302 KAR 50:056. Sampling and THC testing; disposal of non-compliant harvests; post-testing actions.

RELATES TO: KRS Chapter 217B, 260.850-260.869, 7 U.S.C. 1639p, 7 C.F.R. Part 990

STATUTORY AUTHORITY: KRS 260.862, 7 U.S.C. 1639p

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 260.862(1) authorizes the department to promulgate administrative regulations for a Hemp Licensing Program in the Commonwealth of Kentucky. KRS 260.862(1)(a) authorizes the department to license persons who wish to participate in a Hemp Licensing Program by cultivating, handling, processing, or marketing hemp. KRS 260.862(1)(c) authorizes the department to prescribe sampling and testing procedures to ensure that hemp and hemp products cultivated, handled, processed, or marketed do not exceed the federal law. This administrative regulation establishes procedures and requirements for sampling and THC testing, and establishes procedures for the movement or disposal of hemp following the completion of THC testing.

Section 1. Definitions.

(1) "Acceptable Hemp THC Level" means the sum of the Measurement of Uncertainty plus the 0.300% delta-9-THC limit on a dry weight basis established in federal law, 7 U.S.C. 1639, and KRS Chapter 260.

(2) "Cannabis":

(a) Means the plant that, depending on its THC concentration level, is defined as either "hemp" or "marijuana." Cannabis is a genus of flowering plants in the family Cannabaceae of which Cannabis sativa is a species, and Cannabis indica and Cannabis ruderalis or subspecies thereof. Cannabis includes all parts of the plant, whether growing or not, including its seeds, resin, compounds, salts, derivatives, and extracts; and

(b) Does not mean a "publicly marketable hemp product," as defined by 302 KAR 50:021, Section 1(37).

(3) "CBD" means cannabidiol.

(4) "Certified seed":

(a) Means the progeny of breeder, foundation, or registered seed handled to maintain satisfactory genetic purity and varietal identity and certified to AOSCA (Association of Official Seed Certifying Agencies) standards and having an official AOSCA seed label; and

(b) Does not include a state's THC compliance verification program.

(5) "Decarboxylated" means the completion of the chemical reaction that converts delta-9-THC-acid into delta-9-THC, the intoxicating component of cannabis. The decarboxylated value is also calculated using a conversion formula that sums delta-9-THC and eighty-seven and seven tenths (87.7) percent of delta-9-THC-acid.

(6) "Delta-9-THC" means delta-9-tetrahydrocannabinol concentration (the primary intoxicating component of cannabis). For compliance purposes, all delta-9-THC concentrations are measured post- decarboxylation or by another method which includes both delta-9-THC and delta-9-THCA (also known as total THC).

(7) "Department" or "KDA" is defined by KRS 260.850(3).

(8) "Hemp" or "industrial hemp" is defined by KRS 260.850(5).

(9) "Hemp transplants" means hemp seedlings, rooted cuttings, immature plants produced from tissue culture, or other means of reproduction, which are not harvested, but transplanted into a large container or field to mature for harvest. The movement of transplants from their original location to the crop production location is not considered a harvest.

(10) "Inspector" means an employee or other representative of the department who has been properly trained by the department to collect samples and perform inspections.

(11) "Lot" means a contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of hemp throughout.

(12) "Measurement of uncertainty" means the parameter, associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to the measurement.

(13) "MSU BVC" means the Breathitt Veterinary Center at the Murray State University in Hopkinsville.

(14) "Person" means an individual or business entity.

(15) "Post-harvest sample" means a sample taken from the harvested hemp from a particular lot's harvest in accordance with the procedures as established in this administrative regulation . The entire lot's harvest is in the same form (for example, intact-plant, or ground materials), homogenous, and not mixed with non-hemp materials or hemp from another lot.

(16) "Pre-harvest sample" means a composite, representative portion from living plants in a hemp lot collected in accordance with the procedures as established in this administrative regulation .

(17) "Program" means the department's Hemp Licensing Program.

(18) "Propagule" means a plant or plant part that can be utilized to grow a new plant.

(19) "UK DRS" means the Division of Regulatory Services at the University of Kentucky College of Agriculture, Food, and Environment in Lexington.

Section 2. Procedures for Inspection and Sample-Collection Visits.

(1) A hemp plant shall not be harvested from any lot before a department inspector completes an inspection and sample-collection visit.

(2) The licensed grower shall submit to the department a completed Harvest Report form, as incorporated by reference in 302 KAR 50:080, at least fifteen (15) days prior to the grower's expected harvest date.

(3) Upon receiving a completed Harvest Report form, the department shall contact the licensed grower to schedule an inspection and sample-collection visit for a specific time on a date that is not later than the grower's expected harvest date.

(4) The licensed grower, or the grower's authorized representative, shall be present during the inspection and sample-collection visit.

(5) During the inspection and sample-collection visit, the licensed grower shall provide to the inspector, complete and unrestricted access to all hemp and other cannabis plants, whether growing or harvested; all land, buildings, and other structures used for the cultivation and storage of hemp and other cannabis plants; and all locations listed in the Hemp Grower License.

(6) During the inspection and sample-collection visit, the inspector shall perform a visual inspection of each location listed in the Hemp Grower License in order to verify the GPS coordinates and look for evidence that hemp plants or other cannabis plants were harvested without authorization prior to the inspector's inspection and sample-collection visit or any other suspicious circumstance.

(7) The licensed grower shall complete the harvest of the crop from a lot not more than thirty (30) days following the date of the inspection and sample-collection visit.

(8) If the licensed grower fails to complete the harvest of the crop from a lot within thirty (30) days following the date of sample collection, then the licensed grower shall submit a new Harvest Report and may be required to pay a secondary pre-harvest sample fee established in 302 KAR 50:060.

(9) Floral material shall not be moved outside the Commonwealth, nor moved beyond a processor; nor commingled, extracted, converted into a consumer-ready product, enter commerce, until the department releases the material in writing.

Section 3. Standards and Procedures for Performance Based Sampling.

(1) The department intends to sample and test every lot of hemp prior to harvest every year. If it is not feasible to sample and test every lot, then the department may implement these performance-based sampling procedures.

(2) The goal is to ensure at a confidence level of ninety-five (95) percent that no more than one (1) percent of the plants in each lot will exceed the acceptable THC level, and that a representative sample is collected that represents a homogenous composition of the lot.

(3) A lot of hemp shall only be eligible for performance based sampling consideration if the licensee maintains records documenting the variety or cultivar's compliance with the acceptable THC concentration.

(4) The transfer of hemp transplants from one (1) location to the location at which the plants will grow to maturity and from which the plants will be harvested shall not be considered to be a harvest. Hemp transplants shall not be subject to sampling before the plants are transferred to the location at which these plants will grow to maturity. Instead, the mature crop produced from hemp transplants shall be subject to sampling and testing.

(5) A hemp licensee who has met all four (4) of the compliance history requirements as established in this subsection may not be subject to the sampling and testing requirement in the current year:

(a) Produced hemp for the past three (3) consecutive years;

(b) Underwent THC testing by the department each of those three (3) years;

(c) Received THC testing results below the acceptable THC level (total THC not more than 0.3%) each of those three (3) years; and

(d) Currently growing the same variety(s) or cultivar(s) as in the previous three (3) years.

(6) Hemp crops which were planted with known Certified seed varieties for grain or fiber, and which are to be harvested only for grain or fiber (with no leaf or floral material harvested) may not be subject to the sampling and testing requirement. Previous testing of those varieties in Kentucky by the department revealed that only nine (9) of 179 lots (five (5) percent) tested above the acceptable hemp THC level. At least fifty (50) percent of all lots produced from these varieties shall be sampled each year on a random basis.

(7) Hemp varieties appearing on the department's Summary of Varieties list available at https://www.kyagr.com/marketing/documents/HEMP\_LH\_Summary\_of\_Varieties\_List.pdf and that have been tested below the acceptable THC level at least ninety (90) percent of the time may be subject to a lower frequency of sampling and testing. At least fifty (50) percent of all lots produced from these varieties shall be sampled each year on a random basis.

Section 4. Procedure for Collecting Samples.

(1) The inspector shall use the following equipment and supplies:

(a) An Inspection and Sample Collection form;

(b) Alcohol wipes;

(c) Pruning shears;

(d) Paper sample-collection bags;

(e) A permanent marker;

(f) Security tape or a stapler;

(g) A GPS unit, or a device with GPS-capable technology;

(h) Nitrile disposable gloves; and

(i) A ruler.

(2) The inspector shall take cuttings from five (5) plants in each lot to make up a composite sample for that lot. The number of plants selected to form a composite sample was calculated using the Codex Alimentarius Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLS CAC/GL 33-1999 available at https://apeda.gov.in/apedawebsite/Announcements/CODEX\_method\_for\_sampling\_for\_determination\_of\_pesticides.pdf. In 2019, Kentucky's hemp testing program showed that 43% of the pre-harvest samples were above 0.30% THC; therefore "I" is equal to 0.43. For a confidence level of ninety-five (95) percent, the minimum plant number required shall be three (3). A lot from a thousand-acre field would require five and three-tenths (5.3) plants.

(3) The inspector shall select the individual plants to be sampled from each lot by selecting at random at least five (5) plants that appear to be representative of the composition of the lot and avoiding selecting plants that are close to the perimeter of the lot.

(4) From each individual plant selected for sampling, the inspector shall cut the highest twenty (20) centimeters from the plant's primary stem of female flower. The inspector shall not remove seed, stem, or other material from the sample that is cut from the plant.

(5) The inspector shall place the cuttings from the lot into a paper sample-collection bag, shut the bag by folding over its top, and secure the fold with security tape or a stapler.

(6) Using a permanent marker, the inspector shall write on the sealed paper sample collection bag the Sample ID consistent with:

(a) The last four (4) digits of the Grower License number,

(b) The date, in MMDDYY format; and

(c) A two (2) digit sample number assigned by the inspector.

(d) Example: For Grower License 21\_1234, with a sample collected on October 15, 2020, from the third lot sampled by the inspector on that date, the Sample ID is 1234-101520-03.

(7) The inspector shall complete the Inspection and Sample Collection form by entering:

(a) The licensed grower's name and contact information;

(b) The address where the lot is located;

(c) The Grower License number;

(d) The inspector's name;

(e) The date of the inspection and sample collection visit; and

(f) For each sample collected, the Location ID, the Sample ID, the hemp variety or strain name, and a description of the crop.

(8) Following the completion of the inspection and sample-collection visit, the inspector shall deliver the sealed sample-collection bag to the department's designated drying facility.

(9) The department shall not unseal sample-collection bags during the drying process.

Section 5. Procedure for THC Testing.

(1) THC testing shall be completed by a Drug Enforcement Administration-registered testing lab designated by the department.

(2) Upon receipt of a sealed sample-collection bag from the department, the laboratory shall receive, prepare, and release hemp samples in accordance with the UK DRS SOP# HM-LB-001 (Procedures for Receiving, Preparing and Releasing Hemp Samples) or MSU BVC SOP # TOX WIN 0042 (Hemp Receiving) and MSU BVC SOP # TOX WIN 0043 (Hemp Storage and Destruction), as applicable.

(3) Hemp material not used by the laboratory for delta-9-THC testing shall be stored as a retained sample.

(4) The laboratory shall measure delta-9-THC content, including both delta-9-THC and delta-9-THCA, on a dry weight basis in accordance with the UK DRS SOP# HM-MT-001 (Procedures for Measuring THC Content in Hemp by Gas Chromotography with Flame Ionization Detection (GC/FID)) or MSU BVC SOP # TOX WIN 0069 (Hemp Potency), as applicable, including the Measurement of Uncertainty.

(5) A person shall not add to, amend, or in any way alter the composition of the retained sample.

Section 6. Post-testing Actions.

(1) Not later than sixty (60) after the date of the inspection and sample-collection visit, the department shall notify the licensed grower of the results of the THC test results and the grower's eligibility to move the harvested materials into commerce.

(2) For the purpose of determining if a test result is compliant with the definition of hemp (0.3000% delta-9-THC on a dry-weight basis), the department shall evaluate it against the Acceptable Hemp THC Level that is applicable for the current year (that is, 0.300% delta-9-THC on a dry-weight basis plus the Measurement of Uncertainty).

(3) A sample from a lot with a measured THC concentration not exceeding the Acceptable Hemp THC Level shall be deemed compliant (conforming to the legal definition of hemp).

(4) A sample from a lot with a measured THC concentration exceeding the Acceptable Hemp THC Level shall be deemed non-compliant.

(5) Within seven (7) days of receiving notice of a measured THC concentration that exceeds the Acceptable Hemp THC Level, but is less than 1.000%, the Licensed Grower shall consent to the destruction of all cannabis from that lot or he or she may request remediation and a post-harvest re-test in accordance with the procedures established in Section 7 of this administrative regulation.

(6) The retest fee shall be paid in an amount established in 302 KAR 50:060.

(7) Samples with a measured THC concentration of 1.000% or greater shall not be eligible for a post-harvest retest and shall be destroyed. A licensee who refuses to comply with a destruction order shall be subject to the license suspension and revocation proceedings set forth in 302 KAR 50:021 or 50:031, as appropriate.

(8) The sample for a retest shall be collected on a date determined by the department.

(9) Samples with a measured THC concentration of 3.000% or greater shall be grounds for license suspension and revocation proceedings set forth in 302 KAR 50:021.

Section 7. Procedure for Collecting Samples for Post-harvest Retests of Remediated Material.

(1) The inspector shall use the following equipment and supplies:

(a) An Inspection and Sample Collection form;

(b) Alcohol wipes;

(c) Pruning shears;

(d) Paper sample-collection bags for wet samples;

(e) Plastic sample-collection bags for dry samples;

(f) A permanent marker;

(g) Security tape or a stapler;

(h) A GPS unit, or a device with GPS-capable technology; and

(i) Nitrile disposable gloves.

(2) The material selected for Post-Harvest Sampling from this lot shall be determined by the inspector, not the grower.

(3) The inspector shall perform a visual inspection to verify that the harvested material is in a homogenous state. If the harvested material is not in a homogenous state, then the inspector shall notify the Hemp Program Manager and convey any instructions the Hemp Program Manager may designate to undertake additional remediation steps to bring the entire harvest into a homogenous state. If the license holder refuses or fails to undertake the designated activities, he or she shall be deemed to have waived any right to request a post-harvest retest and the material shall be designated for disposal.

(4) Harvested material selected for Post-Harvest Sampling shall be taken following remediation by grinding the plant into biomass or removing and disposing of all leaf and flower, in accordance with the instructions established in paragraphs (a) and (b) of this subsection.

(a) For ground plant post-harvest samples:

1. Ensure that the entire harvest is accounted for and in the same form. All harvested material whether whole plant or floral material only shall be ground with no intact plants or whole flowers remaining from that harvest;

2. Sample material from bag or container without removing seed, stem, or other material;

3. Sample from a minimum of five (5) locations within the containers for at least one (1) cup of material from the lot;

4. Place the complete sample in a plastic sample container; and

5. Seal the plastic sample container.

(b) For Post-Harvest Samples following the removal and disposal of leaf and flower:

1. Ensure that the entire harvest is accounted for and in the same form (grain or stalk);

2. Sample material from bag, bale, or container without removing seed, stem, or other material;

3. Sample from a minimum of five (5) locations within the containers, collecting at least one (1) cup of material from the lot;

4. Place the complete sample in a plastic sample container; and

5. Seal the plastic sample container.

(5) Post-Harvest Samples of non-remediated crops is not recommended, but if the grower requests and pays for a Post-Harvest Sample of harvested intact plants, the sampling will be conducted according to the instructions established in paragraphs (a) through (e) of this subsection:

(a) Ensure that the entire harvest is accounted for and in the same form (intact plants);

(b) Clip the top twenty (20) cm of hemp plant, primary stem, including female floral material, without removing seed, stem, or other material;

(c) Take cuttings from at least five (5) hemp plants within the harvest's storage or drying area at the discretion of the inspector ;

(d) Place the complete sample in a paper bag ; and

(e) Seal the paper bag by folding over the top once and stapling to keep closed.

(6) The inspector shall place the cuttings or composite sample from the lot into a sample collection bag and secure the bag with security tape or staples.

(7) Using a permanent marker, the inspector shall write on the sealed sample-collection bag the Sample ID consistent with the following format:

(a) The last four (4) digits of the Grower License number;

(b) The date, in MMDDYY format;

(c) A two (2) digit sample number assigned by the inspector; and

(d) Example: For Grower License 21\_1234, with a sample collected on October 15, 2020, from the third lot sampled by the inspector on that date, the Sample ID is 1234-101520-03.

(8) The inspector shall complete the Inspection and Sample Collection form by entering:

(a) The licensed grower's name and contact information;

(b) The address where the lot was grown and where it is currently located;

(c) The Grower License number;

(d) The inspector's name;

(e) The date of the inspection and sample collection visit; and

(f) For each sample collected, the Location ID, the Sample ID, the hemp variety or strain name, and a description of the crop.

(9) Following the completion of the inspection and sample-collection visit, the inspector shall deliver the sealed sample-collection bag to the department's designated drying facility.

(10) The department shall not unseal sample-collection bags during the drying process.

(11) The procedure for THC testing used by UK DRS shall be the same for post-harvest retests as those established in Section 5 of this administrative regulation.

(12) A lot having a post-harvest sample with a measured THC concentration exceeding the Acceptable Hemp THC Level shall be deemed non-compliant and designated for disposal.

Section 8. Disposal of Non-compliant Harvested Materials.

(1) If a lot is designated for mandatory disposal, then the department shall ensure that all leaf material and floral material from that lot is disposed of using one (1) of the procedures established in this Section of this administrative regulation. The costs of disposal, if any are incurred by the department, shall be charged to the license holder.

(2) Disposal by on-site destruction with department supervision. Without removing the harvested material from the license holder's premises (or other licensed premises where the harvested material is located), a department employee shall personally observe the harvested material's destruction (the act of rendering it into a useless and non-retrievable state) using one (1) of these methods:

(a) By grinding it up and incorporating it into the soil; or

(b) By controlled incineration.

(3) Disposal by on-farm transfer to a person who is registered or authorized by the department to accept controlled substances for the purposes of destruction. At the premises of the license holder (or other licensed premises where the harvested material is located), a department employee shall load, or observe the loading, of the harvested material until the transfer is complete.

(4) Disposal by vehicle transport to a department-approved location.

(a) Prior to the transport: At the premises of the license holder (or other licensed premises where the harvested material is located), a department employee shall load, or observe the loading, of the harvested material until the material is completely secured on or in the vehicle.

(b) During the transport: A department employee shall accompany the harvested material as it moves in a vehicle directly to a department-approved location. The vehicle shall constantly move towards its final destination without unnecessary stops, stops for reasons unrelated to the transport task, or stops of an extended duration.

(c) After the transport: Upon arrival at the department-approved location, a department employee shall unload, or observe the unloading, of the harvested material until the material is completely removed from the vehicle.

(d) Following the material's removal from the vehicle, a department employee shall personally observe the harvested material's destruction (the act of rendering it into a useless and non-retrievable state) using one (1) of these methods:

1. By grinding it up and incorporating it into the soil; or

2. By controlled incineration.

Section 9. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "UK DRS SOP# HM-MT-001 (Procedures for Measuring THC Content in Hemp by Gas Chromotography with Flame Ionization Detection (GC/FID)", 2021;

(b) "UK DRS SOP# HM-LB-001 (Procedures for Receiving, Preparing and Releasing Hemp)", 2021 ;

(c) "MSU BVC SOP # TOX WIN 0042 (Hemp Receiving)", 2020;

(d) "MSU BVC SOP # TOX WIN 0043 (Hemp Storage and Destruction)", 2020;

(e) "MSU BVC SOP # TOX WIN 0069 (Hemp Potency)", 2020; and

(f) "Inspection and Sample Collection Form", 1/2022.

(2) These materials may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department of Agriculture, Office of Agricultural Marketing, 105 Corporate Drive, Frankfort, Kentucky 40601, Monday through Friday, 8:00 a.m. to 4:30 p.m. These materials may also be obtained at www.kyagr.com.

(47 Ky.R. 659, 1210; eff. 3-2-2021; 48 Ky.R. 1647, 2478; eff. 7-5-2022.)