RULES
OF
THE TENNESSEEE DEPARTMENT OF AGRICULTURE
HEMP

CHAPTER 0080-10-02
MANUFACTURING AND DISTRIBUTION OF HEMP-DERIVED CANNABINOID PRODUCTS

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0080-10-02-.01 SCOPE.

(1) This chapter applies to any person who manufactures or distributes in commerce any HDC product.

(2) Persons who manufacture or distribute HDC products are subject to all requirements and regulatory authority applicable to the type of product sold, including but not limited to regulation under the Act and this chapter, and T.C.A. title 53, chapter 1, parts 1 and 2, and title 39, chapter 17, part 15, and Tenn. Comp. R. & Regs. 0080-04-13. HDC products are excluded from all regulatory exemptions including but not limited to those afforded under the Food Freedom Act at T.C.A. § 53-1-118.

(3) The department shall not refund fees for early termination of any license issued under this chapter.

(4) Licenses under this chapter are not transferable from person to person or location to location.

Authority: *T.C.A. §§ 4-3-203 and 43-27-211.* ***Administrative History:*** *New rules filed September 27, 2024; effective December 26, 2024.*

0080-10-02-.02 DEFINITIONS.

(1) Terms in this chapter share those meanings of terms in T.C.A. title 43, chapter 27, parts 1 and 2.

(2) When used in this chapter, unless the context requires otherwise:

(a) Act means T.C.A. §§ 43-27-201, et seq.;

(b) Batch, in addition to its definition under the Act, means an individual production lot of manufactured product;

(c) Cannabis means any plant or any part of a plant of the genera Cannabis and includes hemp;

(d) Certificate of Analysis (COA) means a written document from a laboratory approved by the department for testing samples under this chapter, and which communicates the results of those tests performed;

(e) Commerce or similar words mean involving payment for an item or payment for services incident to production of the item;

(Rule 0080-10-02-.02, continued)

(f) Distribute means to transport or to introduce into commerce and includes delivery for sale or manufacturing, or holding for subsequent sale or manufacturing;

(g) Food means articles used for food or drink for humans or other animals; chewing gum; and articles used for components of food or drink or chewing gum;

(h) Hemp-derived cannabinoid (HDC) product means a product that contains or that is labeled to contain a hemp-derived cannabinoid and that is produced, marketed, or otherwise intended to be consumed orally ("ingestible"), inhaled ("inhalable"), or absorbed through the skin ("transdermal"). HDC products also include intermediate products intended for subsequent use as a component in a later finished ingestible, inhalable, or transdermal HDC product. Topical products mean products solely intended to be applied to the skin or hair and are not intended to be absorbed through transdermal application; topical products are not included within the definition of HDC product even if they contain a hemp-derived cannabinoid;

(i) In a manner similarly reliable to post-decarboxylation means a manner sufficient to quantify by percentage the resulting THC of a sample if carboxyl groups are removed from all molecules containing THC within the sample. A manner similarly reliable to post-decarboxylation is shown by a post-decarboxylation THC value equal to the sum of the sample's THC percentage plus the product of its delta-9 tetrahydrocannabinolic acid (THCa) percentage and 0.877;

(j) Manufacture, in addition to its definition under the Act, includes any action that transforms cannabis physically or chemically beyond its principal form as a farm product or that filters, cleans, or trims that product to isolate any of its particular parts or components;

(k) Move, transport, or similar words mean to relocate in any manner an item from one real property to another;

(l) Person means an individual, partnership, corporation, or any other form of legal entity;

(m) Sample means to take material or the material taken from a location used to manufacture or distribute HDC products; and,

(n) Serving, in addition to its definition under the Act, means an amount of product designated by its manufacturer as reasonably understood to be a single unit of the product for consumption.

Authority: *T.C.A. §§ 4-3-203 and 43-27-211.* ***Administrative History:*** *New rules filed September 27, 2024; effective December 26, 2024.*

0080-10-02-.03 LICENSE APPLICATION AND FEES.

(1) An HDC supplier license is required per person per location for any person who manufactures or distributes an HDC product in commerce.

(2) Applicants for an HDC supplier license must submit required information on forms provided by the department, which may include:

(a) Name of the applicant;

(b) Date of birth of any applicant who is an individual or a partner in a general partnership;

(Rule 0080-10-02-.03, continued)

(c) Proof of registration in its state of incorporation for any applicant that is a formalized business entity;

(d) Proof of registration with the Tennessee Department of Revenue;

(e) Contact information for applicant, to include name of person legally responsible for applicant's operations, telephone number, email address, and address of principal place of business;

(f) Address of location to be licensed;

(g) A nationwide criminal background check, facilitated through the Tennessee Bureau of Investigation, for the person identified as legally responsible for applicant's operations; and,

(h) Other information as required by the department.

(3) Licensees must notify the department of any changes to the contents of their application on file within 30 days after the change takes place, including any change of contact information;

(4) Payment of an annual HDC supplier license fee of $500 shall be due upon approval of an application and must be paid in full prior to a license being issued. The license fee may be prorated in the initial year of licensure at the rate of $50 per each full calendar month remaining in the license period, provided the total fee not exceed $500. License fees shall not be prorated for any person licensed in the previous licensure year. License fees are waived for any accredited college or university that offers programs of study in agricultural sciences and that is seeking licensure for HDC product manufacturing on its college or university property.

(5) HDC supplier licenses expire on June 30 of the licensing cycle for which they are issued. Applicants for renewal must submit to the department on or before the following July 1 the HDC supplier license fee and an updated criminal background check for the licensee.

(6) The department may deny any application for licensure that is not completed in full or that is not completed in conformance with this rule.

Authority: *T.C.A. §§ 4-3-203 and 43-27-211.* ***Administrative History:*** *New rules filed September 27, 2024; effective December 26, 2024.*

0080-10-02-.04 MANUFACTURING.

(1) General requirements.

(a) In production of HDC products, manufacturers shall:

1. Assign each product batch a unique batch number;

2. Not add nicotine to any HDC product; and

3. Not use dimethylsulfoxide in any HDC product.

(2) Inhalable HDC products.

(a) A person shall not manufacture or distribute an inhalable HDC product made with a non-hemp derived cannabinoid ingredient unless the ingredient is listed in, and the

(Rule 0080-10-02-.04, continued)

concentration and route of the ingredient is authorized under, the federal Food and Drug Administration (FDA) inactive ingredient database at https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm.

(b) A person shall not manufacture or distribute an inhalable HDC product in which any of the following substances are used in its manufacture:

1. Vitamin E acetate;

2. Medium-chain triglycerides;

3. Polyethylene glycol;

4. Propylene glycol; or,

5. 2, 3-butanedione.

(c) A person shall not manufacture or distribute an inhalable HDC product unless its water activity is less than 0.65 and its total combined yeast and mold count is less than 100,000 colony forming units per gram.

(3) Solvents. A person shall not manufacture or distribute an HDC product in which solvents were used in its manufacture. Use of the following substances are allowable exceptions: water, vegetable glycerin, vegetable oils, animal fats, butane, propane, carbon dioxide, ethanol, isopropanol, acetone, heptane, ethyl acetate, and pentane.

(a) If butane, propane, heptane, or pentane is used as a solvent, the solvent must be documented on its COA as at least 99 percent purity.

(b) If water, vegetable glycerin, vegetable oil, animal fat, carbon dioxide, ethanol, isopropanol, acetone, or ethyl acetate is used as a solvent, the solvent must be food grade according to FDA standards under 21 CFR Part 174.

Authority: *T.C.A. §§ 4-3-203 and 43-27-211.* ***Administrative History:*** *New rules filed September 27, 2024; effective December 26, 2024.*

0080-10-02-.05 SAMPLING AND TESTING.

(1) Frequencies.

(a) If an HDC product is created from hemp or hemp products, the HDC supplier licensee must sample and test each batch of the product for conformance with this rule. Once full panel testing required by this rule is conducted on hemp or a hemp product, additional testing in downstream commerce is not required except as provided:

1. After the initial HDC product in commerce conforms to testing under subparagraph (a), if a downstream HDC supplier uses the product as an input to make a new HDC product and during production of the new product the HDC input underwent either a chemical change (e.g. through exposure to heat or solvents) or a reconstitution through addition or removal of other components, the supplier must cause each batch of new HDC product to be sampled and tested for conformance with this rule.

2. After the initial HDC product in commerce conforms to testing under subparagraph (a), if a downstream HDC supplier uses the product as an input to make a new

(Rule 0080-10-02-.05, continued)

HDC product but does not alter the chemical composition or formulation of the HDC product compared to the input used (e.g. raw flower that is only physically changed through cutting and filtering or bulk orders that are repackaged into smaller units of like product), additional sampling and testing of the resulting product batches are not required and prior test results in commerce of HDCs within the product are presumptively valid. This part shall not limit the department's authority to test any cannabis products for compliance with the Act and this chapter.

(b) Prior to transport of any HDC product in commerce, HDC suppliers must confirm conformance of the batch to all testing requirements under this rule.

(2) Standards. Tolerances for each required testing analyte are listed below. Any test result exceeding allowable limits is grounds for embargo, recall, remediation, and/or destruction of the entire batch represented by the sample, regardless of whether the test result is discovered through manufacturing testing or subsequent sampling and testing of retail HDC product.

(a) For all HDC products:

1. Hemp-derived cannabinoids:

(i) Delta-8 tetrahydrocannabinol [Reserved];

(ii) Delta-10 tetrahydrocannabinol [Reserved];

(iii) Hexahydrocannabinol [Reserved];

(iv) Tetrahydrocannabiphorol (THCp) [Reserved];

(v) Tetrahydrocannabivarin (THCv) [Reserved]; and,

(vi) Tetrahydrocannabinolic acid (THCa):

(I) HDC products in commerce to an HDC supplier licensee (sample test result, less the measurement uncertainty, showing a post-decarboxylation THC value ≤ 5%);

(II) HDC products in commerce to any person who is not an HDC supplier licensee (sample test result, less the measurement uncertainty, showing a post-decarboxylation THC value ≤ 0.3%);

2. Microbial contaminants:

(i) Shiga toxin-producing Escherichia coli (undetectable in at least one gram);

(ii) Salmonella spp. (undetectable in at least one gram);

3. Mycotoxins:

(i) Aflatoxin B1 (total aflatoxin B1, B2, G1, and G2 ≤ 20 µg/kg);

(ii) Aflatoxin B2 (total aflatoxin B1, B2, G1, and G2 ≤ 20 µg/kg);

(iii) Aflatoxin G1 (total aflatoxin B1, B2, G1, and G2 ≤ 20 µg/kg);

(Rule 0080-10-02-.05, continued)

(iv) Aflatoxin G2 (total aflatoxin B1, B2, G1, and G2 ≤ 20 µg/kg);

(v) Ochratoxin A (≤ 20 µg/kg);

4. Residual pesticides:

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

(Rule 0080-10-02-.05, continued)

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

5. Heavy metals:

   (i) Arsenic (≤ 0.4 ppm);

   (ii) Cadmium (≤ 0.4 ppm);

   (iii) Lead (≤ 1 ppm);

   (iv) Mercury (≤ 1.2 ppm);

6. Residual solvents and manufacturing chemicals:

Solvent or manufacturing chemical	CAS assigned number	Maximum allowable concentration (ppm)
Acetone	67-64-1	1,000 ppm
Benzene*	71-43-2	2 ppm
Butanes, (measured as the cumulative residue of n-butane and iso-butane),	106-97-8 and 75-28-5	1,000 ppm
Ethanol	64-17-5	1,000 ppm
Ethyl Acetate	141-78-6	1,000 ppm
Heptanes	142-82-5	1,000 ppm
Hexanes* (measured as the cumulative residue of n-hexane, 2-methylpentane, 3-methylpentane, 2,2-dimethylbutane, and 2,3-dimethylbutane)	110-54-3, 107-83-5 and 79-29-8	60 ppm
Methanol*	67-56-1	600 ppm
Pentanes (measured as the cumulative residue of n-pentane, iso-pentane, and neo-pentane)	109-66-0, 78-78-4 and 463-82-1	1,000 ppm
2-Propanol (IPA)	67-63-0	1,000 ppm
Propane	74-98-6	1,000 ppm
Toluene*	108-88-3	180 ppm
Total Xylenes* (measured as the cumulative residue of 1,2-dimethylbenzene, 1,3-dimethylbenzene, and 1,4-dimethylbenzene, and the non-xylene, ethylbenzene)	1330-20-7 (95-47-6, 108-38-3 and 106-42-3 and 100-41-4)	430 ppm
Any other solvent not permitted for use		undetected

*These solvents are not individually approved for use. Due to their possible presence in other solvents that are approved for use, limits have been listed here for concentrations in final products.

(b) Additional testing requirements for inhalable HDC products:

1. Microbial contaminants:

(i) Aspergillus A. fumigatus (undetectable in at least one gram);

(ii) Aspergillus A. flavus (undetectable in at least one gram);

(iii) Aspergillus A. niger (undetectable in at least one gram);

(iv) Aspergillus A. terreus (undetectable in at least one gram);

2. Heavy metals:

(i) Arsenic (≤ 0.2 ppm);

(ii) Cadmium (≤ 0.2 ppm);

(iii) Lead (≤ 0.5 ppm);

(iv) Mercury (≤ 0.1 ppm).

(3) Sampling. HDC product manufacturers must draw samples for testing that are representative of each batch.

(4) Testing.

(a) Third-party laboratories.

1. COAs required under this chapter may be supplied by a third-party laboratory provided the laboratory is registered with the department.

2. To register and to maintain registration with the department, a third-party laboratory applicant must:

(i) Complete in full an application for registration on forms provided by the department;

(ii) Host and notify the department of one landing page for retrieval of all COAs issued by the laboratory through use of quick reference (QR) codes;

(iii) For any test method conducted pursuant to this rule, be fully accredited to standards established under International Organization for Standardization (ISO) 17025 by an International Laboratory Accreditation Cooperation recognized accreditation body;

(iv) Maintain ISO 17025 accreditation;

(v) Test and report analyte(s) using limits of detection and quantitation no greater than the respective tolerance(s) under this chapter for the tested analyte(s);

(Rule 0080-10-02-.05, continued)

(vi) Test and report hemp-derived cannabinoids under this chapter using a limit of quantitation ≤ 1 mg/g;

(vii) Perform and report component testing as detailed under this rule;

(viii) Store all samples in a secure manner that reasonably protects them from degradation, contamination, and tampering; and, prior to its disposal, render all sample material unusable;

(ix) If available, produce reserve sample material to the department upon request; and,

(x) Provide other information as required by the department.

3. Failure to adhere to these requirements or requirements for issuance of COAs under this rule is grounds for denial or revocation of any registration or authorization issued by the department.

(b) COAs.

1. Third-party laboratories must include at a minimum the following on each COA issued:

(i) The laboratory's name and address as it is registered with the department;

(ii) The HDC product manufacturer's name and address;

(iii) The batch number of HDC product represented by the sample;

(iv) Unique identifying information for the sample, if applicable;

(v) Sample history including date received and date range of each test conducted on the sample;

(vi) Analytical methods, limits of detection, limits of quantitation, and test results for each analyte evaluated for the sample, regardless of whether the testing conducted is required by this rule; and,

(vii) A collective "pass"/"fail" assessment for the entire batch that accounts for either passage of all or failure of any one test conducted on the sample.

2. When reporting quantitative results, third-party laboratories must include in the COA the corresponding units of measurement as required for tolerances under this rule, as well as measurement uncertainties.

3. A result of "< LOQ" for any analyte detected below the limit of quantification (LOQ).

4. A result of "ND" for any analyte that was tested for and not detected.

(c) Failed testing.

1. Retesting. Any sample failure may be re-submitted as follows for confirmation of testing failure.

(Rule 0080-10-02-.05, continued)

(i) If a reserve sample was retained by the same third-party registered laboratory that produced the COA exhibiting a test failure, that laboratory may re-test the reserve sample following the failed test in order to confirm component compliance.

(ii) If the re-tested sample passes for the suspect component(s), a new sample from the same batch must be drawn and submitted to a second third-party registered laboratory for complete re-testing of all components listed under this rule. If the second re-testing conforms to all required tolerances, the batch is deemed compliant with testing requirements and may be transported and distributed in commerce.

(iii) If a reserve sample is not available from the initial third-party registered laboratory or if a sample fails either of the re-tests, the batch is deemed nonconforming with regulatory requirements.

2. Remedy.

(i) Microbial contaminants. An HDC supplier is prohibited from transporting or allowing transport of a batch that has failed microbial contaminant testing unless:

(I) The batch is further processed by a method that effectively sterilizes the batch, is re-tested, and those test results show conformance with required tolerances;

(II) The supplier submits a corrective action plan for effective sterilization of the batch by another licensed HDC supplier, receives written approval of the plan from the department, and places the batch under immediate transport to the approved HDC supplier; or,

(III) The batch is rendered unusable.

(ii) Over-concentrated product. An HDC product manufacturer is prohibited from transporting or allowing transport of a batch that has failed THC concentration testing unless:

(I) The batch is further processed by a method that effectively dilutes the batch, is retested, and those results show conformance with required tolerances;

(II) The manufacturer submits a corrective action plan for effective dilution of the batch by another licensed HDC supplier, receives written approval of the plan from the department, and places the batch under immediate transport to the approved HDC supplier; or,

(III) The batch is rendered unusable.

(iii) For all other component testing failures, an HDC product manufacturer must render the batch unusable prior to disposition.

Authority: *T.C.A. §§ 4-3-203 and 43-27-211.* ***Administrative History:*** *New rules filed September 27, 2024; effective December 26, 2024.*

0080-10-02-.06 LABELS.

(1) HDC product manufacturers must, in addition to labeling requirements under the Act, label each HDC product with the following:

(a) Batch number;

(b) Name and address of the HDC product manufacturer or distributor;

(c) A list of all ingredients, ordered by weight, including direct and indirect additives;

(d) A separate allergen statement, stating common name of allergen, if product contains any of the following ingredients: eggs; fish; milk; tree nuts; peanuts; sesame; shellfish; soy; or wheat;

(e) A QR code that when scanned links the viewer to COA testing results conducted under this chapter. A QR code that does not link to the landing page designated by the testing laboratory as registered with the department shall be considered invalid and a violation of this rule;

(f) Serving size of the product and the total number of servings per package of the product (applicable only for ingestible HDC products); and,

(g) The numerical count, net weight, or net volume of the product per package. Net weight and net volume must be reported in both standard and metric measurements.

(2) Warning statements. HDC product manufacturers must include the following warning statement(s), printed in at least six-point, easily legible font on the label panel of associated HDC products, and shall be conspicuous and in distinct contrast (e.g. by typography, layout, color, or embossing) to other information on the package.

(a) For all HDC products.

1. “Warning: Keep out of reach of children. Must be 21 or older to possess or consume. May be harmful to those who are pregnant or breastfeeding. May impair ability to drive or operate machinery. May contain unidentified substances that are harmful or toxic. This product is not approved by FDA for cure, mitigation, treatment, or prevention of any disease.”

2. The word “Warning” must be printed in bold font, all capital letters.

(b) Additional warning statement for inhalable HDC products.

1. “Warning: Inhalation of cannabis smoke has been associated with lung injury.”

2. The word “Warning” must be printed in bold font, all capital letters.

(3) A person shall not manufacture or distribute any HDC product labeled as a dietary supplement.

Authority: *T.C.A. §§ 4-3-203 and 43-27-211.* ***Administrative History:*** *New rules filed September 27, 2024; effective December 26, 2024.*

0080-10-02-.07 TRANSPORTATION.

(1) In addition to transportation requirements under the Act, HDC supplier licensees must make immediately available upon request COAs for any HDC product, including raw product, that is transported in commerce.

Authority: *T.C.A. §§ 4-3-203 and 43-27-211.* ***Administrative History:*** *New rules filed September 27, 2024; effective December 26, 2024.*

0080-10-02-.08 RECORDS.

(1) For each batch of HDC product manufactured or distributed, HDC supplier licensees shall maintain the following for two years:

(a) COAs, copies of which shall be submitted to all immediate downstream purchasers of the product;

(b) A current copy of safety data sheets for all solvents used in manufacturing the HDC product; and,

(c) Invoices and bills of lading for all HDC product distribution conducted by the HDC supplier licensee.

(2) For any HDC product rendered unusable or disposed pursuant to this chapter, HDC supplier licensees must maintain documentation of the following for two years following disposal:

(a) Date(s) and manner(s) in which the product was rendered unusable and disposed;

(b) Batch number; and,

(c) Total volume of product that was disposed.

Authority: *T.C.A. §§ 4-3-203 and 43-27-211.* ***Administrative History:*** *New rules filed September 27, 2024; effective December 26, 2024.*

0080-10-02-.09 INSPECTIONS.

(1) Scope. The department may enter any licensed premises or conveyance during normal business hours for purposes of inspecting and sampling any cannabis, HDC product, product lists and labels, or other material and copying records necessary to determine compliance with the Act and this chapter.

(2) Frequency. The department may conduct inspections as often as necessary to determine compliance with the Act and this chapter.

Authority: *T.C.A. §§ 4-3-203 and 43-27-211.* ***Administrative History:*** *New rules filed September 27, 2024; effective December 26, 2024.*

0080-10-02-.10 VIOLATIONS.

(1) In addition to other requirements of the Act and this chapter, persons subject to this chapter must:

(a) Maintain areas and vehicles where HDC products are manufactured or distributed so as to be readily accessible for inspection;

(Rule 0080-10-02-.10, continued)

(b) Provide adequate lighting necessary for inspection of all HDC products manufactured or distributed;

(c) Provide full access to facilities, inventory, records, and invoices necessary to departmental inspection;

(d) Give full information as to the source of any cannabis or HDC product currently or previously held in their possession;

(e) Consent to sampling of all HDC product manufactured or distributed by the licensee; and,

(f) Consent to recall of all associated HDC product batches when subsequent testing of HDC product in commerce indicates a failure of testing requirements under this chapter, or a foodborne outbreak or other illness is causally linked by federal authorities or the department of health to particular HDC product batches.

(2) In addition to other requirements of the Act and this chapter, persons subject to this chapter must not:

(a) Manufacture or distribute HDC products without first securing a license from the department;

(b) Manufacture or distribute HDC products that do not meet manufacturing and testing requirements under this chapter;

(c) Transport or allow transport of HDC products without a COA issued by a third-party laboratory registered with the department;

(d) Interfere with an authorized representative of the department in performance of their duties;

(e) Violate any federal or state quarantine of plants, regulated articles, or other material;

(f) Sell, offer for sale, move, or allow movement of any apparently infested material; or,

(g) Violate any departmental order issued under the Act or this chapter, including but not limited to orders for embargo or destruction of HDC product.

(3) Violation of any workplace safety or environmental protection standard enforced by state or federal authorities is grounds for denial of program inspection and denial or revocation of any license issued by the department.

(4) A person is responsible for violations of the Act or this chapter when committed by either the person or their agent.

(5) Each violation of the Act or this chapter is grounds for issuance of embargo or destruction orders for any HDC product held by the violator or their agent, denial or revocation of any license or registration issued by the department, actions for injunction, imposition of civil penalties, and/or pursuit of criminal charges against the violator.

Authority: *T.C.A. §§ 4-3-203 and 43-27-211.* ***Administrative History:*** *New rules filed September 27, 2024; effective December 26, 2024.*