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

**902 KAR 45:031. Hemp-derived cannabinoid product sampling and testing requirements.**

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, 217.155

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 217.155 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 hemp-derived cannabinoid product sampling and testing requirements.

Section 1. Product Sampling and Testing Requirements.

(1) Sampling and testing for all cannabinoid products shall be:
  (a) Done for each batch or process lot; and
  (b) Conducted with representative samples to ensure:
    1. All batches or process lots are adequately assessed for contaminants; and
    2. The cannabinoid profile is consistent throughout.

(2) Testing shall only be performed on the final product equivalent to what will be consumed.

(3) Samples shall be collected using appropriate aseptic techniques.

(4) A cannabinoid processing or manufacturing facility shall assign each batch or process lot a unique batch or lot number that shall be:
  (a) Documented and maintained in the processing and manufacturing facility for at least two (2) years and available to the department upon request;
  (b) Provided to the individual responsible for taking samples; and
  (c) Included on the product **package or** label.

(5) Sample size, handling, storage, and disposal.
  (a) Cannabinoid products samples shall consist of enough material from the batch or process lot to ensure that the required attributes in the products are homogenous and consistent with the testing facility's accredited sampling policies and procedures.
  (b) A cannabinoid processing or manufacturing permittee shall prepare sampling policies and procedures that contain the information necessary for collecting and transporting samples from cannabinoid products in a manner that does not endanger the integrity of the sample for any analysis required by this administrative regulation.

(6) Reserve samples.
  (a) Processors and manufacturers shall collect and hold reserve samples of each batch or process lot of packaged and labeled product.
  (b) The reserve samples shall:
    1. Be held using the same container-closure system that the packaged and labeled product is distributed, or if distributing to be packaged and labeled, using a container-closure system that provides the same characteristics to protect against contamination or deterioration;
    2. Be identified with the batch or process number;

3. Be retained for the shelf-life date, as applicable, or for two (2) years from the date of distribution of the last batch or process lot of the product associated with the reserve sample; and

4. Consist of at least twice the quantity necessary for all tests or examinations to determine if the product meets specifications.

(7) Laboratory requirements.

(a) Testing facilities used by the cannabinoid processing or manufacturing facility shall be an independent third-party, fully accredited to the standard established by International Organization for Standardization (ISO) 17025 by an International Laboratory Accreditation Cooperation recognized accreditation body.

(b) The testing facility shall:

1. Maintain ISO 17025 accreditation; and

2. Comply with all required analytes standards for the relevant test methods of:

a. Cannabinoids;

b. Microbial impurities;

c. Mycotoxins;

d. Residual pesticides;

e. Heavy metals; and

f. Residual solvents, if applicable.

(c) Cannabinoid processing or manufacturing facilities shall maintain on file proof of a valid certificate of accreditation for the laboratory completing product testing that:

1. Is issued by an accreditation organization; and

2. Attests to the laboratory's competence to perform testing, including all the required analytes for the relevant test methods required.

(8) Testing requirements.

(a) A processing or manufacturing facility shall test every batch or process lot of cannabinoid product for sale or distribution prior to sell or transfer.

(b) Test shall be performed using cannabinoid quantification technique with a high enough specificity and sensitivity to differentiate between cannabinoids and isomers of cannabinoids.

(c) Cannabinoid products shall be tested for:

1. Cannabinoids, which shall include all cannabinoids specified in 902 KAR 45:021, Section 1(3)(a);

2. Microbial impurities;

3. Mycotoxins;

4. Residual pesticides;

5. Heavy metals; and

6. Residual solvents, if applicable.

(d) Infused cannabinoid products may not require additional testing for microbial impurities, mycotoxins, residual pesticides, heavy metals, or residual solvents, as applicable, if the cannabinoid distillate used to make an infused product was:

1. Tested for microbial impurities, mycotoxins, residual pesticides, heavy metals, or residual solvents in compliance with this administrative regulation; and

2. Test results indicate the batch or process lot was within established limits.

(e) An infused cannabinoid product shall be tested if the addition of ingredients or processing practice create a reasonable or foreseeable microbial impurity, mycotoxin, residual pesticide, heavy metals, or residual solvents hazard.

(f) All vaporizer delivery device or pressurized metered dose inhaler cartridge batches or process lots shall be tested for Acetates.

(g) In accordance with KRS 217.039, all applicable certificates of analysis shall accompany the final product.

Section 2. Standards for Cannabinoid Testing.

(1) A testing facility shall establish a limit of quantitation of one (1) milligram per gram (mg/g) or lower for all adult-use cannabinoids analyzed and reported.

(2) A testing facility shall report the result of the cannabinoid testing on the certificate of analysis, that includes at minimum:

(a) Total tetrahydrocannabinol concentration, calculated in accordance with subsection (3) of this section and reported in percentages;

(b) Tetrahydrocannabinol-A concentration;

(c) Milligrams per serving for total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics, as applicable;

(d) Milligrams per package for total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics, as applicable; and

(e) The results of all other hemp-derived cannabinoids analyzed on the COA both as a percentage and milligrams per gram (mg/g).

(3) The following calculation shall be used for calculating total tetrahydrocannabinol concentration expressed in weight: Total cannabinoid concentration (mg/g) = (cannabinoid acid form concentration (mg/g) x 0.877) + cannabinoid concentration (mg/g) **on a dry weight basis**.

(4) For cannabinoid infused products, excluding cosmetics, potency shall be reported as milligrams of total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics per gram.

(5) Cannabinoid products shall not contain a delta-9 tetrahydrocannabinol concentration of more than three-tenths of one percent (0.3) on a dry weigh basis.

(6) The serving size from a vaporizer delivery device or pressurized metered dose inhaler shall not exceed one (1) inhalation lasting two (2) seconds per serving.

Section 3. Standards for Microbial Impurities.

(1) Cannabinoid products shall be tested by a testing facility for the presence of microbial impurities.

(2) The sample of inhalable cannabinoid products shall be deemed to have passed the microbial impurities testing if the following conditions are met:

(a) Total Escherichia coli is not detected above 100 colony forming units/gram;

(b) Shiga toxin–producing Escherichia coli is not detected in one (1) gram;

(c) Salmonella spp. is not detected in one (1) gram;

(d) Pathogenic Aspergillus species A. fumigatus, A. flavus, A. niger, and A. terreus are not detected in one (1) gram; **and**

(e) ~~**[Listeria Spp. is not detected in one (1) gram; and]**~~

~~**[(f)]**~~ A total combined yeast and mold do not exceed 100,000 colony forming units per gram.

(3) The sample of ingestible or cosmetic cannabinoid products shall be deemed to have passed the microbial impurities testing if the following conditions are met:

(a) Total Escherichia coli is not detected above 100 colony forming units/gram;

(b) Shiga toxin–producing Escherichia coli is not detected in one (1) gram;

(c) Salmonella spp. is not detected in one (1) gram; **and**

(d) ~~**[Listeria Spp. is not detected in one (1) gram; and]**~~

~~**[(e)]**~~ A total combined yeast and mold do not exceed 100,000 colony forming units per gram.

(4) If the sample fails microbial impurities testing, the batch or process lot from which the sample was collected shall not be released for retail sale.

(5) If a sample from a batch or process lot of a cannabinoid product fails microbiological contaminant testing, the batch may be further processed if the processing method effectively sterilizes the batch.

(6) A batch or process lot that is sterilized in accordance with subsection (5) of this section shall be sampled and tested in accordance with this administrative regulation, if not otherwise required for that product, for microbiological contaminants, and residual solvents.

(7) A batch or process lot that fails microbiological contaminant testing after undergoing a sterilization process in accordance with subsection (5) of this section shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

Section 4. Standards for Mycotoxin Testing.

(1) Cannabinoid products shall be tested by a testing facility for the following mycotoxins: aflatoxin B1, B2, G1, and G2 ochratoxin A.

(2) A batch or process lot shall be deemed to have passed mycotoxin testing if the following conditions are met:

(a) Total of aflatoxin B1, B2, G1, and G2 does not exceed twenty (20) microgram per kilogram (µg/kg) of substance; and

(b) Ochratoxin A does not exceed twenty (20) µg/kg of substance.

(3) A batch or process lot that fails mycotoxin testing in accordance with this subsection shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

Section 5. Standards for Testing Residual Pesticides.

(1) Cannabinoid products shall be tested by a testing facility for the following residual pesticides and shall not exceed the maximum allowable concentration for each:

| Residual pesticide | Chemical Abstract Service (CAS) assigned number | Maximum allowable concentration stated in parts per million (ppm) |
|---|---|---|
| Abamectin | 71751-41-2 | 0.5 ppm |
| Acephate | 30560-19-1 | 0.4 ppm |
| Acequinocyl | 57960-19-7 | 2.0 ppm |
| Acetamiprid | 135410-20-7 | 0.2 ppm |
| Aldicarb | 116-06-3 | 0.4 ppm |
| Azoxystrobin | 131860-33-8 | 0.2 ppm |
| Bifenazate | 149877-41-8 | 0.2 ppm |
| Bifenthrin | 82657-04-3 | 0.2 ppm |
| Boscalid | 188425-85-6 | 0.4 ppm |
| Carbaryl | 63-25-2 | 0.2 ppm |
| Carbofuran | 1563-66-2 | 0.2 ppm |
| Chlorantraniliprole | 500008-45-7 | 0.2 ppm |
| Chlorfenapyr | 122453-73-0 | 1.0 ppm |
| Chlormequat chloride | 7003-89-6 | 0.2 ppm |
| Chlorpyrifos | 2921-88-2 | 0.2 ppm |
| Clofentezine | 74115-24-5 | 0.2 ppm |
| Cyfluthrin | 68359-37-5 | 1.0 ppm |
| Cypermethrin | 52315-07-8 | 1.0 ppm |
| Daminozide | 1596-84-5 | 1.0 ppm |
| DDVP (Dichlorvos) | 62-73-7 | 0.1 ppm |

| | | |
|---|---|---|
| Diazinon | 333-41-5 | 0.2 ppm |
| Dimethoate | 60-51-5 | 0.2 ppm |
| Ethoprophos | 13194-48-4 | 0.2 ppm |
| Etofenprox | 80844-07-1 | 0.4 ppm |
| Etoxazole | 153233-91-1 | 0.2 ppm |
| Fenoxycarb | 72490-01-8 | 0.2 ppm |
| Fenpyroximate | 134098-61-6 | 0.4 ppm |
| Fipronil | 120068-37-3 | 0.4 ppm |
| Flonicamid | 158062-67-0 | 1.0 ppm |
| Fludioxonil | 131341-86-1 | 0.4 ppm |
| Hexythiazox | 78587-05-0 | 1.0 ppm |
| Imazalil | 35554-44-0 | 0.2 ppm |
| Imidacloprid | 138261-41-3 | 0.4 ppm |
| Kresoxim-methy | 143390-89-0 | 0.4 ppm |
| Malathion | 121-75-5 | 0.2 ppm |
| Metalaxyl | 57837-19-1 | 0.2 ppm |
| Methiocarb | 2032-65-7 | 0.2 ppm |
| Methomyl | 16752-77-5 | 0.4 ppm |
| Methyl parathion | 298-00-0 | 0.2 ppm |
| Myclobutanil, | 88671-89-0 | 0.2 ppm (prohibited at any concentration for inhalation) |
| Naled | 300-76-5 | 0.5 ppm |
| Oxamyl | 23135-22-0 | 1.0 ppm |
| Paclobutrazol | 76738-62-0 | 0.4 ppm |
| Permethrins (measured as the cumulative residue of cis- and trans-isomers) | 52645-531 (54774-45-7 and 51877-74-8) | 0.2 ppm |
| Phosmet | 732-11-6 | 0.2 ppm |
| Piperonyl_butoxide | 51-03-6 | 2.0 ppm |
| Prallethrin | 23031-36-9 | 0.2 ppm |
| Propiconazole | 60207-90-1 | 0.4 ppm |
| Propoxur | 114-26-1 | 0.2 ppm |
| Pyrethrins (measured as the cumulative residue of pyrethrin 1, cinerin 1 and jasmolin 1) | 8003-34-7(121-21-1,25402-06-6 and 4466-14-2) | 1.0 ppm |
| Pyridaben | 96489-71-3 | 0.2 ppm |
| Spinosad | 168316-95-8 | 0.2 ppm |
| Spiromesifen | 283594-90-1 | 0.2 ppm |
| Spirotetramat | 203313-25-1 | 0.2 ppm |
| Spiroxamine | 118134-30-8 | 0.4 ppm |
| Tebuconazole | 107534-96-3 | 0.4 ppm |
| Thiacloprid | 111988-49-9 | 0.2 ppm |

| | | |
|---|---|---|
| Thiamethoxam | 153719-23-4 | 0.2 ppm |
| Trifloxystrobin | 141517-21-7 | 0.2 ppm |

(2) A batch or process lot that fails residual pesticide testing in accordance with this section shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

Section 6. Standards for Testing for Heavy Metals.

(1) Cannabinoid products shall be tested by a testing facility for the following metals and shall not exceed the maximum allowable concentration for each:

(a) Arsenic, maximum allowable concentration: one and five-tenths (1.5) ppm;

(b) Cadmium, maximum allowable concentration: zero and four-tenths (0.4) ppm;

(c) Lead, maximum allowable concentration: one (1) ppm; and

(d) Mercury, maximum allowable concentration: one and two-tenths (1.2) ppm.

(2) Cannabinoid distillate intended for inhalable products shall be tested by a testing facility for the following metals and shall not exceed the maximum allowable concentration for each:

(a) Arsenic, maximum allowable concentration: zero and two-tenths (0.2) ppm;

(b) Cadmium, maximum allowable concentration: zero and two-tenths (0.2) ppm;

(c) Lead, maximum allowable concentration: zero and five-tenths (0.5) ppm; and

(d) Mercury, maximum allowable concentration: zero and one-tenths (0.1) ppm.

(3) A batch or process lot that fails heavy metals testing in accordance with this section shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

Section 7. Standards for Testing Residual Solvents.

(1) Cannabinoid products shall be tested by a testing facility for residual solvents, as appropriate, and shall not exceed the maximum allowable concentration for each solvent used according to the table below:

| Solvent | CAS assigned number | Maximum allowable concentration stated in parts per million (ppm) |
|---|---|---|
| Acetone | 67-64-1 | 1,000 ppm |
| Benzene | 71-43-2 | 2 ppm |
| Butanes, (measured as the cumulative residue of n-butane and iso-butane), | 106-97-8 and 75-28-5 | 1,000 ppm |
| Ethanol | 64-17-5 | 5,000 ppm |
| Ethyl Acetate | 141-78-6 | 1,000 ppm |
| Heptane | 142-82-5 | 1,000 ppm |
| Hexanes (measured as the cumulative residue of n-hexane, 2-methylpentane, 3-methylpentane, 2,2-dimethylbutane, and 2,3-dimethylbutane) | 110-54-3, 107-83-5 and 79-29-8 | 60 ppm |
| Methanol | 67-56-1 | 600 ppm |
| Pentanes (measured as the cumulative residue of n-pentane, iso-pentane, and neo-pentane) | 109-66-0, 78-78-4 and 463-82-1 | 1,000 ppm |

| | | |
|---|---|---|
| 2-Propanol (IPA) | 67-63-0 | 1,000 ppm |
| Propane | 74-98-6 | 1,000 ppm |
| Toluene* | 108-88-3 | 180 ppm |
| Total Xylenes* (measured as the cumulative residue of 1,2-dimethylbenzene, 1,3-dimethylbenzene, and 1,4-dimethylbenzene, and the non-xylene, ethylbenzene), | 1330-20-7 (95-47-6, 108-38-3 and 106-42-3 and 100-41-4) | 430 ppm |

*Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use, limits have been listed here accordingly.

(2) A processing or manufacturing facility shall be exempt from testing for solvents if the facility:

(a) Did not use any solvent listed in subsection (1) of this section;

(b) Used a mechanical extraction process to separate cannabinoids; or

(c) Used only water, animal fat, or vegetable oil as a solvent to separate the cannabinoids.

(3) If a sample from a batch or process lot fails solvent testing, the batch or process lot may be remediated using procedures that would reduce the concentration of solvents to less than the action level.

(4) A batch or process lot that is remediated in accordance with subsection (3) of this section shall be:

(a) Sampled and tested in accordance with this administrative regulation; and

(b) Tested for solvents if not otherwise required for that product under this administrative regulation.

(5) A batch or process lot that fails solvent testing that is not remediated or that if remediated fails testing shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

Section 8. Standards for Water Activity.

(1) Plant material, such as flower, shake, and plant trim, used to process and manufacture hemp-derived cannabinoid products shall have a water activity (Aw) rate of less than 0.65.

(2) If the plant material sample fails testing for water activity, the batch from which the sample was taken may:

(a) Be used to make a cannabinoid distillate; or

(b) Continue to dry or cure.

(3) Plant material that undergoes additional drying or curing as described in subsection (2)(b) of this section shall be re-sampled and tested in accordance with this section.

Section 9. Failed Testing and Remediation.

(1) A sample that fails any initial testing may be reanalyzed by the testing facility.

(2) If the reanalyzed sample passes, the processing or manufacturing facility shall resample the batch or process lot using another accredited testing facility to confirm the result in order for the batch or process lot to pass testing.

(3) A batch or process lot shall fail testing if the testing facility detects the presence of a contaminant in a sample above any limit of detection (LOD) established in this administrative regulation:

(a) During an initial test where no reanalysis is requested; or

(b) Upon reanalysis as described in this subsection.

(4) If a sample fails a test or a reanalysis, the batch or process lot:

(a) May be remediated or sterilized in accordance with this administrative regulation; or

(b) If it cannot be remediated or sterilized in accordance with this administrative regulation, it shall be destroyed in a manner that renders the batch or process lot denatured and unusable.

(5) A hemp-derived cannabinoid product batch or process lot shall only be remediated twice. If the batch or process lot fails after a second remediation attempt and the second retesting, the entire batch or process lot shall be destroyed in a manner approved by the cabinet.

(6) A hemp-derived cannabinoid product from a batch or process lot that failed testing shall not be combined with another batch or process lot. Mixed products shall be considered adulterated, regardless of the LOD or defect level of the final product.

Section 10. Certificate of Analysis.

(1) The testing facility shall:

(a) Generate a certificate of analysis (COA) for each representative sample that the testing facility analyzes; and

(b) Ensure the COA contains the results of all required analyses performed for the representative sample.

(2) The COA shall contain, at minimum:

(a) The testing facility's name, premises address, and license number, processor's or manufacturer's name, and premises address;

(b) Batch or lot number of the batch or process lot from which the sample was obtained. For products that are already packaged at the time of sampling, the labeled batch or lot number on the packaged hemp-derived cannabinoid products shall match the batch or lot number on the COA;

(c) Sample identifying information, including matrix type and unique sample identifiers;

(d) Sample history, including the date collected, the date received by the testing facility, and the date of all sample analyses and corresponding testing results;

(e) The analytical methods, analytical instrumentation used, and corresponding LOD and limits of quantitation (LOQ);

(f) Analytes detected during the analyses of the sample that are unknown, unidentified, or injurious to human health if consumed, if any; and

(g) A chromatograph of the cannabinoid test results.

(3) The testing facility shall report test results for each representative sample on the COA as an overall "pass" or "fail" for the entire batch:

(a) When reporting qualitative results for each analyte, the testing facility shall indicate "pass" or "fail";

(b) When reporting quantitative results for each analyte, the testing facility shall use the appropriate units of measurement as required in accordance with this administrative regulation;

(c) When reporting results for each test method, the testing facility shall indicate "pass" or "fail";

(d) When reporting results for any analytes that were detected below the analytical method LOQ, indicate "<LOQ", notwithstanding cannabinoid results;

(e) When reporting results for any analytes that were not detected or detected below the LOD, indicate "ND"; and

(f) Indicate "NT" for any test that the testing facility did not perform.

(4)

(a) In accordance with 2023 Ky. Acts ch. 78, a cannabinoid manufacturer or processor that ships adult-use products out of state for use or sale outside the Commonwealth of

Kentucky:

1. Shall abide by the testing and labeling requirements of this administrative regulation if the receiving state or jurisdiction does not have testing and labeling requirements; or

2. May defer to the receiving state's testing requirements if that state has equivalent testing requirements.

3. Products intended for out-of-state sale shall be stored separately from in-state products and shall have signage indicating the products are for out-of-state sale.

(b) Batch number of the batch from which the sample was obtained shall be on the COA for all products shipped out of state.

*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.