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File Date: 12/14/2023

Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. § 4-5-204. For questions and copies of the notice, contact the person listed below.

Agency/Board/Commission:	Department of Agriculture
Division:	Consumer & Industry Services
Contact Person:	Annie Balghiti
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Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

ADA Contact:	Liz Sneed
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Hearing Location(s) (for additional locations, copy and paste table)

Address 1:	Tennessee Department of Agriculture, Porter Building Atrium		
Address 2:	436 Hogan Road		
City:	Nashville, TN		
Zip:	37220		
Hearing Date:	02/06/2024		
Hearing Time:	10:00 a.m.	_x_CST/CDT ___EST/EDT	

Additional Hearing Information:

This rule is intended to clarify requirements for manufacturing, distribution, and retail sale of hemp products in accordance with T.C.A. § 43-27-101 and 201 et seq.

Revision Type (check all that apply):

x Amendment
x New
x Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	**Chapter Title**
0080-04-09	Retail Food Store Sanitation
Rule Number	**Rule Title**
0080-04-09-.01	Definitions

0080-04-09-.03	Food

Chapter Number	Chapter Title
0080-04-13	Food Manufacturers and Warehouses
Rule Number	**Rule Title**
0080-04-13-.02	Definitions
0080-04-13-.05	Standards for Manufacturing and Processing

Chapter Number	Chapter Title
0080-06-28	Hemp
Rule Number	**Rule Title**
0080-06-28-.01	Scope
0080-06-28-.02	Definitions
0080-06-28-.03	License Application and Fees
0080-06-28-.04	USDA Reports
0080-06-28-.05	Movement Permits
0080-06-28-.06	Sampling and Inspections
0080-06-28-.07	Violations
0080-06-28-.08	Repealed
0080-06-28-.09	Repealed

Chapter Number	Chapter Title
0080-10-01	Hemp Producers
Rule Number	**Rule Title**
0080-10-01-.01	Scope
0080-10-01-.02	Definitions
0080-10-01-.03	License Application and Fees
0080-10-01-.04	Movement Permits
0080-10-01-.05	Inspections and Testing
0080-10-01-.06	Violations

Chapter Number	Chapter Title
0080-10-02	Manufacturing and Distribution of Hemp-derived Cannabinoid Products
Rule Number	**Rule Title**
0080-10-02-.01	Scope
0080-10-02-.02	Definitions
0080-10-02-.03	License Application and Fees
0080-10-02-.04	Manufacturing
0080-10-02-.05	Sampling and Testing Requirements
0080-10-02-.06	Labels
0080-10-02-.07	Transportation Requirements
0080-10-02-.08	Records
0080-10-02-.09	Inspections
0080-10-02-.10	Violations

Chapter Number	Chapter Title
0080-10-03	Retail Sale of Hemp-derived Cannabinoid Products
Rule Number	**Rule Title**
0080-10-03-.01	Scope
0080-10-03-.02	Definitions
0080-10-03-.03	License Application and Fees
0080-10-03-.04	Manner of Sale
0080-10-03-.05	Records
0080-10-03-.06	Inspections and Testing
0080-10-03-.07	Violations

New

Chapter 0080-10-01
HEMP

Division 0080-10 Hemp is created.

Authority: T.C.A. §4-3-203.

CHAPTER 0080-10-01
HEMP PRODUCERS

0080-10-01-.01 Scope.

(1) This chapter applies to any person who possesses rooted hemp or who cultivates cannabis for introduction into commerce.

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

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

Authority: T.C.A. §§ 4-3-203 and 43-27-104.

0080-10-01-.02 Definitions.

(1) Terms in this chapter share those meanings of terms in T.C.A. § 43-27-101, et seq.

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

(a) Act means T.C.A. § 43-27-101, et seq.;

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

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

(d) Cultivate or similar words mean to foster the growth of plant material and includes growing and cloning;

(e) Growing area means any contiguous land area that is used for cultivation of cannabis regardless of whether it is under structure. Bifurcation of a growing area by roads, fencing, or the like shall not render the area non-contiguous under this definition;

(f) Harvest means to gather, in any manner, cannabis material from rooted plants and to transport it from the property where it was cultivated;

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

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

(i) Sample means to take plant material or the plant material taken from a location used to cultivate cannabis;

(j) Stop movement order means a written directive issued by the department to prohibit or to limit the movement of plants or plant parts;

(k) Total THC means the potential total delta-9 tetrahydrocannabinol (THC) content derived from the sum of THC and delta-9 tetrahydrocannabinol acid (THCA) reported on a dry weight basis, calculated as: (cannabinoid concentration (mg/g)) + (cannabinoid acid form concentration (mg/g) x 0.877); and,

(l) USDA means United States Department of Agriculture.

Authority: T.C.A. §§ 4-3-203 and 43-27-104.

0080-10-01-.03 License Application and Fees.

(1) A hemp producer license is required per person per location for any person who possesses rooted hemp or who cultivates cannabis for introduction into commerce.

(2) Applicants for a hemp producer 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;

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

(d) 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;

(e) Address of location to be licensed;

(f) Acreages for each growing area at the location to be licensed;

(g) Global Positioning System coordinates for the central most point of each growing area at the location to be licensed;

(h) An Identity History Summary issued by the Federal Bureau of Investigation for the person identified as legally responsible for applicant's operations;

(i) Designation, if applicable, of any authorized representative for the applicant; and,

(j) 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 or new hemp crops that have been planted;

(4) Applicants must include with their application payment of an annual hemp producer license fee, calculated as follows:

(a) Cumulative growing areas less than five acres: $250;

(b) Cumulative growing areas of five to 20 acres: $300;

(c) Cumulative growing areas of more than 20 acres: $350; and,

(d) License fees are waived for any accredited college or university that offers programs of study in agricultural sciences and that is seeking licensure for growing areas on its college or university property.

(5) Hemp producer licenses expire on June 30 following their issuance. Applicants for renewal must submit to the department on or before July 1 each year the hemp producer license fee and an updated Identity History Summary for the licensee. If an applicant for renewal fails to pay the annual license fee by July 16 following expiration, the applicant shall also be required to pay a late charge under T.C.A. § 43-1-703 prior to renewal of the applicant's license.

(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, 43-1-703, and 43-27-104.

0080-10-01-.04 Movement Permits.

(1) Licensees shall not move rooted hemp plants without a valid movement permit issued by the department. Licensees shall not move any hemp to anyone who treats or transforms harvested hemp for distribution in commerce without a valid movement permit issued by the department.

(2) Hemp movement permits are required per vehicle per day. To receive a movement permit, the licensee shall submit a movement permit request on forms provided by the department, which may require:

(a) The hemp license number of the person requesting the permit;

(b) Origin and destination of movement;

(c) Date of intended movement; and,

(d) Weight, volume, or number of units of material to be moved.

(3) The department may deny any application for a movement permit that is not completed in accordance with this rule.

Authority: T.C.A. §§ 4-3-203 and 43-27-104.

0080-10-01-.05 Inspections and Testing.

(1) Scope. The department may enter any premises during normal business hours where the department has reason to believe that rooted hemp is possessed or that cannabis is being cultivated for introduction into commerce. The department may enter for purposes of inspecting and sampling any cannabis 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.

(3) Sampling and testing.

(a) A sample collected and tested according to protocols issued by either USDA or the department is deemed representative of the growing area from which the sample was obtained.

(b) Comingling of sample material from different growing areas invalidates the results of the sample testing.

(c) Collection of a sample by a licensee or their agent invalidates the results of the sample testing.

(d) Any sample test result less the measurement of uncertainty that is greater than 0.3% total THC is grounds for destruction or remediation of all cannabis represented by the sample material.

(e) Third party.

1. The department may approve third-party samplers for collection of cannabis material and third-party test laboratories to conduct official analysis of samples. The department will accept test results for a third-party collected or tested sample only if the sample was collected and tested in conformance with sampling guidelines and testing requirements issued by either USDA or the department, and for which test results are submitted by the third-party testing laboratory directly to the department.

2. If a sample test result from an approved third-party laboratory is the initial test for a growing area and shows the sample to be within allowable limits, the department will recognize the sample as compliant without further testing. If the sample test is either not the initial test of the crop or is not within allowable limits, the department will re-sample and re-test the growing area prior to determining regulatory compliance.

(f) Department.

1. Sampling by the department must be attended by the licensee or the licensee's authorized representative, if applicable. If the licensee or authorized representative does not appear for scheduled sampling, the department may assess a $150 travel charge against the licensee for departmental costs in visiting the location to be sampled.

2. The department serves as the reference laboratory for all samples. Its test results of any sample are considered conclusive.

3. Licensees must pay a $150 laboratory analysis fee for each sample tested by the department.

Authority: T.C.A. §§ 4-3-203, 43-1-703, and 43-27-104.

0080-10-01-.06 Violations.

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

(a) Maintain areas where cannabis is grown or kept so as to be readily accessible for inspection;

(b) Provide adequate lighting necessary for inspection of all cannabis and areas where cannabis may be grown or held;

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

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

(e) Identify each growing area with the cultivar and USDA Farm Service Agency (FSA) field and/or subfield number, as applicable;

(f) Consent to sampling of all cannabis cultivated by the licensee;

(g) Harvest a hemp crop within 30 days of sampling for testing, unless directed otherwise by the department; and,

(h) Report hemp crop acreage to FSA annually and within 30 days of new crops being planted. Reports must meet all FSA requirements, including:

1. Street address and GPS location of site where each area where hemp will be grown;

2. Total acreage or square footage dedicated to production of hemp; and

3. Licensee's hemp producer license number.

(i) Record each transaction in which the licensee sells or introduces rooted hemp into commerce. The licensee must keep the record for two years from the transaction date. The record must include: the name, contact information, and hemp producer license number for any person who purchased or received the cannabis.

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

(a) Possess or receive rooted hemp without first securing a license from the department;

(b) Cultivate cannabis for introduction into commerce without first securing a license from the department;

(c) Sell, supply, or move rooted cannabis to any person in this state not licensed under this chapter;

(d) Possess or cultivate cannabis other than hemp;

(e) Grow more than one variety of cannabis per growing area;

(f) Possess rooted hemp outside a licensed growing area unless it is under immediate transport to another licensed growing area or a licensed hemp-derived cannabinoid product manufacturer, distributor, or retailer;

(g) Harvest hemp or introduce rooted hemp into commerce prior to:

1. Sampling within the previous 30 days, and

2. Departmental receipt of sample test results showing the sample tested within allowable limits for total THC;

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

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

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

(k) Violate applicable hemp movement regulations of any state or federal agency; or,

(l) Violate any departmental order issued under the Act or this chapter, including but not limited to orders to stop movement, destroy, or remediate cannabis.

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

(4) Each violation of the Act or this chapter is grounds for issuance of stop movement, destruction, or remediation orders for any cannabis held by the violator or their agent, denial or revocation of any license issued by the department, actions for injunction, and imposition of civil penalties or pursuit of criminal charges against the violator.

Authority: T.C.A. §§ 4-3-203 and 43-27-104.

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

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 TDA 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.

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

(5) 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.

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) Adulterated shares the definition as provided under T.C.A. § 53-1-104;

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

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

(e) 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;

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

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

(h) 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;

(i) 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;

(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 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;

(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; and,

(o) Total THC means the potential total delta-9 tetrahydrocannabinol (THC) content derived from the sum of THC and delta-9 tetrahydrocannabinol acid (THCA) reported on a dry weight basis, calculated as: (cannabinoid concentration (mg/g)) + (cannabinoid acid form concentration (mg/g) x 0.877).

Authority: T.C.A. §§ 4-3-203 and 43-27-211.

0080-10-02-.03 License Application and Fees.

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

(2) Applicants for an HDC product 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;

(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) Product list and label for all HDC products to be manufactured or distributed by the applicant. The product list must include the trade name of the product and identification of hemp-derived cannabinoids used in production of each product;

(h) An Identity History Summary issued by the Federal Bureau of Investigation for the person identified as legally responsible for applicant's operations; and,

(i) 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 product license fee of $500, which may be prorated in the initial year of licensure at the rate of $50 per each full calendar month remaining in the license period, shall be due

upon approval of an application and must be paid in full prior to a license being issued. 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 product licenses expire on June 30 following their issuance. Applicants for renewal must submit to the department on or before July 1 each year the HDC product license fee and an updated Identity History Summary 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.

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 concentration 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 extraction or manufacture:

1. Vitamin E acetate;

2. Medium-chain triglycerides;

3. Polyethylene glycol;

4. Propylene glycol;

5. 2, 3-butanedione; or

6. Myclobutanil.

(c) A person shall not manufacture or distribute an inhalable HDC product unless its water activity rate 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) A person shall not manufacture or distribute an HDC product in which solvents were used in its manufacture. Use of the following substances is excluded from this requirement: water, vegetable glycerin, vegetable oils, animal fats, butane, propane, carbon dioxide, ethanol, isopropanol, acetone, heptane, ethyl acetate, and pentane.

(b) If butane, propane, heptane, or pentane are used as solvents, the solvent must be at least 99 percent purity and the COA for the corresponding HDC product must document those solvents' purity level.

(c) If water, vegetable glycerin, vegetable oils, animal fats, carbon dioxide, ethanol, isopropanol, acetone, or ethyl acetate are used as solvents, the solvent must be food grade according to FDA standards.

Authority: T.C.A. §§ 4-3-203 and 43-27-211.

0080-10-02-.05 Sampling and Testing.

(1) Tolerances. HDC product manufacturers shall sample and test or cause to be sampled and tested each batch of HDC product they manufacture. Prior to transport of any HDC product, HDC product manufacturers must confirm conformance of the batch with all testing requirements under this rule. The manufacturer must maintain a COA for each batch tested. Tolerances for each analyte are listed below. Any test result exceeding allowable limits is grounds for 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) Total THC less the measurement of uncertainty shall be ≤ 0.3%;

2. Microbial contaminants:

(i) Shiga toxin-producing Escherichia coli (undetected in one gram);

(ii) Salmonella spp. (undetected in 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);

(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
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) Specific testing for inhalable HDC products:

1. Microbial contaminants:

(i) Pathogenic Aspergillus species A. fumigatus (undetected in one gram);

(ii) Pathogenic Aspergillus species A. flavus (undetected in one gram);

(iii) Pathogenic Aspergillus species A. niger (undetected in one gram);

(iv) Pathogenic Aspergillus species A. terreus (undetected in 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);

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

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

(iii) Maintain ISO 17025 accreditation;

(iv) Comply with all limits of detection or quantitation requirements for analytes tested under a COA;

(v) Establish a limit of quantitation ≤ 1 mg/g for each hemp-derived cannabinoid tested and reported under this chapter;

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

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

3. Reserve samples. Third-party registered laboratories must retain a reserve sample of any sample material not used in the testing process and must maintain the reserve sample for 60 days following completion of all testing. The laboratory must store the reserve sample in a secure manner that reasonably protects it from degradation, contamination, and tampering. If requested by the department during that time, the laboratory must make the reserve sample available for additional testing. If not requested during that time, the laboratory must render the reserve sample unusable and dispose of the material.

4. Failure to adhere to these requirements 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 as it is registered with the department;

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

(iv) Unique identifying information for the sample, if applicable, e.g. matrix type;

(v) Sample history including date collected and by whom, date received by the laboratory, 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;

(vii) If applicable, a statement indicating the HDC product's batch was remediated in accordance with subparagraph (c) of this rule and the sterilization method that was used; 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. An HDC product licensee must report to the department within 24 hours of receiving any COA reporting test results for a product sample that does not meet all tolerances set forth in this rule.

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

(i) The same third-party registered laboratory that produced the COA exhibiting a test failure may re-test the reserve sample following the failed test in order to confirm component tolerance.

(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.

3. Remedy.

(i) Microbial contaminants. An HDC product manufacturer 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; or,

(II) The batch is rendered unusable.

(ii) For all other component testing failures, an HDC product manufacturer must render the batch unusable.

Authority: T.C.A. §§ 4-3-203 and 43-27-211.

0080-10-02-.06 Labels.

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

(a) Batch number;

(b) Name and address of the HDC product manufacturer or distributor as it is registered with the department;

(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 quick reference (QR) code that when scanned links the viewer to COA testing results conducted under this chapter;

(f) Serving size of the product and the total number of servings per package of the product; 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 (by typography, layout, color, embossing, or molding) to other information on the package.

(a) For all HDC products.

1. "Warning: This product contains hemp-derived cannabinoids. Must be at least 21 years of age to possess or consume. Use of this product while pregnant or breastfeeding may be harmful. Consumption may impair ability to drive or operate machinery. This product is not approved by FDA for cure, mitigation, treatment, or prevention of disease. May contain unknown or unidentified substances that have harmful or toxic effects. Keep out of reach of children and animals."

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. Do not eat."

2. The words "Warning" and "Do not eat" 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.

0080-10-02-.07 Transportation Requirements.

(1) In addition to transportation requirements under the Act, HDC product 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.

0080-10-02-.08 Records.

(1) For each batch of HDC product manufactured or distributed, HDC product 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) Distribution records, including but not limited to invoices and bills of lading.

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

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

(b) Batch number; and,

(c) Total volume of product that was disposed.

Authority: T.C.A. §§ 4-3-203 and 43-27-211.

0080-10-02-.09 Inspections.

(1) Scope. The department may enter any premises or conveyance during normal business hours where the department has reason to believe that HDC products are manufactured or distributed in commerce. The department may enter for purposes of inspecting and sampling any cannabis, HDC product, 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.

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;

(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 retail sale HDC product 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 under this chapter.

(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, and imposition of civil penalties or pursuit of criminal charges against the violator.

Authority: T.C.A. §§ 4-3-203 and 43-27-211.

CHAPTER 0080-10-03
RETAIL SALE OF HEMP-DERIVED CANNABINOID PRODUCTS

0080-10-03-.01 Scope.

(1) This chapter applies to any person who sells or offers to sell at retail any HDC product.

(2) Persons who sell or offer to sell HDC products are subject to all requirements and TDA 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 8, and title 39, chapter 17, part 15, and Tenn. Comp. R. & Regs. 0080-04-09. 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.

0080-10-03-.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) Adulterated has the same meaning as provided under T.C.A. § 53-1-104;

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

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

(e) Certificate of Analysis (COA) means a written document from a laboratory approved by the department for testing samples under Tenn. Comp R. & Regs. 0080-10-02, and which communicates the results of those tests performed;

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

(g) Counter means a physical barrier that necessitates the seller's assistance in order to access product prior to its sale;

(h) 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;

(i) 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;

(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 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) Proof of age means a driver license or other generally accepted means of identification that describes the individual, indicates his or her age, contains a photograph or other likeness of the individual, and appears on its face to be valid. In the case of sales by mail or online orders, proof of age is satisfied by a written, affirmative statement from the addressee that he or she is at least 21 years of age;

(n) Sample means to take material or the material taken from a location where HDC products are sold or offered for sale at retail; and,

(o) Total THC means the potential total delta-9 tetrahydrocannabinol (THC) content derived from the sum of THC and delta-9 tetrahydrocannabinol acid (THCA) reported on a dry weight basis, calculated as: (cannabinoid concentration (mg/g)) + (cannabinoid acid form concentration (mg/g) x 0.877).

Authority: T.C.A. §§ 4-3-203 and 43-27-211.

0080-10-03-.03 License Application and Fees.

(1) An HDC retail license is required per person per location for any person who offers for sale an HDC product. Licensed locations must be fixed address facilities but may include temporary locations such as fairs, flea markets, and farmers markets, provided that license fees for temporary locations cannot be prorated on the basis of temporary use.

(2) Applicants for an HDC retail 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;

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

(d) 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;

(e) Address of location to be licensed;

(f) Identification of nearest school serving any grades K-12 and the distance from that school to the location to be licensed, in feet measured as a straight line along the shortest route;

(g) Product list for all HDC products to be offered for sale by the applicant, including the trade name of each product;

(h) An Identity History Summary issued by the Federal Bureau of Investigation for the person identified as legally responsible for applicant's operations; and,

(i) 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 retail license fee of $250, which may be prorated in the initial year of licensure at the rate of $25 per each full calendar month remaining in the license period, shall be due upon approval of an application and must be paid in full prior to a license being issued. License fees shall not be prorated for any person licensed in the previous licensure year.

(5) HDC retail licenses expire on June 30 following their issuance. Applicants for renewal must submit to the department on or before July 1 each year the HDC retail license fee and an updated Identity History Summary 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.

0080-10-03-.04 Manner of Sale.

(1) HDC retail licensees shall not sell an HDC product to a purchaser unless the purchaser has provided proof of age showing him or herself to be at least 21 years of age.

(2) HDC retail licensees shall not offer for sale an HDC product unless it conforms with requirements of the Act and is manufactured, produced, packaged, and labeled in accordance with Tenn. R. & Regs. 0080-10-02.

(3) HDC retail licensees shall not sell an HDC product unless either:

(a) The product is pre-packaged in conformance with Tenn. R. & Regs. 0080-10-02; or,

(b) The product is an ingestible HDC product that:

1. Is intended for on-site consumption at the retail license location;

2. Was received by the licensee as a pre-packaged product in conformance with Tenn. R. & Regs. 0080-10-02;

3. Is maintained by the licensee in its original packaging immediately prior to sale; and,

4. Its QR code, product label, and warning statement are immediately available to the customer upon request.

Authority: T.C.A. §§ 4-3-203 and 43-27-211.

0080-10-03-.05 Records.

(1) For each HDC product offered for sale, HDC retail licensees shall maintain for two years and readily produce upon request all records received from their immediate upstream seller of the product, including but not limited to:

(a) COAs; and

(b) Inventory records, including but not limited to invoices and bills of lading.

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

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

(b) Batch number; and,

(c) Total volume of product that was disposed.

Authority: T.C.A. §§ 4-3-203 and 43-27-104.

0080-10-03-.06 Inspections and Testing.

(1) Scope. The department may enter any premises during normal business hours where the department has reason to believe that HDC products are offered for retail sale. The department may enter for purposes of inspecting and sampling any cannabis, HDC product, or other material, examining and copying records, and conducting random checks for manner of sale of HDC products as 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.

(3) Product testing. Upon purchase of HDC products offered for retail sale, the department may sample and test or cause to be sampled and tested the product for compliance with testing requirements under Tenn. Comp. R. & Regs. 0080-10-02-.04 and .05. Any test result exceeding allowable limits of those rules is grounds for destruction of the batch of HDC represented by the sample. A sample collected and tested according to departmental protocols is deemed representative of the HDC product batch from which the sample was obtained.

Authority: T.C.A. §§ 4-3-203 and 43-27-211.

0080-10-03-.07 Violations.

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

(a) Maintain areas where HDC products are offered for retail sale or held for inventory so as to be readily accessible for inspection;

(b) Provide adequate lighting necessary for inspection of all HDC products offered or held for retail sale;

(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 during the previous two years;

(e) Consent to sampling of all HDC product offered or held for retail sale by the licensee; and,

(f) Consent to recall of all associated HDC product batches when testing of the product indicates a failure under Tenn. Comp. R. & Regs. 0080-10-02-.04 or .05 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) Offer HDC products for retail sale without first securing a license from the department;

(b) Offer HDC products for retail sale unless they meet manufacturing, labeling, and testing requirements under Tenn. Comp. R. & Regs. 0080-10-02;

(c) Transport or allow transport of HDC products other than movement from a licensed HDC retail location to another retail location under the same ownership;

(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) Violate any departmental order issued under the Act or this chapter, including but not limited to orders to hold or dispose 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 under this chapter.

(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 hold 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, and imposition of civil penalties or pursuit of criminal charges against the violator.

Authority: T.C.A. §§ 4-3-203 and 43-27-211.

Amendments

Chapter 0080-04-09
Retail Food Store Sanitation

Rule 0080-04-09-.01 Definitions is amended by inserting the following as a newly captioned paragraph (57) and renumbering all subsequent paragraphs of the rule such that the rule contains 122 paragraphs.

(57) Hemp-derived cannabinoid has the same meaning as provided under T.C.A. § 43-27-202.

Authority: T.C.A. §§ 4-3-203 and 53-8-104.

Subparagraph 0080-04-09-.03(2)(a) Sources is amended by adding the following as a new item.

8. Hemp. In addition to requirements under this chapter of rules, any person who offers for retail sale any food product labeled to contain or containing a hemp-derived cannabinoid shall also comply with regulations under Tenn. R. & Regs. 0080-10-03.

Authority: T.C.A. §§ 4-3-203 and 53-8-104.

Chapter 0080-04-13
Food Manufacturers and Warehouses

Paragraph 0080-04-13-.02(2) is amended by inserting the following as a newly captioned subparagraph (g) and renumbering all subsequent subparagraphs of the paragraph such that the rule contains eight subparagraphs, (a)-(h).

(g) Hemp-derived cannabinoid has the same meaning as provided under T.C.A. § 43-27-202.

Authority: T.C.A. §§ 4-3-203 and 53-1-202.

Rule 0080-04-13-.05 Standards for Manufacturing and Processing is amended by adding the following as a new paragraph.

(6) Hemp. In addition to requirements under this chapter of rules, any person who manufactures, processes, packs, holds, or transports for introduction in commerce any food product labeled to contain or containing a hemp-derived cannabinoid shall also comply with regulations under Tenn. R. & Regs. 0080-10-02.

Authority: T.C.A. §§ 4-3-203 and 53-1-202.

Repeal

Chapter 0080-06-28
Hemp

Chapter 0080-06-28 Hemp is repealed in its entirety.

Authority: T.C.A. §§ 4-3-203 and 43-27-104.

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: 12/13/2023

Signature: 

Name of Officer: Danny Sutton

Title of Officer: Assistant Commissioner, Consumer & Industry Services, Department of Agriculture

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Tre Hargett
Secretary of State

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