B. all mandatory testing is completed by a testing facility licensed by the office;

C. the identity and integrity of all samples collected are maintained from the time of sample collection until the testing facility or the licensed transporter receives the sample; and

D. the license holder makes complete and accurate disclosures to the testing facility of all cultivation and production methods required in Minnesota Statutes, section 342.61, subdivision 4, or other information necessary for the accurate laboratory analysis and reporting of testing results.

Subp. 9. **Remediation.**

A. A license holder must ensure that batches of regulated products that fail to meet acceptance criteria established by the office for contaminant categories or homogeneity are:

(1) disposed of according to part 9810.1200; or

(2) remediated according to a plan approved by the office under this subpart.

B. A license holder must submit to the office a written remediation plan on forms prescribed by the office.

C. A license holder must not conduct any remediation activities with a batch-tested product until the office approves the license holder's remediation plan.

D. A license holder must identify and quarantine any product awaiting remediation or disposal to prevent the product's use. A license holder must not use any method of remediation that is not described in the license holder's remediation plan approved by the office.

E. A license holder must ensure that all remediated material meets the office's acceptance criteria, standards, and specifications as part of the approved remediation plan.

F. The office must approve a remediation plan that renders a product compliant with this chapter and Minnesota Statutes, chapter 342. The office must not approve of a remediation plan that relies on increasing the batch size to achieve compliance with this chapter and Minnesota Statutes, chapter 342.

Subp. 10. **Mandatory notifications.**

A. A license holder whose product fails to meet mandatory testing criteria must notify the office of all noncompliant testing reports and include the following information in the notice:

(1) the mandatory testing criteria that was not met;

(2) the production status of the batch represented; and

(3) the license holder's decision to dispose of the batch or remediate the batch under subpart 9.

B. A license holder must notify the office of all testing results of regulated products, including batches that have completed production processes and batches that have not completed production processes.

Subp. 11. **Research and development.** Cannabis flower and cannabis product batches are exempt from the requirements of this part if:

A. a cannabis microbusiness licensed under Minnesota Statutes, section 342.28, subdivision 1a, produces the cannabis flower or cannabis product batches solely for the purposes of research and development; and

B. the cannabis flower or cannabis product batches are not consumed by humans.

Statutory Authority: *MS s 342.02*

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