STATEMENT OF EMERGENCY

902 KAR 45:001E.

This emergency administrative regulation is being promulgated to implement the requirements of HB 544, 2023 Ky. Acts ch. 78. This emergency administrative regulation is needed pursuant to KRS 13A.190(1)(a)3. to continue the process of regulating delta-8 tetrahydrocannabinol and any other hemp-derived substances. This emergency administrative regulation is necessary to implement the requirements of HB 544, 2023 Ky. Acts ch. 78, which requires the cabinet to regulate covered products, as specified in EO 2022-799, to prohibit the sale of intoxicating products to anyone under twenty-one (21) years of age, to set the laboratory testing requirements, and to require products be labeled in accordance with the act and KRS 217.037. This emergency administrative regulation will be filed with an ordinary administrative regulation. The ordinary administrative regulation is identical to this emergency administrative regulation.

ANDY BESHEAR, Governor

ERIC C. FRIEDLANDER, Secretary

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

EFFECTIVE: April 24, 2024

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

STATUTORY AUTHORITY: KRS 217.125, 217.135

CERTIFICATION STATEMENT:

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.