

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amended After Comments)

902 KAR 45:001. Definitions for hemp-derived cannabinoid products.

RELATES TO: KRS Chapter 13B, 217.015, 217.025, 217.035, 217.037, 217.039, 260.850, 438.305(4), 2023 Ky Acts ch. 78, **7 C.F.R. 990.1**

STATUTORY AUTHORITY: KRS 217.125, 217.135

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) authorizes the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 through 217.215. KRS 217.135 authorizes the secretary to establish food standards by administrative regulation including a reasonable definition, standard of identity, and designation of optional ingredients that shall be named on the label. This administrative regulation establishes the definitions applicable to hemp-derived cannabinoid products.

Section 1. Definitions.

- (1) "Adult-use cannabinoid" means a product with intoxicating properties that changes the function of the nervous system and results in alterations of perception, cognition, or behavior.
- (2) "Approved source" means:
 - (a) A Kentucky hemp grower or handler licensed by the Kentucky Department of Agriculture, or an out-of-state hemp grower or handler who is duly authorized to produce hemp under the laws of the applicable jurisdiction;
 - (b) A hemp product manufacturer or processor permitted by the Kentucky Department for Public Health or
 - (c) A manufacturer or processor permitted by another state regulatory authority for hemp-derived cannabinoid products if that state has been approved by the department as having equivalent state standards for processing, laboratory testing, and labeling requirements.
- (3) "Cabinet" is defined by KRS 217.015(3).
- (4) "Cannabidiol" or "CBD" is defined by KRS 217.039(1)(a).
- (5) "Cannabinoid" means a compound found in the hemp plant *Cannabis sativa* L from a United States Department of Agriculture sanctioned domestic hemp production program and does not include cannabinoids derived from any other substance.
- (6) "Cannabinoid product class" means a group of cannabinoid products that:
 - (a) Have all ingredients in common; and
 - (b) Are produced by or for the same company.
- (7) "Cartoon" means any drawing or other depiction of an object, person, animal, creature or any similar caricature that satisfies any of the following criteria:
 - (a) The use of comically exaggerated features;
 - (b) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or
 - (c) The attribution of unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds or transformation.
- (8) "Child-resistant" means packaging that is:
 - (a) Designed or constructed to be significantly difficult for children under five (5) years of age to open and not difficult for adults to use properly; and

- (b) Resealable to maintain this effectiveness for children through multiple openings for any product intended for more than a single use or containing multiple servings.
- (9) "Cosmetic" is defined by KRS 217.015(7).
- (10) "Direct supervision" means the continuous, on-site observation of an employee with the supervisor physically present.
- (11) "Food service establishment" is defined by KRS 217.015(21).
- (12) "Hemp" is defined by KRS 260.850(5).
- (13) "Hemp-derived cannabinoid" means an ingestible, inhalable, or cosmetic product that is processed or derived from hemp.
- (14) "Home-based processor" is defined by KRS 217.015(56).
- (15) "Hydrogenation" means the chemical reaction between molecular hydrogen (H₂) and another compound or element.
- (16) "Imminent health hazard" is defined by KRS 217.015(24).
- (17) "Infused" means adding a cannabinoid ingredient to an ingestible cannabinoid product.
- (18) "Non-intoxicating cannabinoid" means a product with non-psychoactive properties that does not change the function of the nervous system and does not result in alteration of perception, cognition, or behavior.
- (19) "Person" is defined by KRS 217.015(32).
- (20) "Proof of age" is defined by KRS 438.305(4).
- (21) "Revocation" means the permit to operate is cancelled by the department.
- (22) "Serious adverse event" means a medical occurrence associated with the use of a cannabinoid product that results in one (1) or more of the following:
- (a) Death;
 - (b) A life-threatening event;
 - (c) Inpatient hospitalization, or prolongation of an existing hospitalization;
 - (d) A persistent or significant incapacity, or substantial disruption in the ability to conduct normal life functions; or
 - (e) A congenital anomaly or birth defect.
- (23) "Tentatively identified compounds" or "TIC" means compounds detected in a sample that are not among the target analytes.
- (24) "Total THC" is defined by 7 C.F.R. 990.1.**

STEVEN J. STACK, MD, MBA, Commissioner
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: September 9, 2024

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REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Krista Quarles or Julie Brooks

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the terms used for hemp-derived cannabinoid product sampling and testing requirements, cannabinoid processing and manufacturing, and retail sales including sells at food service establishments. The amended after comments version of this administrative regulation adds a definition for total THC for clarification.

(b) The necessity of this administrative regulation:

Many hemp-derived cannabinoid products sold in Kentucky continue to be unregulated. This administrative regulation is necessary to ensure a consistent understanding of the terms related to cannabinoid processing, manufacturing, sampling and testing, and retail sales.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

KRS 217.125(1) authorizes the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 through 217.215.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation ensures a consistent understanding of the terms used in the processing, manufacturing, sampling, testing, and retail sales of hemp-derived cannabinoid products.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation:

This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes:

This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes:

This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

There are currently thirty-eight (38) manufacturers of cannabinoid products registered with the department. The department is unclear of the number of retail establishments that sell cannabinoid products. The department does not permit the testing facilities and has no method to determine the number of facilities in the commonwealth.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

Cannabinoid processor and manufacturers, testing laboratories, and retail establishments will need to be aware of the defined terms.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

Compliance with this new administrative regulation will not add to the cost for the regulated entities.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

All entities will have a consistent understanding of the terms related to cannabinoid products.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

The current budget for the food manufacturing permitting and inspection program is \$1,080,900. The increase in required permitting and inspection processes to implement this administrative regulation will cost the department an additional \$1,551,397 in the first year.

(b) On a continuing basis:

The department will continue to need an additional \$1,551,397, at a minimum, in subsequent years.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

Funding to implement and enforce this administrative regulation will be from a mix of fees paid to the department and state general fund dollars.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

An increase in fees or funding is not needed to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This administrative regulation does not contain fees.

(9) TIERING: Is tiering applied?

Tiering is not applied. The terms defined in this administrative regulation are applicable to all regulated entities.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 217.125 and 217.155.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:

The Department for Public Health, Division of Public Health Protection and Safety is the promulgating agency.

(a) Estimate the following for the first year:

Expenditures: Expenditures to the department to implement this administrative regulation will be approximately \$1,551,397 per year.

Revenues: This administrative regulation does not generate revenue.

Cost Savings: This administrative regulation will not result in cost savings.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

Expenditures for the Department for Public Health may be impacted by changes in salary, fringe benefits and travel cost for state and local health department employees. These changes cannot be determined at this time.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts):

There are no affected local entities.

(a) Estimate the following for the first year:

Expenditures:

Revenues:

Cost Savings:

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

(4) Identify additional regulated entities not listed in questions (2) or (3):

Additional regulated entities are processors and manufacturers of hemp-derived cannabinoid products, testing facilities, and retail establishments including food service establishments.

(a) Estimate the following for the first year:

Expenditures: This administrative regulation does not impact the expenditures of the regulated entities.

Revenues: This administrative regulation does not generate revenue.

Cost Savings: This administrative regulation does not result in cost savings.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

There will be no difference in subsequent years.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:

This administrative regulation does not have a significant fiscal impact.

(b) Methodology and resources used to determine the fiscal impact:

This administrative regulation is a definitions only regulation.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). (\$500,000 or more, in aggregate)

This administrative regulation will not have an overall negative or adverse major economic impact.

(b) The methodology and resources used to reach this conclusion:

Not applicable.