

902 KAR 45:190. Hemp-derived cannabinoid products; packaging and labeling requirements.

RELATES TO: KRS 217.015, 217.025, 217.035, 217.037, 217.155, 260.850

STATUTORY AUTHORITY: KRS 217.125, 217.127, 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 217.125(2) requires the secretary to provide by administrative regulation a schedule of fees for permits to operate and for inspection activities carried out by the cabinet pursuant to KRS 217.025 through 217.390. 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 registration process to utilize hemp-derived cannabinoid products in foods and cosmetics, the labeling and packaging requirements for products containing hemp-derived cannabinoid, and methods for use of hemp-derived cannabinoid as an additive to food products.

Section 1. Definitions.

- (1) "Approved source" means a Kentucky hemp grower, processor, or handler licensed by the Kentucky Department of Agriculture, or an out-of-state hemp grower, processor, or handler who is duly authorized to produce hemp under the laws of the applicable jurisdiction.
- (2) "Cabinet" is defined by KRS 217.015(3).
- (3) "Cannabinoid" means a non-intoxicating compound found in the hemp plant *Cannabis sativa*.
- (4) "Cosmetic" is defined by KRS 217.015(7).
- (5) "Department" means the Kentucky Department for Public Health.
- (6) "Food service establishment" is defined by KRS 217.015(21).
- (7) "Hemp" is defined by KRS 260.850(5).
- (8) "Home-based processor" is defined by KRS 217.015(56).
- (9) "Person" is defined by KRS 217.015(32).

Section 2. Permits.

- (1) A person located in Kentucky seeking to manufacture a hemp-derived ingestible or cosmetic cannabinoid product shall submit an Application for Permit to Operate a Food Plant or Cosmetic Manufacturing Plant, DFS-260, incorporated by reference in 902 KAR 45:160, to the department.
- (2) The permit shall be:
 - (a) Nontransferable in regards to person or address; and
 - (b) Renewed annually.
- (3) The fee shall be paid in accordance with:
 - (a) 902 KAR 45:180, for a food processing establishment;
 - (b) 902 KAR 45:180, for a cosmetic manufacturer; and
 - (c) 902 KAR 45:110, Section 1(3) and (6), for a food service establishment.
- (4) Ingestible hemp-derived cannabinoid products shall not be manufactured, marketed, sold, or distributed by a home-based processor.

Section 3. Product Packaging and Labeling.

- (1) Each hemp-derived cannabinoid product manufactured, marketed, sold, or distributed in the Commonwealth shall be packaged and labeled in accordance with KRS 217.037 and this administrative regulation.

(2) Except as established in subsection (3) of this section, an ingestible or cosmetic product label shall include, in a print no less than six (6) point font, the following information:

- (a) A statement of identity or common product name that shall be stated upon the principal display panel of the label;
 - (b) The net quantity of contents expressed in both standard English and metric units of measurement located in the lower thirty (30) percent of the principal display panel of the label parallel to the base of the container;
 - (c) The ingredients of the hemp-derived cannabinoid product, in descending order of predominance by weight;
 - (d) The name of the manufacturer or distributor;
 - (e) A statement that the hemp-derived cannabinoid product is within the federal legal limit of zero and three-tenths (0.3) percent delta-9 tetrahydrocannabinol;
 - (f) The total amount of cannabinoid per serving for ingestible products, or the total amount per container for cosmetic products;
 - (g) Suggested use instructions or directions, including serving sizes; and
 - (h) An expiration date, if any.
- (3) An ingestible or cosmetic product that has a total area of twelve (12) square inches or less available to bear labeling shall be labeled in accordance with subsection (2) of this section, except the print may be smaller than six (6) point font but shall not measure less than 1/32 of an inch in height.
- (4) Each container of ingestible or cosmetic hemp-derived cannabinoid product shall have a tamper evident seal.
- (5) Product packaging, labeling or advertising material for any hemp-derived cannabinoid product shall not bear any implicit or explicit health claims stating that the product can diagnose, treat, cure, or prevent any disease.

Section 4. Hemp-derived Ingestible Cannabinoid Products.

- (1) Hemp-derived cannabinoid may be added to an ingestible product during the manufacturing process or prior to retail sale at a food service establishment.
 - (2) The hemp-derived cannabinoid shall be obtained from an approved source.
 - (3) The food processor or food service establishment shall obtain a valid certificate of analysis from the approved source and provide a copy upon inspection.
 - (4) Food or ingestible product shall not contain a total delta-9 tetrahydrocannabinol concentration of more than zero and three-tenths (0.3) percent on a dry weight basis or contain tetrahydrocannabinol as the primary cannabinoid.
 - (5) A food service establishment offering hemp-derived cannabinoid products in a finished food product shall provide to consumers upon request:
 - (a) The common name of the product;
 - (b) The manufacturer or distributor of the product; and
 - (c) A statement that the hemp-derived cannabinoid product is within the federal legal limit of zero and three-tenths (0.3) percent delta-9 tetrahydrocannabinol.
- (47 Ky.R. 1157, 1767, 1995; 48 Ky.R. 60; eff. 6-16-2021.)