STATEMENT OF EMERGENCY
902 KAR 45:021E.

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

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(New Emergency Administrative Regulation)

902 KAR 45:021E. Hemp-derived cannabinoid products registration, processing, manufacturing, storage and distribution requirements.

RELATES TO: KRS Chapter 13B, 217.015, 217.025, 217.035, 217.037, 217.039, 217.992, 2023 Ky Acts ch. 78

STATUTORY AUTHORITY: KRS 217.125, 217.127, 217.135, 217.155

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(12) 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. KRS 217.155 allows the cabinet or its duly authorized agent free access at reasonable times for the purpose of inspecting any factory, warehouse, or establishment where foods, drugs, devices, or cosmetics are manufactured or held for sale. This administrative regulation establishes the product registration, the processing and manufacturing procedures for hemp-derived cannabinoid products, including the permit fee, and the labeling and packaging requirements for products containing hemp-derived cannabinoids. Establishments permitted with the department prior to the effective date of this administrative regulation shall be exempted from the permit fee requirement until the annual renewal date.

Section 1. Permit and Product Registration.

(1) In-state permit.

(a) A person located in Kentucky seeking to process, manufacture, store, or distribute hemp-derived cannabinoid products shall be permitted by the cabinet.

(b) The permit shall be:

1. Nontransferable in regard to person or address;
2. Posted in a conspicuous place in the facility;
3. Renewed annually; and
4. Include the fee paid in accordance with:
   a. For a hemp processing permit, the fee is $3,000.
   b. For a hemp manufacturing permit, the fee is $1,000.
   c. For a hemp cannabinoid wholesale warehouse and distributor permit, the fee is $1,000.
   d. For a hemp cosmetic permit, the fee is $200.
5. Include the product registration fee required by subsection (4) of this section.

(2) The permit fee established pursuant to subsection (1)(b)4. of this section shall be waived for all facilities permitted as of April 27, 2024, and such facilities shall pay the permit fee at next annual renewal date.

(3)

(a) All out-of-state processors and manufacturers of hemp-derived cannabinoid products available for distribution in Kentucky shall submit an annual registration to the department.

(b) The registration for an out-of-state processor or manufacturer shall:

1. Be renewed annually by December 31 each year; and
2. Include:
   a. A copy of the current, valid permit to process or manufacture hemp-derived cannabinoids issued from the state regulatory authority;
   b. A copy of the state regulation pertaining to the production of hemp-derived cannabinoid products; and
   c. The product registration fee required by subsection (5) of this section.

(4) Cannabinoids requiring registration:

(a) Adult-use cannabinoids shall include:

Cannabinoid	CAS Number
Delta-10-tetrahydrocannabinol (Delta-10-THC)	95543-62-7
Delta-9-tetrahydrocannabinol (THC) with three tenths of one percent (0.3%) or less Total THC	1972-08-3
Delta-8-tetrahydrocannabinol (Delta-8-THC)	5957-75-5
Delta-9-tetrahydrocannabinolic acid A (THCA-A) with three tenths of one percent (0.3%) or less Total THC	23978-85-0
Delta-9-tetrahydrocannabivarin (THCV)	31262-37-0
Delta-9-tetrahydrocannabivarinic acid (THCVA)	39986-26-0
Delta-6-tetrahydrocannabinol (Delta 6)	95720-02-8
Hexahydrocannabinol (HHC)(-)	6692-85-9
Tetrahydrocannabiphorol (THCp)	54763-99-4
Tetrahydrocannabinol methyl ether (THCM)	36403-68-6

(b) Non-intoxicating cannabinoids shall include:

Cannabinoid	CAS Number
Cannabidiol (CBD)	13956-29-1
Cannabidiolic acid (CBDA)	1244-58-2
Cannabidivarin (CBDV)	24274-48-4
Cannabidivarinic acid (CBDVA)	31992-13-5
Cannabichromene (CBC)	20675-51-8
Cannabichromenic acid (CBCA)	185505-15-1
Cannabigerolic acid (CBGA)	25555-57-1
Cannabigerol (CBG)	25654-31-3
Cannabinol (CBN)	521-35-7
Cannabitriol (CBT)	11003-36-4

(c) All other cannabinoids are prohibited for sale in Kentucky unless pre-approved by the cabinet.

(5) Product registration fee.

(a) A product registration fee of $200 shall be paid for each cannabinoid product or cannabinoid product class sold in Kentucky.

(b) The fee shall be paid to the cabinet by check or money order made payable to the Kentucky State Treasurer.

(6) A new product registration shall be required for changes:

(a) In the chemical composition or formula of the cannabinoid product; or

(b) To the serving size or directions for use.

(7) All in-state processors and manufacturers permitted by the cabinet, and all out-of-state processors and manufacturers registering with the cabinet shall submit:

(a) The name and address of the applicant;

(b) The name and address of the brand or company whose name shall appear on the label, if other than the applicant's;

(c) The name of the product;

(d) The name and address of the origin of the adult-use cannabinoid product with which the final product was manufactured;

(e) A complete copy of the front and back of the label that will appear on the product; and

(f) A certificate of analysis from an accredited third-party laboratory for the lot for each product.

(8) A new in-state processor or manufacturer permit, or out-of-state registration shall be required for any changes to the requirements of subsection (7) of this section.

Section 2. Processing, Manufacture, Storage, or Distribution of Hemp-derived Cannabinoid Products.

(1) All processors and manufacturers shall meet:

(a) The applicable requirements of 902 KAR 45:160 Section 2(1)(u); and

(b) The requirements of 902 KAR 45:160, Sections 4, 5, 6, 7, 8, 9, 10, 11, and 14.

(2) Cannabinoid products shall not be manufactured, marketed, sold, or distributed by a home-based processor.

(3) The following hemp-derived products shall not be manufactured:

(a) Hemp cigarettes;

(b) Hemp cigars;

(c) Chew, dip, or other smokeless material consisting of hemp leaf material or hemp floral material; and

(d) Hemp leaf material or floral material teas.

(4) A business that processes, manufactures, warehouses, distributes, sells, or serves adult-use hemp-derived cannabinoid products shall not employ any person who is under twenty-one (21) years of age, unless the person employed is at least eighteen (18) years of age and under the direct supervision of a person twenty-one (21) years of age or older.

(5) Non-intoxicating cannabinoid products shall:

(a) Have at least a fifteen (15) non-intoxicating cannabinoid to one (1) adult-use cannabinoid ratio;

(b) Contain two and five-tenths (2.5) milligrams or less of adult-use cannabinoid per serving.

(6) The serving size of an ingestible cannabinoid product shall be:

(a) As a whole unit where one (1) unit equals one (1) serving;

(b) Equal the maximum amount recommended, as appropriate, on the label for consumption per occasion in whole units; and

(c) Based on the amount typically consumed.

(7) A hemp-derived cannabinoid processing or manufacturing facility shall not treat or otherwise adulterate a cannabinoid product with:

(a) Any non-cannabinoid additive that increases toxicity or addictive potential, excluding caffeine;

(b) Alcohol;

(c) Nicotine; or

(d) Other chemicals that may increase carcinogenicity or cardiac effects.

(8) All products shall be homogenized to ensure uniform distribution of cannabinoids throughout the product.

(9) Only permitted hemp-derived cannabinoid processing facilities shall perform cannabinoid extraction, conversion, catalyzation, distillation, hydrogenation, or other refinement processes.

(10) A hemp-derived cannabinoid processor or manufacturer shall only use the following solvents: water, glycerin, vegetable oils, animal fats, butane, propane, carbon dioxide, ethanol, isopropanol, acetone, heptane, ethyl acetate, and pentane. The use of any other solvent is expressly prohibited unless pre-approved by the cabinet.

(11) A hemp-derived cannabinoid processor using hydrocarbon-based solvents shall use only such solvents of ninety-nine (99) percent or better purity. Nonhydrocarbon-based solvents shall be food grade.

(12)

(a) A current copy of safety data sheets and a receipt of purchase for all solvents used or to be used in an extraction process shall be kept on file;

(b) The processor shall retain in its facility a certificate of analysis (COA) from the original manufacturer with purity and impurity limits and results for all solvents used; and

(c) Certificates shall be retained for two (2) years.

(13)

(a) Solvents shall be collected and stored in food-grade containers to maintain purity; and

(b) Solvent containers shall be replaced or safely purged, cleaned, and sanitized periodically.

(14) Extraction processes shall take place in an environment properly ventilated to control all sources of ignition where a flammable atmosphere is, or could be, present.

(15) Cannabinoid processing facilities shall not use pressurized canned flammable fuel, such as butane intended for use in outdoor activities, handheld torch devices, and refillable cigarette lighters.

(16) Cannabinoid processing facilities using carbon dioxide shall have equipment and facilities approved by local fire code officials, if applicable.

(17) Processes using flammable gas or flammable liquid shall have leak or gas detection measures, or both.

(18) A permittee shall not use dimethylsulfoxide (DMSO) in the manufacture of hemp-derived cannabinoid products, and possession upon the permitted premises is prohibited.

(19)

(a) A hemp-derived cannabinoid manufacturer may use terpenes or other hemp essential oil but shall not use non-cannabinoid derived inactive ingredients not listed in the federal Food and Drug Administration inactive ingredient database at https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm in the manufacture of inhalable hemp-derived cannabinoid product and distillate intended for use through a vaporizer delivery device or pressurized metered dose inhaler; and

(b) Any non-cannabinoid derived inactive ingredients used shall be less than or equal to the concentration listed in the database.

(20) The following substances shall be prohibited in hemp-derived cannabinoid extraction intended for inhalation:

(a) Acetates;

(b) Medium-chain triglycerides (MCT);

(c) Polyethylene glycol (PEG);

(d) Propylene glycol (PG or PPG);

(e) Diketones:

1. 2,3-butanedione (Diacetyl);
2. 2,3-pentanedione (acetylpropionyl); and
3. 3-hydroxybutanone (acetoin);

(f) Myclobutanil;

(g) Artificial food coloring; and

(h) Benzoic acid.

(21) Hazard analysis and risk-based preventive controls.

(a) Processing facilities shall conduct a hazard analysis in accordance with 902 KAR 45:160 Section 2(1)(u) to identify and evaluate, based on experience, illness data, scientific report, and other information known, or reasonably foreseeable hazards associated with each type of cannabinoid product produced by extraction, conversion, catalyzation, distillation, hydrogenation, or other refinement processes, and shall include:

1. Processing reagents or catalysis;
2. Processing by-products or compounds; and
3. Tentatively identified compounds.

(b) The hazard analysis shall include an evaluation of the hazards identified to assess the severity of illness or injury from the hazard and the probability that the hazard will occur in the absence of preventive controls.

(c) A processing facility shall identify and implement preventive controls to provide assurances that any hazards requiring a preventive control shall be significantly minimized or prevented, and the hemp-derived cannabinoid product not adulterated.

(d) The cabinet may initiate an investigation of a processing facility as a result of a by-product or compound with no toxicity study or a TICs report from a testing facility and may require a processing or manufacturing facility to submit samples for additional testing, including testing for analytes that are not required by this administrative regulation, at the processing or manufacturing facility's expense.

Section 3. Record Keeping.

(1) A master formulation record shall be prepared and maintained for each unique hemp-derived cannabinoid product.

(2) The master formulation record shall include at least the following information:

(a) Name of the cannabinoid product;

(b) Ingredient identities and amounts;

(c) Specifications on the delivery device (if applicable);

(d) Complete instructions for preparing the cannabinoid product, including equipment, supplies, and description of the manufacturing steps;

(e) Process controls and procedures; and

(f) Any other information needed to describe the production and ensure its repeatability.

(3) A batch or process lot manufacturing record shall be created for each production batch of cannabinoid product.

(4) The batch manufacturing record shall include at the least the following information:

(a) Name of the cannabinoid product;

(b) Master formulation record reference for the cannabinoid product;

(c) Date and time of preparation of the cannabinoid product;
(d) Production batch number;
(e) Signature or initials of individuals involved in each manufacturing step;
(f) Name, vendor, or manufacturer, production batch number, and expiration date of each ingredient;
(g) Weight or measurement of each ingredient;
(h) Documentation of process controls;
(i) Any deviations from the master formulation record, and any problems or errors experienced during the manufacture, and corrective actions; and
(j) Total quantity of the cannabinoid product manufactured.

Section 4. Product Packaging and Labeling.

(1) Each cannabinoid product manufactured, marketed, sold, or distributed in the commonwealth shall be packaged and labeled in accordance with KRS 217.037, HB 544, 2023 Ky. Acts ch. 78, and this administrative regulation.

(2) Each container of adult-use cannabinoid product shall:
(a) Have a tamper-evident seal; and
(b) Be in child-resistant packaging.

(3) Each container of non-intoxicating cannabinoid product or cosmetic shall have a tamper-evident seal.

(4) Cannabinoid product packaging shall not include:
(a) Any cartoon images;
(b) Likeness to images, characters, or phrases that are popularly used to advertise to children;
(c) Likeness to or imitation of any commercially available candy, snack, baked good, or beverage packaging or labeling;
(d) The terms "candy" or "candies", or any variation in the spelling of these words; or
(e) The logo of the department or cabinet, or any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe the product has been endorsed, manufactured, or used by any state, county, or municipality or any agency thereof, excluding the use of seals associated with state or federal programs used in accordance with state or federal law and regulations.

(5) The total amount of hemp-derived cannabinoid per serving and the total amount per container shall accurately reflect testing results and shall not contain less than eighty (80) percent or more than 120% of the concentration of total cannabinoid content as listed on the product label:
(a) For hemp-derived cannabinoid ingestible and inhalable products, potency shall be labeled as milligrams per serving for total tetrahydrocannabinol and the primary cannabinoid marketed, as applicable; and milligrams per package for total tetrahydrocannabinol and the primary cannabinoids marketed; and
(b) Other hemp-derived cannabinoids labeled milligrams per gram (mg/g) per serving, excluding cosmetics, and milligrams per package, if listed on the label.

(6) Adult-use hemp-derived cannabinoid products shall include the following warning label statements:
(a) "Warning: Contains THC."
(b) "This product is intended for use by adults 21 years and older. Keep out of reach of children."
(c) "There may be health risks associated with the consumption of this product."
(d) "There may be additional health risks associated with the consumption of this product for those who are pregnant, nursing, or plan to become pregnant."
(e) "The intoxicating effects of this product may be delayed by two or more hours."

(f) "May cause drowsiness or impairment. Do not drive a motor vehicle or operate machinery while using this product."

(g) "Use of this product may result in a positive drug screen."

(7) A quick response or QR code may be used as a link to the warning statements required by subsection (6) of this section. The QR code shall be labeled as "Warning Statements" directly above or below the code and shall be large enough to be smart-phone readable.

Section 5. Inspection and Enforcement.

(1) The cabinet or its duly authorized agent shall conduct an onsite inspection of all permitted cannabinoid processing and manufacturing establishments, storage warehouses, and distribution centers.

(2) The location of the permitted establishment, all general business records, including employee records, and vehicles utilized to transport products are subject to reasonable inspection.

(3) All cannabinoid establishments, whether permitted or not, shall cooperate with the cabinet or its duly authorized agent during any inspections, complaint investigation, and requests for information or data, in order to verify compliance with this administrative regulation.

(4) All products not in compliance with this administrative regulation may be seized and destroyed by the cabinet or its duly authorized agent.

(5) The permit holder shall take immediate steps to correct conditions that have caused an imminent health hazard.

(6)

(a) The permit holder shall notify the cabinet within twenty-four (24) hours of the knowledge of an imminent health hazard that cannot be controlled by immediate corrective action or if product, product packaging, cosmetic, or cosmetic packaging has become contaminated because of an imminent health hazard.

(b) Notification to the cabinet shall be made by:

1. Email to food.safety@ky.gov; or
2. Phone to (502)564-7181.

(7) If the cabinet has evidence that a permit holder has failed to act to correct an imminent health hazard, the following enforcement provisions shall be initiated:

(a) Suspend the permit without an administrative hearing; or

(b) Suspend that portion of the operation affected by the imminent health hazard without an administrative hearing.

(8) If a permit suspension is due to an imminent health hazard, the permit holder may submit a request for an administrative hearing to the cabinet in accordance with KRS Chapter 13B.

(9) A permit holder shall notify the cabinet within twenty-four (24) hours of becoming aware of any serious adverse event to a hemp-derived cannabinoid product sold or transferred by the permit holder.

(10) In all other instances of violation of this administrative regulation, the cabinet shall serve the permit holder with a written notice specifying the violation and afford the holder an opportunity to correct.

(11) If a permit holder has failed to comply with the written notice within the timeframe granted, the cabinet shall issue a notice of intent to suspend the permit.

(12)

(a) The notice in subsection (11) of this section shall include notification that the permit shall be suspended at the end of ten (10) days following service of the notice, unless a written request for an administrative hearing is filed with the cabinet by the permit holder within the ten (10) day period; and

(b) The administrative hearing shall be conducted in accordance with KRS 13B.080.

(13) For a permitted facility that has had a suspended permit two (2) or more times within a five (5) year period, the cabinet shall initiate permit revocation proceedings. Prior to this action, the cabinet shall notify the permit holder in writing, stating the reasons for which the permit revocation is being sought and advising that the permit shall be permanently revoked at the end of ten (10) days following service of the notice, unless a request for an administrative hearing is filed with the cabinet pursuant to KRS Chapter 13B by the permit holder within the ten (10) day period.

(14) Any person who violates any provision of this administrative regulation may be fined, found guilty of a criminal offense, or both pursuant to KRS 217.992.

(15) State and local law enforcement officers shall have concurrent jurisdiction to enforce violations of this section.

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

APPROVED BY AGENCY: April 22, 2024

FILED WITH LRC: April 24, 2024 at 12:30 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on June 24, 2024, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by June 17, 2024, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until June 30, 2024. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-7476; fax 502-564-7091; email CHFSregs@ky.gov.