

3796:2-2-01

Cultivator operations and quality assurance plan.

(A) A cultivator shall establish, maintain, and comply with the policies and procedures contained in the operations plan submitted by the cultivator as part of the application that was approved by the department. The operations plan shall include policies and procedures for the production, storage, inventory, and transportation of medical marijuana. At a minimum, a facility's operations plan shall accomplish the following:

(1) Designate areas in the facility that are compartmentalized based on function, such as the marijuana cultivation area, with restricted access between the different areas of the facility;

(2) Implement policies and procedures that provide best practices for secure and proper cultivation of medical marijuana, which includes restricted movement between the different production areas by personnel based on access credentials assigned by the facility;

(3) Document the chain for all medical marijuana in the inventory tracking system;

(4) Establish a standard for the facility to be maintained in a clean and orderly condition, which includes free from infestation by rodents, insects, birds, and other animals of any kinds; and

(5) Maintain a facility with adequate lighting, ventilation, temperature, sanitation, equipment and security for the safe and consistent cultivation of medical marijuana.

(B) A cultivator shall submit, as part of the application process, and maintain a quality assurance and quality control plan for the cultivation of medical marijuana in its facility. The purpose of the plan is to ensure a safe, consistent product supply and minimize the deviation in quality of the production batches of medical marijuana.

(1) A cultivator shall submit any proposed changes to its plan to the department sixty days before the effective date of the proposed changes.

(2) The department shall have thirty days to review and approve or reject the proposed changes.

(C) The department, with assistance from the Ohio department of agriculture, shall maintain an approved list of permitted pesticides, fertilizers, and other chemicals. The department shall make this list with the label type, active ingredients, and concentration of the approved pesticides, fertilizers, and other chemicals available electronically. A cultivator that utilizes any approved pesticides, fertilizers, or other chemicals during the cultivation process shall meet the requirements contained in this rule.

(1) The pesticides must be registered with the Ohio department of agriculture and

meet either of the following requirements:

- (a) Registered with the United States Environmental Protection Agency under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 - 136y (2012); or
 - (b) Exempt from registration under 40 C.F.R. 152.25(f) (2015) and the active inert ingredients of the pesticide product are authorized for use on crops or plants intended for human consumption by the United States Environmental Protection Agency.
- (2) Any specialty fertilizer, as defined in division (Q) of section 905.31 of the Revised Code, must be registered with the Ohio department of agriculture pursuant to section 905.33 of the Revised Code.
- (3) No foliar application of approved pesticides, fertilizers, or other chemicals shall be made after the twenty-first day following the date that a plant is moved into the flowering stage of growth, unless otherwise permitted on the department's approved list.
- (4) All individuals applying pesticides, fertilizers, or other chemicals shall adhere to the use requirements of the label and shall employ all applicable personal protective equipment.
- (5) The cultivator shall comply with all posting requirements of the standard protection language stated on the label.
- (6) A record of all pesticide, fertilizer, or other chemical applications shall be maintained by the cultivator for at least five years and shall be made available to the department upon request. The application record shall include the following information:
- (a) Date and time of application;
 - (b) Stage of cultivation process;
 - (c) Date when the plants in the application area were moved to the flowering stage, if applicable;
 - (d) United States Environmental Protection Agency registration number, if applicable;
 - (e) Analysis of the fertilizer applied;
 - (f) Application site, which shall be identified by the location legend maintained by the cultivator;

(g) Name of the product being applied;

(h) Amount applied;

(i) Unique plant identifier or other information that identifies which plants received the application;

(j) Size of the application area;

(k) Name of individual making the application; and

(l) Comments or special conditions related to the application.

(7) Disposal of all unused pesticides, fertilizers, and other chemicals shall be performed in compliance with all state and federal laws and regulations, which require compliance with all directions on the product label.

(8) The use of a pesticide, fertilizer, or other chemical by a cultivator that is inconsistent with the product's label or in violation of paragraph (C) of this rule may result in action being taken by the department pursuant to rule 3796:5-6-01 of the Administrative Code.

(D) A cultivator shall maintain a facility in the following manner:

(1) A cultivator shall keep all floors and benches free of debris, dust, and any other potential contaminants, remove dead and unusable plant parts from the marijuana cultivation area, and control rodents and other non-plant related pests.

(2) A cultivator shall use chemicals, cleaning solutions, and other sanitizing agents approved for use around vegetables, fruit, or medicinal plants and shall store them in a manner that protects against contamination.

(3) A cultivator shall keep its equipment in a clean, professional environment and maintain a cleaning and equipment maintenance log at the facility.

(4) The cultivator shall have its scales, balances, or other weight and/or mass measuring devices routinely calibrated using National Institute of Standards and Technology (NIST)-traceable reference weights, at least once each calendar year, by an independent third party approved by the department.

(5) The water supply shall be derived from a source that is a regulated water system or a private water supply and shall meet the needs of the cultivator. A private water supply shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water.

(6) A cultivator shall implement policies and procedures related to receiving, inspecting, transporting, segregating, preparing, packaging, and storing medical marijuana in accordance with adequate sanitation principles.

Effective:

Five Year Review (FYR) Dates:

Certification

Date

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