

4770.1700 MEDICAL CANNABIS MANUFACTURER; PRODUCTION REQUIREMENTS.**Subpart 1. Cultivation and processing; generally.**

A. Only a registered medical cannabis manufacturer is authorized to produce and manufacture medical cannabis.

B. All phases of production must take place in designated, restricted access areas that are monitored by a surveillance camera system in accordance with part 4770.0900.

C. All areas must be compartmentalized based on function, and employee access must be restricted between compartments.

D. The production process must be designed to limit contamination. Examples of contamination include mold, fungus, bacterial diseases, rot, pests, nonorganic pesticides, and mildew.

E. Each production area must have an open aisle for unobstructed access, observation, and inventory of each plant group.

F. Biosecurity measures must be in effect and documented according to part 4770.0400, subpart 1.

G. The manufacturer must maintain a record at the facility of all crop inputs for at least five years. The record must include the following:

- (1) the date of application;
- (2) the name of the employee applying the crop input;
- (3) the name and description of the crop input that was applied, including the chemical name, product name, and manufacturer, where applicable;
- (4) the section, including the square footage, that received the application by batch number;
- (5) either the amount or concentration of crop input, or both, that was applied;
- (6) a copy of the label of the crop input applied; and
- (7) the vendor or other origin of the crop input.

H. At the time of planting, all plants must be tracked in a batch process with a unique batch number that must remain with the batch through final packaging.

I. A manufacturer must record any removal of plants from the batch on a record maintained at the manufacturing facility for at least five years.

J. The batch number must be displayed on the label of the medical cannabis.

Subp. 1a. Crop inputs used in cultivation of dried raw cannabis.

A. A manufacturer cultivating plants intended to become dried raw cannabis must follow practices and procedures that minimize the risk of chemical contamination or adulteration of the medical cannabis.

B. A manufacturer may only apply a pesticide in the cultivation of medical cannabis if the pesticide has been:

(1) deemed to be minimum risk by the United States Environmental Protection Agency in accordance with Code of Federal Regulations, title 40, section 152.25 (f), and exempted from United States Code, title 7, section 136 et seq., the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the pesticide's label does not exclude its use on a genus cannabis plant;

(2) registered with the United States Environmental Protection Agency under section 3 of FIFRA, United States Code, title 7, section 136 et seq., and is labeled for use on medical cannabis or cannabis used for human consumption; or

(3) registered with the United States Environmental Protection Agency under section 3 of FIFRA, United States Code, title 7, section 136 et seq., and:

(a) the active ingredient found in the pesticide is either exempt from the tolerance requirements in Code of Federal Regulations, title 40, part 180, subpart D, or does not require an exemption from the tolerance requirement in Code of Federal Regulations, title 40, part 180, subpart E;

(b) the pesticide product label does not prohibit use within an enclosed structure for the site of application;

(c) the pesticide product label expressly has directions for use on unspecified crops or plants intended for human consumption; and

(d) the pesticide product is used in accordance with all applicable instructions, restrictions, and requirements on the product label.

C. A manufacturer may use rooting hormones or cloning gels only during the propagation phase of the plant life cycle.

D. A manufacturer must store all crop input stocks in their original containers with their original labels intact. The manufacturer must ensure that packaged fertilizers and containers of diluted or prepared fertilizer remain labeled with information as required in Minnesota Statutes, section 18C.215, at all times.

E. The manufacturer must apply, store, and dispose of crop inputs, rinsate, and containers according to label instructions and all other applicable laws and regulations.

F. If an audit sample tested under part 4770.3035 shows the presence of a crop input not permitted under this subpart, the batch and any finished good produced from the batch are adulterated and must be disposed of as medical cannabis waste under part 4770.1200, subpart 2. The use of

pesticides not permitted under this part is presumptively classified as a serious violation under Minnesota Statutes, sections 144.989 to 144.993.

Subp. 2. Production of medical cannabis.

A. The commissioner must approve the manufacturer's use of any hydrocarbon-based extraction process. Examples of a hydrocarbon-based extraction process include the use of butane, ethanol, hexane, and isopropyl alcohol.

B. Medical cannabis must be prepared, handled, and stored in compliance with the sanitation requirements in this part.

C. A manufacturer must maintain appropriate temperatures and conditions that will protect plant material and medical cannabis against physical, chemical, and microbial contamination or deterioration of the product or its container.

D. A manufacturer must ensure that the cannabinoid content of the medical cannabis it produces is homogenous.

E. Prior to distributing new finished goods to customers, a manufacturer must obtain the commissioner's approval. The commissioner shall:

(1) for each manufacturer, maintain a registered finished goods list containing packaged product information; and

(2) update the list as needed.

F. The manufacturer must submit a definition of each finished good to the commissioner to include in the registered finished goods list before a batch sample may be tested.

G. Pre-rolls must not contain more than one gram of dried raw cannabis each.

Subp. 3. General sanitation requirements. A manufacturer must take all reasonable measures and precautions to ensure that:

A. any employee who has a communicable disease does not perform any tasks that might contaminate plant material or medical cannabis;

B. hand-washing facilities are:

(1) convenient and furnished with running water at a suitable temperature;

(2) located in all production areas; and

(3) equipped with effective hand-cleaning and sanitizing preparations and sanitary towel service or electronic drying devices;

C. all employees working in direct contact with plant material and medical cannabis must use hygienic practices while on duty, including:

(1) maintaining personal cleanliness; and

(2) washing hands thoroughly in a hand-washing area before starting work and at any other time when the hands may have become soiled or contaminated;

D. litter and waste are routinely removed and the operating systems for waste disposal are routinely inspected;

E. floors, walls, and ceilings are constructed with a surface that can be easily cleaned and maintained in good repair to inhibit microbial growth;

F. lighting is adequate in all areas where plant material and medical cannabis are processed, stored, or sold;

G. screening or other protection against the entry of pests is provided, including that rubbish is disposed of to minimize the development of odor and the potential for the waste becoming an attractant, harborage, or breeding place for pests;

H. any buildings, fixtures, and other facilities are maintained in a sanitary condition;

I. toxic cleaning compounds, sanitizing agents, and other potentially harmful chemicals are identified and stored in a separate location away from plant material and medical cannabis and in accordance with applicable local, state, or federal law;

J. all contact surfaces, utensils, and equipment used in the production of plant material and medical cannabis are maintained in a clean and sanitary condition;

K. the manufacturing facility water supply is sufficient for necessary operations;

L. plumbing size and design meets operational needs and all applicable state and local laws;

M. employees have accessible toilet facilities that are sanitary and in good repair; and

N. plant material and medical cannabis that could support the rapid growth of undesirable microorganisms are isolated to prevent the growth of those microorganisms.

Subp. 4. **Storage.**

A. A manufacturer must store plant material and medical cannabis during production, transport, and testing to prevent diversion, theft, or loss, including ensuring:

(1) plant material and medical cannabis are returned to a secure location immediately after completion of the process or at the end of the scheduled business day; and

(2) the tanks, vessels, bins, or bulk containers containing plant material or medical cannabis are locked inside a secure area if a process is not completed at the end of a business day.

B. A manufacturer must store all plant material and medical cannabis during production, transport, and testing, and all saleable medical cannabis:

(1) in areas that are maintained in a clean, orderly, and well-ventilated condition; and

(2) in storage areas that are free from infestation by insects, rodents, birds, and other pests of any kind.

C. To prevent degradation, a manufacturer must store all plant material and medical cannabis in production, transport, and testing, and all saleable medical cannabis under conditions that will protect it against physical, chemical, and microbial contamination and deterioration of the product and its container.

D. A manufacturer must maintain a separate secure storage area for medical cannabis that is returned, including medical cannabis that is outdated, damaged, deteriorated, mislabeled, or contaminated, or whose containers or packaging have been opened or breached, until the returned medical cannabis is destroyed. For purposes of this part, a separate, secure storage area includes a container, closet, or room that can be locked or secured.

Statutory Authority: *MS s 14.389; 152.25; 152.26; 152.261*

History: *39 SR 1080; 40 SR 1599; 46 SR 1011*

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