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

902 KAR 45:021. 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 **December 31, 2024,**~~**[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 **December 31, 2024**~~**[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 **complete the business registration asrequired by**~~**[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 fee required by subparagraph (1)(b)4.c. of this section; and**

d. 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

(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;

(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 **product**~~**[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 **with the intent for retail sale**:

(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**; and**

(e) Hemp bud or floral material.

(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; and

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

(6) **Products not meeting the requirements of subsection (5) of this section shall be considered adult-use products.**

(7) 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.

(8) ~~**[(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.

(9) ~~**[(8)]**~~ All products shall be homogenized to ensure uniform distribution of cannabinoids throughout the product.

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

(11) ~~**[(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.

(12) ~~**[(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.

(13) ~~**[(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.

(14) ~~**[(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.

(15) ~~**[(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.

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

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

(18) ~~**[(17)]**~~ Processes using flammable gas or flammable liquid shall have leak or gas detection measures, or both.

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

(20) ~~**[(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.

(21) ~~**[(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.

(22) ~~**[(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, or 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**, excluding cosmetics,** 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)

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

(b) The permit holder shall be given notice that they have ten (10) days to file an appeal pursuant to subsection (12) of this section.

(c) If no request for an appeal is filed, seized products shall be destroyed.

(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**~~[or]~~ 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: September 9, 2024

FILED WITH LRC: September 10, 2024 at 2:00 p.m.

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.

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 registration, processing, and manufacturing procedures for hemp-derived cannabinoid products, and the labeling and packaging requirements for products containing hemp-derived cannabinoids. The amended after comments version of this administrative regulation clarifies the timeline and registration process for processors, manufacturers, and distributors, clarifies the materials that can be manufactured or produced, amends the enforcement actions to allow for due process when products are seized, and makes other changes necessary for KRS chapter 13A compliance.

(b) The necessity of this administrative regulation:

Many hemp-derived cannabinoid products sold in Kentucky remain unregulated. This administrative regulation is necessary to ensure that all hemp-derived cannabinoid products produced, manufactured and sold in the state are safe for human consumption.

(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. 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. KRS 217.155 allows the cabinet or its duly authorized agent free access at reasonable times for the purpose of inspection 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.

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

This administrative regulation ensures all hemp-derived cannabinoid products manufactured, processed, distributed, or sold are safe for human consumption, and are labeled in a manner that allows the end user to understand the effects of the 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 cannabidiol (CBD) products registered with the department.

(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:
The requirements of this administrative regulation are not new requirements for processors and manufacturers. Processors and manufacturers will need to make sure their products comply with the requirements of this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):
The permit will cost processors $3,000 plus $200 per registered product or product class. The permit for manufacturers is $1,000 plus $200 per registered product or product class. The permit for warehouses is $1,000. The permit for cosmetic manufacturers is $200. Out-of-state processors and manufacturer will pay $200 per to register products or product class shipped into the commonwealth.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):
Producers and manufacturers will be able to offer products that are safe for human consumption.

(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 emergency 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. An increase in permitted facilities will result in increased costs.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:
State general fund dollars and revenue received from permitting and product registration are the sources of funding for this administrative regulation.

(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:

Processors and manufacturers currently pay between a $125 and $1,000 fee depending on the size of the facility and level of risk of the products produced. The fees established in this administrative regulation are necessary to offset the cost associated with implementing 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 establish permitting and project registration fees. The proposed fee structure is an increase from the current assessed fee. The current fee structure references the fee structure for food manufacturing and processors and manufacturers may pay between a $125 and $1,000 fee depending on the size of the facility. It is not appropriate to regulate cannabinoid products as food products. Products that contain cannabinoids should be regulated under their own classification. This includes the permit and product registration fee structure.

(9) TIERING: Is tiering applied?

Tiering is applied. The fee for all processors and manufacturers currently permitted by the department July 1, 2025, will be waived until the date of the next annual renewal. All new applications for a permit filed after July 1, 2025, will be assessed the fee upon initial filing.

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, 217.127, 217.135, 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 for the department to implement this administrative regulation will be approximately $1,551,397 per year.

Revenues:Revenues for the permitting of processors and manufacturers in this administrative regulation can range between $38,000 to $114,000. The revenue for product registration cannot be determined at this time.

Cost Savings:This administrative regulation does 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. Expenditures for regulated entities will not change without an amendment to this administrative regulation.

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

Local law enforcement entities may be affected by this administrative regulation.

(a) Estimate the following for the first year:

Expenditures:The department is not able to calculate the expenditures for affected local entities at this time.

Revenues:This administrative regulation will not generate revenue for affected local entities.

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

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

The department is not able to determine changes in expenditures, revenues or cost savings for affected local entities.

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

This administrative regulation will impact all cannabinoid processors, manufacturers, storage warehouses, and distributors. Currently there are thirty-eight (38) entities permitted by the department.

(a) Estimate the following for the first year:

Expenditures:Expenditures will range from $200 for cosmetic manufacturers to $3,000 for processors and manufacturers who produce adult-use cannabinoid products.

Revenues:Revenues for the affected entities will be dependent on product sales.

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

(b) How will expenditures, revenues, or cost savings differ in subsequent years?
Expenditures will not change in subsequent years without an amendment to this administrative regulation. Revenues can change depending on product sales.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:
This administrative regulation may generate between $38,000 and $114,000 in revenue. Additional revenue will be generated by the product registration fee, but that total cannot be determined at this time. The cost to the department to administer this administrative regulation is $1,551,397.

(b) Methodology and resources used to determine the fiscal impact:
The total range for the potential revenue was calculated by multiplying the current number of permitted facilities times the lowest and highest permit fee amounts, which is 38X1,000 and 38X3,000 respectively. The total expenditure was calculated based on the need for thirteen (13) additional environmental management staff to oversee the permitting and inspection activities. The thirteen (13) additional staff include a branch manager, administrative support staff, two (2) supervisors, two (2) processing/manufacturing inspectors, five (5) retail inspectors, and two (2) enforcement staff. -- Administrative Clerk: Program Coordinator (Grade 14); Annual Salary + 5% Probationary increase: $59,213.70; Fringe Benefits - FICA - Retirement - Hlth/Life Ins: $53,711.55; Total Annual Salary and Fringe Benefits: $112,925.25 x 1 Employee = Total Amount: $112,926.25 ---- Retail Inspectors: Program Evaluator (Grade 14); Annual Salary + 5% Probationary increase: $59,213.70; Fringe Benefits - FICA - Retirement - Hlth/Life Ins: $53,711.55; Total Annual Salary and Fringe Benefits: $112,925.25 x 5 Employees = Total Amount: $564,626.27 ---- Processor/manufacturing Inspectors, Enforcement staff, and Supervisors: Program Administrator (Grade 15); Annual Salary + 5% Probationary increase: $65,135.20; Fringe Benefits - FICA - Retirement - Hlth/Life Ins: $58,082.80; Total Annual Salary and Fringe Benefits: $123,218.00 x 6 Employees = Total Amount: $739,307.99 ---- Manager: Branch Manager (Grade 16); Annual Salary + 5% Probationary increase: $71,646.12; Fringe Benefits - FICA - Retirement - Hlth/Life Ins: $62,889.17; Total Annual Salary and Fringe Benefits: $134,535.29 x 1 Employee = Total Amount: $134,535.29 ---- TOTAL AMOUNT = $1,551,396.79

(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)
The expenditures for the department will exceed $1,000,000, resulting in an overall negative or adverse major economic impact. The overall economic impact for the regulated entities cannot be determined. While these entities will have expenditures associated with the permit and product registration, these will be offset by the revenue received in product sells.

(b) The methodology and resources used to reach this conclusion:
Legislation has delegated new authority to the Kentucky Department for Public Health (KDPH) to regulate recreational adult-use products, such as delta-8 THC, for the safety of Kentuckians. These products, which may only be sold to adults aged 21 years or older, are increasingly complex, diverse, and evolving. An estimated 1,000-

1,500 retailers and 40 manufacturers of recreational adult-use drugs are believed to be operating in Kentucky. Manufacturers of hemp THC products use complex chemistry conversion methods to process distillates, which increases the technical training required for inspection. Due to the intricacies involved, the successful oversight and regulation of these products in Kentucky will require additional staffing and the use of a hybrid approach that blends the traditional roles of the Department of Alcoholic Beverage Control, such as the enforcement of laws and age verification, with the expertise of the Food and Drug Administration (FDA). In order to adequately oversee the manufacture and retail sale of these products, the department would propose establishing a new branch with specialized staff. An estimated additional thirteen (13) staff will be needed to carryout the following activities: Regulatory Oversight: Establish and enforce standards for product manufacturing, packaging, and labeling for human consumption; Establish and enforce distribution controls to consumers to prohibit and prevent sales of adult-use products to individuals under 21 years of age; Prohibit the manufacture and sale of unallowable products; Protect consumers from harmful exposure to chemicals, contaminants, and adulterants that would have an adverse impact on human health; Evaluate the use of chemicals when added to products, such as food ingredients and substances that come into contact with food through food processing, manufacturing, packaging, storage, or other handling to ensure these uses are safe; Monitor products for contaminants and take action when the level of a contaminant causes a product to be unsafe. Licensing and Inspections: Administer licensure and registration for processors, manufacturers, distributors, and retailers and conduct regular inspections to ensure compliance with regulatory requirements. Surveillance and Monitoring: Collect and analyze data on adverse events and product quality to guide decision-making and interventions. Collaboration and Partnerships: Collaborate with federal/state agencies, professional organizations, academic institutions, and industry stakeholders to exchange information, share best practices, and coordinate efforts to address common challenges.