STATEMENT OF EMERGENCY
902 KAR 45:190E.

This emergency administrative regulation is being promulgated to implement the requirements of 2023 Ky. Acts ch. 78. This emergency administrative regulation is needed pursuant to KRS 13A.190(1)(a)3. to immediately begin the process of regulating delta-8 tetrahydrocannabinol and any other hemp-derived substances. This emergency administrative regulation is necessary to implement 2023 Ky. Acts ch. 78, which requires the cabinet to promulgate an emergency administrative regulation with applicability to covered products that implements Executive Order 2022-799, prohibits the sale of intoxicating products to anyone under twenty-one (21) years of age, sets the laboratory testing requirements, and requires products be labeled in accordance with the act and KRS 217.037. This emergency administrative regulation will not be filed with an ordinary 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
(Emergency Amendment)

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

RELATES TO: KRS Chapter 13B, 217.015, 217.025, 217.035, 217.037, 217.039, ~~[217.155,]~~ 260.850, 438.305(4), 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(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 registration, processing, and manufacturing procedures~~[process]~~ to utilize hemp-derived cannabinoid products in foods and cosmetics, the labeling and packaging requirements for products containing hemp-derived cannabinoids, the requirements for retail sale of hemp-derived cannabinoid products~~[cannabinoid]~~, and methods for use of hemp-derived cannabinoid as an additive to food products.

Section 1. Definitions.
(1) "Adult-use cannabinoid" means tetrahydrocannabinols, tetrahydrocannabinolic acids that are artificially or naturally derived, delta-8 tetrahydrocannabinol, delta-9 tetrahydrocannabinol, the optical isomers of delta-8 tetrahydrocannabinol or delta-9 tetrahydrocannabinol, and any artificially derived cannabinoid that is reasonably determined to have an intoxicating effect.
(2) "Artificially derived cannabinoid" means a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from a plant of the genus Cannabis.
(3) "Approved source" means:
(a) A Kentucky hemp grower~~[, processor,]~~ or handler licensed by the Kentucky Department of Agriculture, or an out-of-state hemp grower~~[, processor,]~~ or handler who is duly authorized to produce hemp under the laws of the applicable jurisdiction; or
(b) A hemp product manufacturer or processor permitted by the Kentucky Department for Public Health.
(4) ~~[(2)]~~ "Cabinet" is defined by KRS 217.015(3).
(5) "Cannabidiol" or "CBD" is defined by KRS 217.039(1)(a).
(6) ~~[(3)]~~ "Cannabinoid" means a ~~[non-intoxicating]~~compound found in the hemp plant Cannabis sativa.
(7) "Child-resistant" means packaging that is:
(a) Designed or constructed to be significantly difficult for children under five (5) years of age to open and not difficult for adults to use properly; and

(b) Resealable to maintain this effectiveness for children through multiple openings for any product intended for more than a single use or containing multiple servings.

(8) ~~[(4)]~~ "Cosmetic" is defined by KRS 217.015(7).

(9) ~~[(5)]~~ ~~["Department" means the Kentucky Department for Public Health.]~~

~~[(6)]~~ "Food service establishment" is defined by KRS 217.015(21).

(10) ~~[(7)]~~ "Hemp" is defined by KRS 260.850(5).

(11) ~~[(8)]~~ "Home-based processor" is defined by KRS 217.015(56).

(12) "Imminent health hazard" is defined by KRS 217.015(24).

(13) ~~[(9)]~~ "Person" is defined by KRS 217.015(32).

(14) "Proof of age" is defined by KRS 438.305(4).

(15) "Revocation" means the permit to operate is cancelled by the department.

(16) "Tentatively identified compounds" or "TIC" means compounds detected in a sample using gas chromatography mass spectrometry that are not among the target analytes for the residual solvent analysis.

(17) "Topical" means a hemp-derived cannabinoid product intended to be applied to the skin or hair.

Section 2. Processing, Manufacture, Storage, or Distribution of Hemp-derived Cannabinoid Products ~~[Permits]~~.

(1) A person located in Kentucky seeking to process, manufacture, store, or distribute hemp-derived cannabinoids shall be permitted by the cabinet~~[a hemp-derived ingestible or cosmetic cannabinoid product shall submit an Application for Permit to Operate a Food Plant or Cosmetic Manufacturing Plant, DFS-260, incorporated by reference in 902 KAR 45:160, to the department]~~.

(2) The permit shall be:

(a) Nontransferable in regard~~[regards]~~ to person or address;~~[and]~~

(b) Posted in a conspicuous place in the facility; and

(c) Renewed annually.

(3) The fee ~~[shall be]~~paid in accordance with:

(a) 902 KAR 45:180, for a food processing establishment;

(b) 902 KAR 45:180, for a cosmetic manufacturer; and

(c) 902 KAR 45:110, Section 1(3) and (6), for a food service establishment.

(4) 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.

(5) ~~[Ingestible]~~Hemp-derived cannabinoid products shall not be manufactured, marketed, sold, or distributed by a home-based processor.

(6) An adult-use hemp-derived cannabinoid processing or manufacturing facility, or distributor, shall not employ anyone under twenty-one (21) years of age.

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

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

(b) Caffeine;

(c) Nicotine; or

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

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

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

(10) A hemp-derived cannabinoid processor or manufacturer shall only use the following solvents: water, vegetable 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 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 medical-grade containers when practical 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 devises, 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 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 hemp-derived cannabinoid product and concentrate 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) Vitamin E acetate (VEA);

(b) Medium-chain triglycerides (MCT);

(c) Polyethylene glycol (PEG);

(d) Propylene glycol (PG or PPG);

(e) 2,3-butanedione (Diacetyl); and

(f) Myclobutanil.

Section 3. Product Sampling and Testing Requirements.

(1) Sampling and testing for all hemp-derived cannabinoid products shall be:

(a) Done for each batch or process lot; and

(b) Conducted with representative samples to ensure all batches or process lots are adequately assessed for contaminants, and that the hemp-derived 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 hemp-derived 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 label.

(5) Sample size, handling, storage, and disposal.

(a) For hemp-derived cannabinoid concentrates, extracts, and edible products, samples shall consist of enough samples 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 hemp-derived cannabinoid processing or manufacturing permittee shall prepare sampling policies and procedures that contain the information necessary for collecting and transporting samples from hemp-derived cannabinoid concentrates, extracts, and edible products in a manner that does not endanger the integrity of the sample for any analysis required by this administrative regulation.

(6) Laboratory requirements.

(a) Testing facilities used by the hemp-derived cannabinoid processing or manufacturing facility shall be 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 and processing chemicals, if applicable.

(c) Hemp-derived 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.

(7) Testing requirements.

(a) A processing or manufacturing facility shall test every batch or process lot of hemp-derived cannabinoid concentrate, extract, or edible products for sale or distribution prior to sell or transfer.

(b) Hemp-derived cannabinoid concentrate, extract, or edible products shall be tested for:

1. Cannabinoids;

2. Microbial impurities;

3. Mycotoxins;

4. Residual pesticides;

5. Heavy metals; and

6. Residual solvents and processing chemicals, if applicable.

(c) Infused hemp-derived cannabinoid products may not require additional testing for microbial impurities, mycotoxins, residual pesticides, heavy metals, or processing chemicals, as applicable, if the cannabinoid concentrate used to make an infused product was:

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

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

(d) An infused hemp-derived 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 processing chemicals hazard.

(e) All vaporizer delivery device or pressurized metered dose inhaler cartridge batches or process lots shall be tested for Vitamin E Acetate.

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

(8) Standards for hemp-derived cannabinoid testing.

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

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

1. Total tetrahydrocannabinol concentration, calculated in accordance with paragraph (c) of this subsection and reported in percentages;

2. Tetrahydrocannabinol-A concentration;

3. Total CBD concentration, calculated in accordance with paragraph (d) of this subsection and reported in percentages;

4. CBD-A concentration;

5. Milligrams per serving for total tetrahydrocannabinol and total CBD, as applicable;

6. Milligrams per package for total tetrahydrocannabinol and total CBD, as applicable; and

7. The results of all other hemp-derived cannabinoids analyzed on the COA both as a percentage and in either milligrams per gram (mg/g) if by weight or milligrams per milliliter (mg/mL) if by volume.

(c) The following calculation shall be used for calculating total tetrahydrocannabinol:

1. For concentration expressed in weight: Total cannabinoid concentration (mg/g) = (cannabinoid acid form concentration (mg/g) x 0.877) + cannabinoid concentration (mg/g); or

2. For concentration expressed in volume: Total cannabinoid concentration (mg/mL) = (cannabinoid acid form concentration (mg/mL) x 0.877) + cannabinoid concentration (mg/mL).

(d) For hemp-derived cannabinoid infused products, potency shall be reported as milligrams of total tetrahydrocannabinol and total CBD per gram.

(e) Adult-use hemp-derived 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.

(f) 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.

(9) Standards for microbial impurities.

(a) Hemp-derived cannabinoid concentrate, extract, or edible products shall be tested by a testing facility for the presence of microbial impurities.

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

1. Total Escherichia coli is not detected above 100 colony forming units/gram;
2. Shiga toxin–producing Escherichia coli is not detected in one (1) gram;
3. Salmonella spp. is not detected in one (1) gram; and
4. Pathogenic Aspergillus species A. fumigatus, A. flavus, A. niger, and A. terreus are not detected in one (1) gram.

(c) The sample of non-inhalable hemp-derived cannabinoid products shall be deemed to have passed the microbial impurities testing if the following conditions are met:
1. Total Escherichia coli is not detected above 100 colony forming units/gram;
2. Shiga toxin–producing Escherichia coli is not detected in one (1) gram; and
3. Salmonella spp. is not detected in one (1) gram.

(d) 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.

(e) If a sample from a batch or process lot of a hemp-derived cannabinoid concentrate or extract fails microbiological contaminant testing, the batch may be further processed, if the processing method effectively sterilizes the batch.

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

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

(10) Standards for mycotoxin testing.

(a) Hemp-derived cannabinoid concentrate, extract, or edible products shall be tested by a testing facility for the following mycotoxins: aflatoxin B1, B2, G1, and G2 ochratoxin A.

(b) A batch or process lot shall be deemed to have passed mycotoxin testing if the following conditions are met:
1. Total of aflatoxin B1, B2, G1, and G2 does not exceed twenty (20) microgram per kilogram (µg/kg) of substance; and
2. Ochratoxin A does not exceed twenty (20) µg/kg of substance.

(c) 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.

(11) Standards for testing residual pesticides.

(a) Hemp-derived cannabinoid concentrate, extract, or edible 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

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

(12) Standards for testing for heavy metals.

(a) Hemp-derived cannabinoid concentrate, extract, or edible products shall be tested by a testing facility for the following metals and shall not exceed the maximum allowable concentration for each:

1. Arsenic, maximum allowable concentration: zero and four-tenths (0.4) ppm;
2. Cadmium, maximum allowable concentration: zero and four-tenths (0.4) ppm;
3. Lead, maximum allowable concentration: one (1) ppm; and
4. Mercury, maximum allowable concentration: one and two-tenths (1.2) ppm.

(b) Hemp-derived cannabinoid concentrate 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:

1. Arsenic, maximum allowable concentration: zero and two-tenths (0.2) ppm;
2. Cadmium, maximum allowable concentration: zero and two-tenths (0.2) ppm;
3. Lead, maximum allowable concentration: zero and five-tenths (0.5) ppm; and
4. Mercury, maximum allowable concentration: zero and one-tenths (0.1) ppm.

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

(13) Standards for testing residual solvents and processing chemicals.

(a) Hemp-derived cannabinoid concentrate, extract, or edible products shall be tested by a testing facility for residual solvents and processing chemicals, as appropriate, and shall not exceed the maximum allowable concentration for each solvent used according to the table below:

Solvent or processing chemical	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	1,000 ppm
Ethyl Acetate	141-78-6	1,000 ppm
Heptanes	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
Any other solvent not permitted for use pursuant to this regulation		None Detected
*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.		

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

1. Did not use any solvent listed in paragraph (a) of this subsection;
2. Used a mechanical extraction process to separate cannabinoids; or
3. Used only water, animal fat, or vegetable oil as a solvent to separate the cannabinoids.

(c) 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.

(d) A batch or process lot that is remediated in accordance with this subsection shall be:

1. Sampled and tested in accordance with this administrative regulation; and

2. Tested for solvents if not otherwise required for that product under this administrative regulation.

(e) 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.

(14) Plant material, such as flower, shake, and plant trim, used to process and manufacture hemp-derived cannabinoid products shall have:

(a) A water activity (Aw) rate of less than 0.65; and

(b) A total combined yeast and mold not to exceed 100,000 colony forming units per gram.

(15) Failed testing and remediation.

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

(b) 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.

(c) 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:

1. During an initial test where no reanalysis is requested; or

2. Upon reanalysis as described in this subsection.

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

1. May be remediated or sterilized in accordance with this administrative regulation; or

2. 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.

(e) 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.

(f) A hemp-derived cannabinoid concentrate, extract, or edible 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.

(16) A processing or manufacturing facility shall:

(a) Have detailed procedures for:

1. Sterilization processes to remove microbiological contaminants; and

2. Reducing the concentration of solvents; and

(b) Document all sampling, testing, sterilization, remediation, and destruction that result from a failed test in accordance with this administrative regulation.

(17) Tentative identification of compounds (TICs).

(a) The testing facility shall provide the processing or manufacturing facility with a complete report of any TICs identified.

(b) The processing or manufacturing facility shall conduct a hazard analysis in accordance with the requirements of 902 KAR 45:160 Section 2(1)(u) to identify and evaluate based on experience, illness data, scientific reports, and other information known or reasonably foreseeable hazards associated with any reported TICs.

(c) 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 a preventive control.

(d) A processing or manufacturing 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 will not be adulterated.

(e) The cabinet may initiate an investigation of a processing or manufacturing facility as a result of 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.

(18) Certificate of analysis.

(a) The testing facility shall:

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

2. Ensure the COA contains the results of all required analyses performed for the representative sample.

(b) The COA shall contain, at minimum:

1. The testing facility's name, premises address, and license number, processor's or manufacturer's name, premises address, and permit number;

2. 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;

3. Sample identifying information, including matrix type and unique sample identifiers;

4. Sample history, including the date collected, the date received by the testing facility, and the date of all sample analyses and corresponding testing results;

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

6. An attestation from the testing facility supervisory or management employee that all LOQ samples required by this administrative regulation were performed and met the acceptance criteria; and

7. Analytes detected during the analyses of the sample that are unknown, unidentified, or injurious to human health if consumed, if any.

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

1. When reporting qualitative results for each analyte, the testing facility shall indicate "pass" or "fail";

2. 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;

3. When reporting results for each test method, the testing facility shall indicate "pass" or "fail";

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

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

6. Indicate "NT" for any test that the testing facility did not perform.

(d) The testing facility shall retain the reserve sample, consisting of any portion of a sample that was not used in the testing process. The reserve sample shall be kept at minimum, for forty-five (45) business days after the analyses, after which time it may be destroyed and denatured to the point the material is rendered unrecognizable and unusable.

(e) The testing facility shall securely store the reserve sample in a manner that prohibits sample degradation, contamination, and tampering.

(f) The testing facility shall provide the reserve sample to the cabinet upon request.

(19)

(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 requirements of this administrative regulation if the receiving state does not have testing requirements; or

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

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

Section 4. 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 hemp-derived cannabinoid product;

(b) Ingredient identities and amounts;

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

(d) Complete instructions for preparing the hemp-derived 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 hemp-derived cannabinoid product.

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

(a) Name of the hemp-derived cannabinoid product;

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

(c) Date and time of preparation of the hemp-derived 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 hemp-derived cannabinoid product manufactured.

Section 5. ~~[Section 3.]~~ Product Packaging and Labeling.

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

(2) Each container of ingestible or cosmetic hemp-derived cannabinoid product shall:

(a) Have a tamper-evident seal; and

(b) Be in child-resistant packaging.

(3) Ingestible hemp-derived 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.

(4) The total amount of hemp-derived cannabinoid per serving and the total amount per container as reported by the testing facility:

(a) For hemp-derived cannabinoid infused edible products, potency shall be labeled as milligrams per serving for total tetrahydrocannabinol and total CBD, as applicable; and milligrams per package for total tetrahydrocannabinol and total CBD, as applicable;

(b) For hemp-derived cannabinoid concentrates total tetrahydrocannabinol and total CBD, as applicable shall be labeled in percentages; and

(c) The results of all other hemp-derived cannabinoids as a percentage, in either milligrams per gram (mg/g) if by weight, or milligrams per milliliter (mg/mL) if by volume, as applicable.

(5) The name of the hemp-derived cannabinoid product that includes a product modifier such as "Delta-8 THC product," or "CBD product" using the same or larger font than the product name.

(6) Adult-use hemp-derived cannabinoid ingestible products shall include the following warning label statements:

(a) "This product is intended for use by adults 21 years and older. Keep out of reach of children."

(b) "There may be health risks associated with the consumption of this product."

(c) "There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or plan to become pregnant."

(d) "The intoxicating effects of this product may be delayed by two or more hours."

(e) "Do not drive a motor vehicle or operate machinery while using this product."

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

Section 6. Retail Sale of Hemp-derived Cannabinoid Products.

(1) All hemp-derived cannabinoid products sold in a retail establishment shall:

(a) Be from an approved source;

(b) Be packaged and labeled in accordance with this administrative regulation; and

(c) Have a valid certificate of analysis available upon request.

(2) Retail establishments offering hemp-derived cannabinoid products shall register with the cabinet at https://redcap.chfs.ky.gov/surveys/?s=C8AHC9AYMP74REEM within ninety (90) days of the effective date of this emergency administrative regulation.

(3) Only cannabidiol products may be sold to persons under the age of twenty-one (21).

(4) All adult-use hemp-derived cannabinoid products shall:

(a) Be secured in the retail setting to prevent theft or other access to persons under the age of twenty-one (21); and

(b) Not be sold, gifted, or otherwise transferred to any person under the age of twenty-one (21).

(5)

(a) Any person who sells adult-use hemp-derived cannabinoid products at retail shall require proof of age of the buyer to verify the buyer is age twenty-one (21) years or older; and

(b) May deliver or ship adult-use hemp-derived cannabinoid products to consumers over twenty-one (21) years of age in packages clearly marked "Adult-use only, adult signature 21 years of age or over) required" and request adult-signature-only service from the carrier.

(6) The cabinet or its duly authorized agent shall inspect retail establishments for compliance with this administrative regulation.

(7) A retail establishment not in compliance with this administrative regulation shall be provided notice of the violation.

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

Section 7. Ingestible Hemp-derived Cannabinoid Products at Food Service Establishments. ~~[Except as established in subsection (3) of this section, an ingestible or cosmetic product label shall include, in a print no less than six (6) point font, the following information:]~~

~~[(a)] [A statement of identity or common product name that shall be stated upon the principal display panel of the label;]~~

~~[(b)] [The net quantity of contents expressed in both standard English and metric units of measurement located in the lower thirty (30) percent of the principal display panel of the label parallel to the base of the container;]~~

~~[(c)] [The ingredients of the hemp-derived cannabinoid product, in descending order of predominance by weight;]~~

~~[(d)] [The name of the manufacturer or distributor;]~~

~~[(e)] [A statement that the hemp-derived cannabinoid product is within the federal legal limit of zero and three-tenths (0.3) percent delta-9 tetrahydrocannabinol;]~~

~~[(f)] [The total amount of cannabinoid per serving for ingestible products, or the total amount per container for cosmetic products;]~~

~~[(g)] [Suggested use instructions or directions, including serving sizes; and]~~

~~[(h)] [An expiration date, if any.]~~

~~[(3)] [An ingestible or cosmetic product that has a total area of twelve (12) square inches or less available to bear labeling shall be labeled in accordance with subsection (2) of this section, except the print may be smaller than six (6) point font but shall not measure less than 1/32 of an inch in height.]~~

~~[(4)] [Each container of ingestible or cosmetic hemp-derived cannabinoid product shall have a tamper evident seal.]~~

~~[(5)] [Product packaging, labeling or advertising material for any hemp-derived cannabinoid product shall not bear any implicit or explicit health claims stating that the product can diagnose, treat, cure, or prevent any disease.]~~

~~[Section 4.] [Hemp-derived Ingestible Cannabinoid Products.]~~

(1) Only cannabidiol or CBD ~~[hemp-derived cannabinoid]~~ may be added to an ingestible product ~~[during the manufacturing process or]~~prior to retail sale at a food service establishment.

(2) The hemp-derived cannabinoid shall be obtained from an approved source.

(3) The ~~[food processor or]~~food service establishment shall obtain a valid certificate of analysis from the approved source and provide a copy upon inspection.

(4) ~~[Food or ingestible product shall not contain a total delta-9] [tetrahydrocannabinol concentration of more than zero and three-tenths (0.3) percent on a dry weight basis or contain tetrahydrocannabinol as the primary cannabinoid.]~~

~~[(5)]~~ A food service establishment offering cannabidiol or CBD~~[hemp-derived cannabinoid]~~ products in a finished food product shall provide to consumers upon request:

(a) The common name of the product; and

(b) The manufacturer or distributor of the product.

(5) A food service establishment shall notify the cabinet within one (1) business day of becoming aware or within one (1) business day of when the food service establishment should have been aware of any adverse reactions to a hemp-derived cannabinoid product sold by the establishment ~~[; and]~~

~~[(c)] [A statement that the hemp-derived cannabinoid product is within the federal legal limit of zero and three-tenths (0.3) percent delta-9 tetrahydrocannabinol]~~.

Section 8. Inspection and Enforcement.

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

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

(3) Permitted or registered establishments shall cooperate with the cabinet or its duly authorized agent during any inspections, complaint investigation, requests for information or data, in order to verify compliance with this administrative regulation.

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

(5)

(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.

(6) If the cabinet has evidence that a processing or manufacturing facility 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 processing or manufacturing operation affected by the imminent health hazard without an administrative hearing.

(7) If a permit suspension is due to an imminent health hazard, the permit holder may request an administrative hearing.

(8) A permit holder shall notify the cabinet within one (1) business day of becoming aware of any adverse reactions to a hemp-derived cannabinoid product sold or transferred by the permit holder.

(9) 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.

(10) 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.

(11) The notice in subsection (10) 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.

(12) Any person whose permit has been suspended may request a reinspection for the purpose of reinstatement of the permit. Within seven (7) days following receipt of a written request, including a statement signed by the applicant that in his or her opinion the condition causing suspension of the permit has been corrected, the cabinet shall make an inspection, and if the inspection reveals that the condition causing suspension of the permit has been corrected, the permit shall be reinstated.

(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.

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

APPROVED BY AGENCY: August 1, 2023
FILED WITH LRC: August 1, 2023 at 2:30 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this emergency administrative regulation shall, if requested, be held on September 25, 2023, at 9 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 September 18, 2023, 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 emergency 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 emergency administrative regulation until September 30, 2023. Send written notification of intent to attend the public hearing or written comments on the proposed emergency 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 emergency 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 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Julie Brooks and Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This emergency administrative regulation establishes the registration, processing, and manufacturing procedures to utilize hemp-derived cannabinoid products in foods and cosmetics, the labeling and packaging requirements for products containing hemp-derived cannabinoids, and methods for use of hemp-derived cannabinoids as an additive to food products.

(b) The necessity of this administrative regulation:

Many hemp-derived cannabinoid products sold in Kentucky are currently unregulated. This emergency administrative regulation is necessary to ensure that all hemp-derived cannabinoid products produced 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 or its duly authorized agents 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.

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

This emergency administrative regulation ensures all hemp-derived cannabinoid products manufactured, processed, distributed, or sold are safe for human consumption, are labeled in a manner that allows the end user to understand the effects of the products, and prohibits the sale of products to a person under the age of twenty-one (21).

(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:

The amendment to this emergency administrative regulation clearly defines hemp-derived cannabinoid products that are for adult-use only and separates these from nonintoxicating hemp-derived cannabinoid products, adds requirements for processing facilities, revises the requirements for manufacturing facilities, adds product testing requirements to incorporate the federal Food and Drug Administration standards for product safety, adds the requirement for a retail store to register with the department, and adds enforcement actions should a processing or manufacturing facility violate the provisions of this administrative regulation.

(b) The necessity of the amendment to this administrative regulation:

The amendment to this emergency administrative regulation is necessary because many hemp-derived cannabinoid products sold in Kentucky are currently

unregulated by both the state and the federal Food and Drug Administration. Some products containing hemp-derived cannabinoids have concentrations that produce a psychoactive effect and are unsafe if consumed in large quantities. The labels of some products make it difficult to determine the amount of hemp-derived cannabinoid per serving, and other products are packaged to mimic candies or other items that may appeal to children and young adults. The amendment to this emergency administrative regulation is necessary to ensure that all hemp-derived cannabinoid products produced and sold in the state are safe for human consumption, are properly label, and are not targeted for sale to persons under the age of twenty-one (21).

(c) How the amendment conforms to the content of the authorizing statutes:

House Bill 544 from the 2023 legislative session requires the cabinet to immediately begin the process of regulating delta-8 tetrahydrocannabinol and any other hemp-derived substances, revises the labeling and testing requirements for all hemp-derived cannabinoid products, and prohibits the possession of covered products by a person under the age of twenty-one (21). The bill contained an emergency clause.

(d) How the amendment will assist in the effective administration of the statutes:

The amendment to this emergency administrative regulation will ensure products manufactured, processed, marketed, and sold in the commonwealth are safe for human consumption.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

There are currently forty-seven (47) manufacturers of cannabidiol (CBD) products registered with the department. Retail stores that sell CBD or other hemp-derived cannabinoid products, including those that contain delta-8, are not registered with the department at this time.

(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:

Current manufacturers permitted by the department will need to ensure their products meet the manufacturing and testing requirements established by this emergency administrative regulation. Retail stores will need to register with the department, allow for inspection by the cabinet or its duly authorized agent, and ensure all products sold meet the requirements of this emergency administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

This emergency administrative regulation will not impact the cost of the currently registered processing and manufacturing facilities.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

Producers and manufacturers will be able to ensure the products offered are of the highest quality and do not unintentionally target the sale to persons under the age of twenty-one (21). Retail stores will be able to sell products that meet the highest manufacturing standards.

(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 $500,800 in the first year.

(b) On a continuing basis:

The department will continue to need an additional $500,800, 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:

Funding to implement and enforce this emergency administrative regulation will be from a mix of fees paid to the department and state general fund dollars.

(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:

The emergency amendment to this administrative regulation does not increase the required fees and does not establish new fees.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This emergency administrative regulation does not establish any new fees and does not increase the existing fees. Currently manufacturers and processors pay the fee in accordance with 902 KAR 45:180.

(9) TIERING: Is tiering applied?

Tiering is applied. Testing for solvents is only required if the products listed in this emergency administrative regulation are used in the manufacturing or processing procedures.

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

The amendment to this emergency administrative regulation will impact the Food Safety Branch in the Department for Public Health.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 217.125, 217.127, and 217.135.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

Current estimates indicate this emergency administrative regulation will generate between $5,875 and $47,000 in the first year. This figure was determined using the current fee structure in 902 KAR 45:180 multiplied by the number of currently permitted facilities. The minimum fee is $125, and the maximum is $1,000.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

This emergency administrative regulation will generate between $5,875 and $47,000 in subsequent years. This figure is subject to change based on changes in the number of permitted facilities.

(c) How much will it cost to administer this program for the first year?

Cost to the department to implement this emergency administrative regulation will be approximately $500,800 in the first year. This figure was determined using the fiscal year 2020 salary and fringe rates for a minimum of four additional environmental health inspection program staff ($125,200X4).

(d) How much will it cost to administer this program for subsequent years?

Ongoing cost to the department to implement this emergency administrative regulation will be approximately $500,800 in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

The amendment to this emergency administrative regulation will not generate cost savings for the regulated entities.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

The amendment to this emergency administrative regulation will not generate cost savings for the regulated entities.

(c) How much will it cost the regulated entities for the first year?

The costs to the regulated entities will be the required permitting fees ($125 up to $1,000), and any costs associated with the testing and labeling requirements.

(d) How much will it cost the regulated entities for subsequent years?

The regulated entities will continue to pay the annual permit fee ($125 up to $1,000) and costs associated with the testing and labeling requirements in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This emergency administrative regulation could have a major economic impact to the Cabinet for Health and Family Services. It is estimated that an additional $500,800 is needed to cover the costs for increased staff. While some of these costs will be offset by the required permitting fees, the total revenue received will not completely cover the anticipated costs.