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

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, 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 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, and methods for use of hemp-derived cannabinoid as an additive to food products.

Section 1. Definitions.

(1) "Adult-use cannabinoid" means a product with intoxicating properties that changes the function of the nervous system and results in alterations of perception, cognition, or behavior.

(2) "Approved source" means:

(a) A Kentucky hemp grower or handler licensed by the Kentucky Department of Agriculture, or an out-of-state hemp grower or handler who is duly authorized to produce hemp under the laws of the applicable jurisdiction;

(b) A hemp product manufacturer or processor permitted by the Kentucky Department for Public Health or

(c) A manufacturer or processor permitted by another state regulatory authority for hemp-derived cannabinoid products if that state has been approved by the department as having equivalent state standards for processing, laboratory testing, and labeling requirements.

(3) "Cabinet" is defined by KRS 217.015(3).

(4) "Cannabidiol" or "CBD" is defined by KRS 217.039(1)(a).

(5) "Cannabinoid" means a compound found in the hemp plant Cannabis sativa L from a United States Department of Agriculture sanctioned domestic hemp production program and does not include cannabinoids derived from any other substance.

(6) "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.

(7) "Cosmetic" is defined by KRS 217.015(7).
(8) "Food service establishment" is defined by KRS 217.015(21).
(9) "Hemp" is defined by KRS 260.850(5).
(10) "Hemp-derived cannabinoid" means an ingestible, inhalable, or cosmetic product that is processed or derived from hemp.
(11) "Home-based processor" is defined by KRS 217.015(56).
(12) "Hydrogenation" means the chemical reaction between molecular hydrogen (H_2) and another compound or element.
(13) "Imminent health hazard" is defined by KRS 217.015(24).
(14) "Infused" means adding a cannabinoid concentrate ingredient to an ingestible cannabinoid product.
(15) "Non-intoxicating cannabinoid" means a product with non-psychoactive properties that does not change the function of the nervous system and does not result in alteration of perception, cognition, or behavior.
(16) "Person" is defined by KRS 217.015(32).
(17) "Proof of age" is defined by KRS 438.305(4).
(18) "Revocation" means the permit to operate is cancelled by the department.
(19) "Serious adverse event" means a medical occurrence associated with the use of a cannabinoid product that results in one or more of the following:
(a) Death;
(b) A life-threatening event;
(c) Inpatient hospitalization, or prolongation of an existing hospitalization;
(d) A persistent or significant incapacity, or substantial disruption in the ability to conduct normal life functions; or
(e) A congenital anomaly or birth defect.
(20) "Tentatively identified compounds" or "TIC" means compounds detected in a sample that are not among the target analytes.

Section 2. Permit and Product Registration.
(1) In-state permit.
(a) A person located in Kentucky seeking to process, manufacture, store, or distribute hemp-derived cannabinoid products shall be permitted by the cabinet.
(b) The permit shall be:
1. Nontransferable in regard to person or address;
2. Posted in a conspicuous place in the facility; and
3. Renewed annually.
4. Include the fee 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; and
5. Include the product registration fee required by subsection (4) of this section.
(2)
(a) Effective January 1, 2024, all out-of-state processors and manufacturers of hemp-derived cannabinoid products available for distribution in Kentucky shall submit an annual registration to the department.
(b) The registration for an out-of-state processor or manufacturer shall:
1. Be renewed annually by December 31 each year; and
2. Include:
a. A copy of the current, valid permit to process or manufacture hemp-derived cannabinoids issued from the state regulatory authority;
b. A copy of the state regulation pertaining to the production of hemp-derived cannabinoid products; and

c. The product registration fee required by subsection (4) of this section.

(3) Cannabinoids requiring registration:

(a) Adult-use cannabinoids shall include:

1. Delta-10-tetrahydrocannabinol (Delta-10-THC);
2. Delta-9-tetrahydrocannabinol (THC) with less than three tenths of one percent (0.3%) Total THC;
3. Delta-8-tetrahydrocannabinol (Delta-8-THC);
4. Delta-9-tetrahydrocannabinolic acid A (THCA-A) with less than three tenths of one percent (0.3%) Total THC;
5. Delta-9-tetrahydrocannabivarin (THCV);
6. Delta-9-tetrahydrocannabivarinic acid (THCVA);
7. Delta-6-tetrahydrocannabinol (Delta 6);
8. Hexahydrocannabinol (HHC)(-);
9. Tetrahydrocannabiphorol (THCp); and
10. Tetrahydrocannabinol (THCM);

(b) Non-intoxicating cannabinoids shall include:

1. Cannabidiol (CBD);
2. Cannabidiolic acid (CBDA);
3. Cannabidivarin (CBDV);
4. Cannabidivarinic acid (CBDVA);
5. Cannabichromene (CBC);
6. Cannabichromenic acid (CBCA);
7. Cannabigerolic acid (CBGA);
8. Cannabigerol (CBG);
9. Cannabinol (CBN); and
10. Cannabitriol (CBT); and

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

(4) An annual registration fee of $200 per adult-use cannabinoid product shall be paid to the cabinet by check or money order made payable to the Kentucky State Treasurer.

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

(a) The name and address of the applicant;

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

(c) The name of the product;

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

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

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

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

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

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

(c) In ownership.

Section 3. Processing, Manufacture, Storage, or Distribution of Hemp-derived Cannabinoid Products.

(1) All processors and manufacturers shall meet:

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

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

(2) Hemp-derived cannabinoid products shall not be manufactured, marketed, sold, or distributed by a home-based processor.
(3) A business that processes, manufactures, warehouses, distributes, sells, or serves adult-use hemp-derived cannabinoid products shall not employ any person who is under twenty-one (21) years of age, unless the person employed is at least eighteen (18) years of age and under the supervision of a person twenty-one (21) years of age or older.
(4) Non-intoxicating cannabinoid products shall:
(a) Have at least a twenty-five (25) non-intoxicating cannabinoid to one (1) adult-use cannabinoid ratio; and
(b) Contain two and five-tenths (2.5) milligrams or less of adult-use cannabinoid per serving.
(5) The serving size of an ingestible cannabinoid product shall be:
(a) As a whole unit where one (1) unit equals one (1) serving;
(b) Equal the maximum amount recommended, as appropriate, on the label for consumption per occasion in whole units; and
(c) Based on the amount typically consumed.
(6) A hemp-derived cannabinoid processing or manufacturing facility shall not treat or otherwise adulterate a cannabinoid product with:
(a) Any non-cannabinoid additive that increases toxicity or addictive potential, excluding caffeine;
(b) Alcohol;
(c) Nicotine; or
(d) Other chemicals that may increase carcinogenicity or cardiac effects.
(7) All products shall be homogenized to ensure uniform distribution of cannabinoids throughout the product.
(8) Only permitted hemp-derived cannabinoid processing facilities shall perform cannabinoid extraction, conversion, catalyzation, distillation, hydrogenation, or other refinement processes.
(9) A hemp-derived cannabinoid processor or manufacturer shall only use the following solvents: water, glycerin, vegetable oils, animal fats, butane, propane, carbon dioxide, ethanol, isopropanol, acetone, heptane, ethyl acetate, and pentane. The use of any other solvent is expressly prohibited unless pre-approved by the cabinet.
(10) 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.
(11)
(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.
(12)
(a) Solvents shall be collected and stored in food-grade containers when practical to maintain purity; and
(b) Solvent containers shall be replaced or safely purged, cleaned, and sanitized periodically.
(13) 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.
(14) 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.

(15) Cannabinoid processing facilities using carbon dioxide shall have equipment and facilities approved by local fire code officials, if applicable.
(16) Processes using flammable gas or flammable liquid shall have leak or gas detection measures, or both.
(17) A permittee shall not use dimethylsulfoxide (DMSO) in the manufacture of hemp-derived cannabinoid products, and possession upon the permitted premises is prohibited.
(18)
(a) A hemp-derived cannabinoid manufacturer may use terpenes or other hemp essential oil but shall not use non-cannabinoid derived inactive ingredients not listed in the federal Food and Drug Administration inactive ingredient database at https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm in the manufacture of inhalable hemp-derived cannabinoid product and 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.
(19) The following substances shall be prohibited in hemp-derived cannabinoid extraction intended for inhalation:
(a) Acetates;
(b) Medium-chain triglycerides (MCT);
(c) Polyethylene glycol (PEG);
(d) Propylene glycol (PG or PPG);
(e) Diketones:
1. 2,3-butanedione (Diacetyl);
2. 2,3-pentanedione (acetylpropionyl); and
3. 3-hydroxybutanone (acetoin);
(f) Myclobutanil;
(g) Artificial food coloring; and
(h) Benzoic acid.

Section 4. 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) Hemp-derived 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 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 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 hemp-derived 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) 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.

(8) Testing requirements.

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

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

(c) Hemp-derived cannabinoid products shall be tested for:

1. Cannabinoids;

2. Microbial impurities;

3. Mycotoxins;

4. Residual pesticides;

5. Heavy metals; and

6. Residual solvents, if applicable.

(d) Infused hemp-derived cannabinoid products may not require additional testing for microbial impurities, mycotoxins, residual pesticides, heavy metals, or residual

solvents, as applicable, if the cannabinoid concentrate 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 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 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.

(9) 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. Milligrams per serving for total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics, as applicable;
4. Milligrams per package for total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics, as applicable; and
5. The results of all other hemp-derived cannabinoids analyzed on the COA both as a percentage and milligrams per gram (mg/g).

(c) 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).

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

(e) 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.

(10) Standards for microbial impurities.

(a) Hemp-derived cannabinoid 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;
4. Pathogenic Aspergillus species A. fumigatus, A. flavus, A. niger, and A. terreus are not detected in one (1) gram;
5. Listeria Spp. is not detected in one (1) gram; and
6. A total combined yeast and mold not to exceed 100,000 colony forming units per gram.

(c) The sample of ingestible or cosmetic 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;
4. Listeria Spp. is not detected in one (1) gram; and
5. A total combined yeast and mold not to exceed 100,000 colony forming units per 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 product 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, and residual solvents.

(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.

(11) Standards for mycotoxin testing.

(a) Hemp-derived cannabinoid 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.

(12) Standards for testing residual pesticides.

(a) Hemp-derived 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

(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.

(13) Standards for testing for heavy metals.

(a) Hemp-derived cannabinoid 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: one and five-tenths (1.5) 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.

(14) Standards for testing residual solvents.

(a) Hemp-derived 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
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		1 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.

(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.

(15) 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.

(16) 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 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.

(17) 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.

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

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

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

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

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

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

(19) 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, and premises address;

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); and

6. 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.

(20)

(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.

Section 5. 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 6. 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 adult-use cannabinoid product shall:

(a) Have a tamper-evident seal; and

(b) Be in child-resistant packaging.

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

(4) Cannabinoid product packaging shall not include:

(a) Any cartoon images;

(b) Likeness to images, characters, or phrases that are popularly used to advertise to children;

(c) Likeness to or imitation of any commercially available candy, snack, baked good, or beverage packaging or labeling;

(d) The terms "candy" or "candies", or any variation in the spelling of these words; or

(e) The logo of the department or cabinet, or any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe the product has been endorsed, manufactured, or used by any state, county, or municipality or any agency

thereof, excluding the use of seals associated with state or federal programs used in accordance with state or federal law and regulations.

(5) The total amount of hemp-derived cannabinoid per serving and the total amount per container shall accurately reflect testing results and shall not contain less than eighty (80) percent or more than 120% of the concentration of total cannabinoid content as listed on the product label:

(a) For hemp-derived cannabinoid ingestible and inhalable products, potency shall be labeled as milligrams per serving for total tetrahydrocannabinol and the primary cannabinoid marketed, as applicable; and milligrams per package for total tetrahydrocannabinol and the primary cannabinoids marketed; and

(b) Other hemp-derived cannabinoids labeled milligrams per gram (mg/g) per serving, excluding cosmetics, and milligrams per package, if listed on the label.

(6) All cannabinoid products shall include the common cannabinoid description in the product name, such as "Delta-8 THC gummies" or "Full-spectrum CBD extract" using the same or larger font than the product name.

(7) Adult-use hemp-derived cannabinoid 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 those who are pregnant, nursing, or plan to become pregnant."

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

(e) " May cause drowsiness or impairment. 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".

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

Section 7. 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 and food service establishments offering adult-use 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 cannabinoid products registered in accordance with Section 2 of this administrative regulation may be offered at retail establishments and food service establishments.

(4) Cannabinoid retailers shall maintain records of cannabinoid product purchase, including the name and address of the cannabinoid processor or manufacturer, and the wholesaler or distributor.

(5) Only non-intoxicating and cosmetic cannabinoid products may be sold to persons under the age of twenty-one (21).

(6) 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).

(7)

(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"

Section 8. Ingestible Hemp-derived Cannabinoid Products at Food Service Establishments.

(1) Only registered, pre-packaged adult-use ingestible cannabinoid products may be offered as ready-to-consume or for direct consumption at food service establishments.

(2) Adult-use cannabinoids shall not be added to an ingestible food product at a food service establishment.

(3) Non-intoxicating cannabinoids may be added to an ingestible product prior to retail sale at a food service establishment.

(4) The non-intoxicating cannabinoid shall be obtained from an approved source.

(5) The food service establishment shall obtain a valid certificate of analysis from the approved source and provide a copy upon inspection.

(6) A food service establishment offering non-intoxicating 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.

(7) 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 serious adverse event to a hemp-derived cannabinoid product sold by the establishment.

Section 9. 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, and distribution centers.

(2)

(a) Retail establishments offering adult-use cannabinoid products shall be inspected by the cabinet or its duly authorized agent; and

(b) Retail establishments offering only non-intoxicating cannabinoid products may be inspected by the cabinet or its duly authorized agent upon complaint, receipt of a report of a serious adverse event, or at the discretion of the cabinet.

(3) 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.

(4) 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.

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

(6)

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

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

1. Email to food.safety@ky.gov; or

2. Phone to (502)564-7181.

(7) If the cabinet has evidence that a 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.

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

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

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

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

(12) 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.

(13) 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.

(14) 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.

(Pursuant to KRS 13A.190(4), emergency expires 270 days after the date of filing, exp. 4-27-2024.)

WESLEY W. DUKE, General Counsel
ERIC C. FRIEDLANDER, Secretary

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