

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

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

RELATES TO: KRS Chapter 13B, 217.015, 217.025, 217.035, 217.037, 217.039, 260.850, 438.305(4), 2023 Ky Acts ch. 78

STATUTORY AUTHORITY: KRS 217.125, 217.155

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) authorizes the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 through 217.215. KRS 217.155 allows the cabinet or its duly authorized agent free access at reasonable times for the purpose of inspection any factory, warehouse, or establishment where foods, drugs, devices, or cosmetics are manufactured or held for sale. This administrative regulation establishes the hemp-derived cannabinoid product sampling and testing requirements.

Section 1. Product Sampling and Testing Requirements.

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

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

(b) Conducted with representative samples to ensure:

1. All batches or process lots are adequately assessed for contaminants; and
2. The cannabinoid profile is consistent throughout.

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

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

(4) A cannabinoid processing or manufacturing facility shall assign each batch or process lot a unique batch or lot number that shall be:

- (a) Documented and maintained in the processing and manufacturing facility for at least two (2) years and available to the department upon request;
- (b) Provided to the individual responsible for taking samples; and
- (c) Included on the product label.

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

(a) Cannabinoid products samples shall consist of enough material from the batch or process lot to ensure that the required attributes in the products are homogenous and consistent with the testing facility's accredited sampling policies and procedures.

(b) A cannabinoid processing or manufacturing permittee shall prepare sampling policies and procedures that contain the information necessary for collecting and transporting samples from cannabinoid products in a manner that does not endanger the integrity of the sample for any analysis required by this administrative regulation.

(6) Reserve samples.

(a) Processors and manufacturers shall collect and hold reserve samples of each batch or process lot of packaged and labeled product.

(b) The reserve samples shall:

1. Be held using the same container-closure system that the packaged and labeled product is distributed, or if distributing to be packaged and labeled, using a container-closure system that provides the same characteristics to protect against contamination or deterioration;
2. Be identified with the batch or process number;

3. Be retained for the shelf-life date, as applicable, or for two (2) years from the date of distribution of the last batch or process lot of the product associated with the reserve sample; and
4. Consist of at least twice the quantity necessary for all tests or examinations to determine if the product meets specifications.

(7) Laboratory requirements.

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

(b) The testing facility shall:

1. Maintain ISO 17025 accreditation; and
2. Comply with all required analytes standards for the relevant test methods of:
 - a. Cannabinoids;
 - b. Microbial impurities;
 - c. Mycotoxins;
 - d. Residual pesticides;
 - e. Heavy metals; and
 - f. Residual solvents, if applicable.

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

1. Is issued by an accreditation organization; and
2. Attests to the laboratory's competence to perform testing, including all the required analytes for the relevant test methods required.

(8) Testing requirements.

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

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

(c) Cannabinoid products shall be tested for:

1. Cannabinoids, which shall include all cannabinoids specified in 902 KAR 45:021, Section 1(3)(a);
2. Microbial impurities;
3. Mycotoxins;
4. Residual pesticides;
5. Heavy metals; and
6. Residual solvents, if applicable.

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

1. Tested for microbial impurities, mycotoxins, residual pesticides, heavy metals, or residual solvents in compliance with this administrative regulation; and
2. Test results indicate the batch or process lot was within established limits.

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

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

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

Section 2. Standards for Cannabinoid Testing.

- (1) A testing facility shall establish a limit of quantitation of one (1) milligram per gram (mg/g) or lower for all adult-use cannabinoids analyzed and reported.
- (2) A testing facility shall report the result of the cannabinoid testing on the certificate of analysis, that includes at minimum:
 - (a) Total tetrahydrocannabinol concentration, calculated in accordance with subsection (3) of this section and reported in percentages;
 - (b) Tetrahydrocannabinol-A concentration;
 - (c) Milligrams per serving for total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics, as applicable;
 - (d) Milligrams per package for total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics, as applicable; and
 - (e) The results of all other hemp-derived cannabinoids analyzed on the COA both as a percentage and milligrams per gram (mg/g).
- (3) The following calculation shall be used for calculating total tetrahydrocannabinol concentration expressed in weight: Total cannabinoid concentration (mg/g) = (cannabinoid acid form concentration (mg/g) x 0.877) + cannabinoid concentration (mg/g).
- (4) For cannabinoid infused products, excluding cosmetics, potency shall be reported as milligrams of total tetrahydrocannabinol and the primary cannabinoid marketed, excluding cosmetics per gram.
- (5) Cannabinoid products shall not contain a delta-9 tetrahydrocannabinol concentration of more than three-tenths of one percent (0.3) on a dry weigh basis.
- (6) The serving size from a vaporizer delivery device or pressurized metered dose inhaler shall not exceed one (1) inhalation lasting two (2) seconds per serving.

Section 3. Standards for Microbial Impurities.

- (1) Cannabinoid products shall be tested by a testing facility for the presence of microbial impurities.
- (2) The sample of inhalable cannabinoid products shall be deemed to have passed the microbial impurities testing if the following conditions are met:
 - (a) Total *Escherichia coli* is not detected above 100 colony forming units/gram;
 - (b) Shiga toxin-producing *Escherichia coli* is not detected in one (1) gram;
 - (c) *Salmonella* spp. is not detected in one (1) gram;
 - (d) Pathogenic *Aspergillus* species *A. fumigatus*, *A. flavus*, *A. niger*, and *A. terreus* are not detected in one (1) gram;
 - (e) *Listeria* Spp. is not detected in one (1) gram; and
 - (f) A total combined yeast and mold do not exceed 100,000 colony forming units per gram.
- (3) The sample of ingestible or cosmetic cannabinoid products shall be deemed to have passed the microbial impurities testing if the following conditions are met:
 - (a) Total *Escherichia coli* is not detected above 100 colony forming units/gram;
 - (b) Shiga toxin-producing *Escherichia coli* is not detected in one (1) gram;
 - (c) *Salmonella* spp. is not detected in one (1) gram;
 - (d) *Listeria* Spp. is not detected in one (1) gram; and
 - (e) A total combined yeast and mold do not exceed 100,000 colony forming units per gram.
- (4) If the sample fails microbial impurities testing, the batch or process lot from which the sample was collected shall not be released for retail sale.
- (5) If a sample from a batch or process lot of a cannabinoid product fails microbiological contaminant testing, the batch may be further processed if the processing method effectively sterilizes the batch.

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

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

Section 4. Standards for Mycotoxin Testing.

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

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

(a) Total of aflatoxin B1, B2, G1, and G2 does not exceed twenty (20) microgram per kilogram ($\mu\text{g}/\text{kg}$) of substance; and

(b) Ochratoxin A does not exceed twenty (20) $\mu\text{g}/\text{kg}$ of substance.

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

Section 5. Standards for Testing Residual Pesticides.

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

Residual pesticide	Chemical Abstract Service (CAS) assigned number	Maximum allowable concentration stated in parts per million (ppm)
Abamectin	71751-41-2	0.5 ppm
Acephate	30560-19-1	0.4 ppm
Acequinocyl	57960-19-7	2.0 ppm
Acetamiprid	135410-20-7	0.2 ppm
Aldicarb	116-06-3	0.4 ppm
Azoxystrobin	131860-33-8	0.2 ppm
Bifenazate	149877-41-8	0.2 ppm
Bifenthrin	82657-04-3	0.2 ppm
Boscalid	188425-85-6	0.4 ppm
Carbaryl	63-25-2	0.2 ppm
Carbofuran	1563-66-2	0.2 ppm
Chlorantraniliprole	500008-45-7	0.2 ppm
Chlorfenapyr	122453-73-0	1.0 ppm
Chloromequat 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
Ettoxazole	153233-91-1	0.2 ppm
Fenoxycarb	72490-01-8	0.2 ppm
Fenpyroximate	134098-61-6	0.4 ppm
Fipronil	120068-37-3	0.4 ppm
Flonicamid	158062-67-0	1.0 ppm
Fludioxonil	131341-86-1	0.4 ppm
Hexythiazox	78587-05-0	1.0 ppm
Imazalil	35554-44-0	0.2 ppm
Imidacloprid	138261-41-3	0.4 ppm
Kresoxim-methy	143390-89-0	0.4 ppm
Malathion	121-75-5	0.2 ppm
Metalaxyl	57837-19-1	0.2 ppm
Methiocarb	2032-65-7	0.2 ppm
Methomyl	16752-77-5	0.4 ppm
Methyl parathion	298-00-0	0.2 ppm
Myclobutanil,	88671-89-0	0.2 ppm (prohibited at any concentration for inhalation)
Naled	300-76-5	0.5 ppm
Oxamyl	23135-22-0	1.0 ppm
Paclobutrazol	76738-62-0	0.4 ppm
Permethrins (measured as the cumulative residue of cis- and trans-isomers)	52645-531 (54774-45-7 and 51877-74-8)	0.2 ppm
Phosmet	732-11-6	0.2 ppm
Piperonyl_butoxide	51-03-6	2.0 ppm
Prallethrin	23031-36-9	0.2 ppm
Propiconazole	60207-90-1	0.4 ppm
Propoxur	114-26-1	0.2 ppm
Pyrethrins (measured as the cumulative residue of pyrethrin 1, cinerin 1 and jasmolin 1)	8003-34-7(121-21-1,25402-06-6 and 4466-14-2)	1.0 ppm
Pyridaben	96489-71-3	0.2 ppm
Spinosad	168316-95-8	0.2 ppm
Spiromesifen	283594-90-1	0.2 ppm
Spirotetramat	203313-25-1	0.2 ppm
Spiroxamine	118134-30-8	0.4 ppm
Tebuconazole	107534-96-3	0.4 ppm
Thiacloprid	111988-49-9	0.2 ppm

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

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

Section 6. Standards for Testing for Heavy Metals.

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

- (a) Arsenic, maximum allowable concentration: one and five-tenths (1.5) ppm;
- (b) Cadmium, maximum allowable concentration: zero and four-tenths (0.4) ppm;
- (c) Lead, maximum allowable concentration: one (1) ppm; and
- (d) Mercury, maximum allowable concentration: one and two-tenths (1.2) ppm.

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

- (a) Arsenic, maximum allowable concentration: zero and two-tenths (0.2) ppm;
- (b) Cadmium, maximum allowable concentration: zero and two-tenths (0.2) ppm;
- (c) Lead, maximum allowable concentration: zero and five-tenths (0.5) ppm; and
- (d) Mercury, maximum allowable concentration: zero and one-tenths (0.1) ppm.

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

Section 7. Standards for Testing Residual Solvents.

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

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

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

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

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

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

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

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

- (a) Sampled and tested in accordance with this administrative regulation; and
- (b) Tested for solvents if not otherwise required for that product under this administrative regulation.

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

Section 8. Standards for Water Activity.

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

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

- (a) Be used to make a cannabinoid distillate; or
- (b) Continue to dry or cure.

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

Section 9. Failed Testing and Remediation.

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

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

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

- (a) During an initial test where no reanalysis is requested; or
- (b) Upon reanalysis as described in this subsection.

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

- (a) May be remediated or sterilized in accordance with this administrative regulation;
or
 - (b) If it cannot be remediated or sterilized in accordance with this administrative regulation, it shall be destroyed in a manner that renders the batch or process lot denatured and unusable.
- (5) A hemp-derived cannabinoid product batch or process lot shall only be remediated twice. If the batch or process lot fails after a second remediation attempt and the second retesting, the entire batch or process lot shall be destroyed in a manner approved by the cabinet.
- (6) A hemp-derived cannabinoid product from a batch or process lot that failed testing shall not be combined with another batch or process lot. Mixed products shall be considered adulterated, regardless of the LOD or defect level of the final product.

Section 10. Certificate of Analysis.

- (1) The testing facility shall:
- (a) Generate a certificate of analysis (COA) for each representative sample that the testing facility analyzes; and
 - (b) Ensure the COA contains the results of all required analyses performed for the representative sample.
- (2) The COA shall contain, at minimum:
- (a) The testing facility's name, premises address, and license number, processor's or manufacturer's name, and premises address;
 - (b) Batch or lot number of the batch or process lot from which the sample was obtained. For products that are already packaged at the time of sampling, the labeled batch or lot number on the packaged hemp-derived cannabinoid products shall match the batch or lot number on the COA;
 - (c) Sample identifying information, including matrix type and unique sample identifiers;
 - (d) Sample history, including the date collected, the date received by the testing facility, and the date of all sample analyses and corresponding testing results;
 - (e) The analytical methods, analytical instrumentation used, and corresponding LOD and limits of quantitation (LOQ);
 - (f) Analytes detected during the analyses of the sample that are unknown, unidentified, or injurious to human health if consumed, if any; and
 - (g) A chromatograph of the cannabinoid test results.
- (3) The testing facility shall report test results for each representative sample on the COA as an overall "pass" or "fail" for the entire batch:
- (a) When reporting qualitative results for each analyte, the testing facility shall indicate "pass" or "fail";
 - (b) When reporting quantitative results for each analyte, the testing facility shall use the appropriate units of measurement as required in accordance with this administrative regulation;
 - (c) When reporting results for each test method, the testing facility shall indicate "pass" or "fail";
 - (d) When reporting results for any analytes that were detected below the analytical method LOQ, indicate "<LOQ", notwithstanding cannabinoid results;
 - (e) When reporting results for any analytes that were not detected or detected below the LOD, indicate "ND"; and
 - (f) Indicate "NT" for any test that the testing facility did not perform.
- (4)
- (a) In accordance with 2023 Ky. Acts ch. 78, a cannabinoid manufacturer or processor that ships adult-use products out of state for use or sale outside the Commonwealth of

Kentucky:

1. Shall abide by the testing and labeling requirements of this administrative regulation if the receiving state or jurisdiction does not have testing and labeling requirements; or
 2. May defer to the receiving state's testing requirements if that state has equivalent testing requirements.
 3. Products intended for out-of-state sale shall be stored separately from in-state products and shall have signage indicating the products are for out-of-state sale.
- (b) Batch number of the batch from which the sample was obtained shall be on the COA for all products shipped out of state.

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

APPROVED BY AGENCY: April 22, 2024

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

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on July 22, 2024, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by July 15, 2024, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until July 31, 2024. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

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