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Emergency Rule Filing Form

Emergency rules are effective from date of filing, unless otherwise stated in the rule, for a period of up to 180 days.

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Revision Type (check all that apply):
x Amendment
x New
___ Repeal

Statement of Necessity:
Under this rule set, and pursuant to Tenn. Code Ann. § 4-5-208(a)(5), the department seeks to establish the process for the licensing program required by statute to be in place by July 1, 2024, of which the public has had notice since codification of the act in July 2023. Generally, the following items will be the subject of outreach, education, and enforcement as necessary regarding hemp-derived cannabinoid (HDC) products, beginning July 1, 2024:

- License requirements for retail, manufacturing, and distribution of HDC products. T.C.A. §§ 43-27-203(a)(1); 43-27-206.
- HDC products offered for sale by unlicensed entity subject to forfeiture. T.C.A. § 43-27-203(a)(2).
- Proof of age requirements at retail. T.C.A. § 43-27-203(b)(1).
- Under 21 sales restrictions at retail. T.C.A. § 43-27-203(b)(2)-(4).
- Sample distribution prohibited on public streets, sidewalks, and parks. T.C.A. § 43-27-203(c).
- HDC product behind counter at retail. T.C.A. § 43-27-204(b).
- Third party testing and provision of certificates of analysis. T.C.A. § 43-27-207(b)(1), (c).
- Product label must be consistent with product potency. T.C.A. § 43-27-207(a)(2).
- Label requirements for ingredients, allergens, amount of cannabinoid per serving, total hemp-derived cannabinoid per package in milligrams, product net weight, QR code, and expiration date. T.C.A. § 43-27-209(a)(2).
- Label prohibition of imagery appealing to persons under 21. T.C.A. § 43-27-209(c).
- Total milligrams limit for hemp-derived cannabinoids per serving. T.C.A. § 43-27-209(d)(1).
- Product shape prohibitions. T.C.A. § 43-27-209(d)(2).
- Transportation requirements for proof of: licensed hemp grower origin (T.C.A. § 43-27-208(a)(1)(A)); satisfaction of statutory limits on hemp-derived cannabinoids (T.C.A. § 43-27-208(a)(1)(B)); and bills of lading (T.C.A. § 43-27-208(a)(2)).
- Child-resistant safety for HDC products sold at retail. T.C.A. § 43-27-209(a)(1).
- Storage of product in original packaging at retail. T.C.A. § 43-27-209(b).

Under this rule the department also provides notification of regulatory requirements that are anticipated if the current statute continues past expiration of this emergency rule set. The requirements below, e.g., will not be effective prior to January 1, 2025.

- Labeling except as detailed under statute. Tenn. Comp. R. & Regs. 0080-10-01-.06.
- Product testing except as to required potency testing. Tenn. Comp. R. & Regs. 0080-10-01-.05.
- Transportation except as detailed under statute. Tenn. Comp. R. & Regs. 0080-10-01-.07.
- Recordkeeping requirements except as detailed under statute. Tenn. Comp. R. & Regs. 0080-10-01-.08.

Despite these requirements not being enforceable prior to January 1, 2025, the department will conduct inspection surveys with licensed firms for all provisions under statute and these rules, including product testing, for purposes of education and outreach re all potential future HDC product requirements.

Rule(s) Revised (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. 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**
0080-10-01	Hemp-derived Cannabinoid Products - Manufacturing and Distribution
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	Manufacturing
0080-10-01-.05	Sampling and Testing Requirements
0080-10-01-.06	Labels
0080-10-01-.07	Transportation Requirements
0080-10-01-.08	Records
0080-10-01-.09	Inspections
0080-10-01-.10	Violations

Chapter Number	**Chapter Title**
0080-10-02	Hemp-derived Cannabinoid Products - Retail Sale
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	Manner of Sale
0080-10-02-.05	Records
0080-10-02-.06	Inspections and Testing
0080-10-02-.07	Violations

New

Division 0080-10 Hemp is created.

Authority: T.C.A. § 4-3-203.

RULES
OF
TENNESSEEE DEPARTMENT OF AGRICULTURE
HEMP

CHAPTER 0080-10-01
HEMP-DERIVED CANNABINOID PRODUCTS - MANUFACTURING AND DISTRIBUTION

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0080-10-01-.01 Scope.

(1) This chapter applies to any person who manufactures or distributes in commerce any HDC product. For purposes of enforcement, all statutory requirements under the Act will be effective beginning July 1, 2024. All requirements under rules 0080-10-01-.04 through .08 will not be effective prior to January 1, 2025.

(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.

0080-10-01-.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" and "COA" mean 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;

(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) "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 in 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 demonstrated by calculation of 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.

0080-10-01-.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) 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 product 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. However, 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 nationwide criminal background check, facilitated through the Tennessee Bureau of Investigation, for the person identified as legally responsible for applicant's operations.

(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.

0080-10-01-.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 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 are used as solvents, the solvent must be documented on its COA as at least 99 percent purity.

(b) 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 under 21 CFR Part 174.

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

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

(1) Tolerances. HDC product manufacturers must cause each batch of HDC product they manufacture to be sampled and tested. Prior to transport of any HDC product in commerce, HDC product manufacturers must confirm conformance of the batch to all testing requirements under this rule.

(a) For raw hemp products in commerce post-harvest (e.g., flower), pre-harvest COAs for the products are presumptively valid for subsequent holders in commerce, provided that:

1. The hemp product was grown by a hemp producer licensed by the department;

2. The holder maintains a copy of the COA for the harvest that produced the product, showing pre-harvest compliance of the product's crop with all testing requirements under this rule; and,

3. The product has not been subjected to physical or chemical alteration post-harvest and has only been filtered, cleaned, or trimmed to isolate particular parts of the hemp plant.

4. This subparagraph shall not limit the department's authority to test raw cannabis products for compliance with the Act and this chapter.

(b) Tolerances for each required testing 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.

1. For all HDC products:

(i) 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 product licensee (post-decarboxylation THC value ≤ 5%);

II. HDC products in commerce to any person who is not an HDC product licensee (post-decarboxylation THC value ≤ 0.3%);

(ii) Microbial contaminants:

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

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

(iii) 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);

(iv) 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

(v) Heavy metals:

(I) Arsenic (≤ 0.4 ppm);

(II) Cadmium (≤ 0.4 ppm);

(III) Lead (≤ 1 ppm);

(IV) Mercury (≤ 1.2 ppm);

(vi) 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.		

(c) 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).

(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) 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);

(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 COA requirements 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 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;

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

(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.

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 (ND).

(c) Failed testing.

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

(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 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) 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 batch is under immediate transport to a licensed HDC product manufacturer for purposes of diluting the batch and the batch and remediation plan are reported to the department prior to transport; or,

(III) The batch is rendered unusable.

(iii) 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.

0080-10-01-.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 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 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+ 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.

0080-10-01-.07 Transportation Requirements.

(1) In addition to transportation requirements under the Act, for transportation of any HDC product in commerce, including raw product, HDC product licensees must ensure that COAs for the product accompany the shipment.

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

0080-10-01-.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.

0080-10-01-.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, 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.

0080-10-01-.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 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 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, imposition of civil penalties, or pursuit of criminal charges against the violator.

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

RULES
OF
TENNESSEEE DEPARTMENT OF AGRICULTURE
HEMP

CHAPTER 0080-10-02
HEMP-DERIVED CANNABINOID PRODUCTS - RETAIL SALE

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0080-10-02-.01 Scope.

(1) This chapter applies to any person who sells or offers to sell at retail any HDC product. For purposes of enforcement, all statutory requirements under the Act will be effective beginning July 1, 2024. All requirements under rules 0080-10-02-.04 through .06 will not be effective prior to January 1, 2025.

(2) Persons who sell or offer to sell 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 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.

0080-10-02-.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" and "COA" means a written document from a laboratory approved by the department for testing samples under Tenn. Comp R. & Regs. 0080-10-01, 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;

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

(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) "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 in 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 demonstrated by calculation of 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 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; and,

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

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

0080-10-02-.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 at retail. 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) 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) 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;

(h) A nationwide criminal background check, facilitated through the Tennessee 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 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 $25 per each full calendar month remaining in the license period, provided the total fee not exceed $250. 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 nationwide criminal background check, facilitated through the Tennessee Bureau of Investigation, for the person identified as legally responsible for applicant's operations.

(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 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. 0080-10-01.

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

(a) The product is pre-packaged in conformance with Tenn. R. & Regs. 0080-10-01; 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. 0080-10-01;

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.

0080-10-02-.05 Records.

(1) For each HDC product offered for sale, HDC retail licensees shall maintain for two years and readily produce upon departmental 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.

0080-10-02-.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.

(a) 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. 0080-10-01-.04 and .05. Any test result exceeding allowable limits of those rules is grounds for destruction of the batch of HDC product represented by the sample.

(b) A sample collected and tested according to departmental protocols is deemed representative of the HDC product batch from which the sample was obtained.

(c) For raw hemp products at retail (e.g., flower) for which the holder has a pre-harvest COA under Tenn. Comp. R. & Regs. 0080-10-01-.05(1)(a), any test failure of requirements under this rule may be remedied either by rendering the product and its batch in inventory unusable or by shipment of the product and its batch in inventory to an HDC product licensee for manufacturing or further processing and retesting of its resulting product.

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

0080-10-02-.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. 0080-10-01-.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. 0080-10-01;

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

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

(e) Violate any departmental order issued under the Act or this chapter, including but not limited to orders to hold or dispose of HDC product; or,

(f) Violate any workplace safety or environmental protection standard enforced by state or federal authorities.

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

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

Amendments

RULES
OF
TENNESSEEE DEPARTMENT OF AGRICULTURE
FOOD

CHAPTER 0080-04-09
RETAIL FOOD STORE SANITATION

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Rule 0080-04-09-.01 Definitions is amended by inserting the following as a newly captioned paragraph (56) and renumbering all subsequent paragraphs of the rule such that the rule contains 122 paragraphs.

(56) "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 part.

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. 0080-10-02.

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

RULES
OF
TENNESSEEE DEPARTMENT OF AGRICULTURE
FOOD

CHAPTER 0080-04-13
FOOD MANUFACTURERS AND WAREHOUSES

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Paragraph 0080-04-13-.02(2) is amended by deleting subparagraphs (f)-(g) and inserting the following language:

(f) Food means those articles as defined under the Act and includes dietary supplements;

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

(h) Potentially hazardous food has the same meaning as T.C.A. § 53-1-104(1)(D).

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. 0080-10-01.

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

* If a roll-call vote was necessary, the vote by the Agency on these rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)

I certify that this is an accurate and complete copy of an emergency rule(s), lawfully promulgated and adopted.

Date: 06/25/2024

Signature:

Name of Officer: Charlie Hatcher, D.V.M.

Title of Officer: Commissioner

Agency/Board/Commission: Department of Agriculture

Rule Chapter Number(s): 0080-10-01; 0080-10-02; 0080-04-09; 0080-04-13

All emergency rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Jonathan Skrmetti
Attorney General and Reporter

June 27, 2024
Date

Department of State Use Only

Filed with the Department of State on: 6/28/2024

Effective for: 180 *days

Effective through: 12/25/2024

** Emergency rule(s) may be effective for up to 180 days from the date of filing.*

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Secretary of State

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228, "On any rule and regulation proposed to be promulgated, the proposing agency shall state in a simple declarative sentence, without additional comments on the merits or the policy of the rule or regulation, whether the rule or regulation may have a projected financial impact on local governments. The statement shall describe the financial impact in terms of increase in expenditures or decrease in revenues."

No impact is expected on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

All effective regulatory requirements in this rule are either newly established or reiterations of statutory requirements in law.

The rule is required by T.C.A. § 43-27-201, et seq. to establish required licensing for the sale and manufacture of HDC products. Under this rule the department also provides notification of regulatory requirements that are anticipated if the current statute continues past expiration of this emergency rule.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

No known federal law or regulation specific to manufacture, distribution, and sale of hemp-derived cannabinoid (HDC) products. 7 U.S.C.A. § 1639 authorizes but does not mandate creation of state plans for regulation of hemp production.

Under T.C.A. § 43-27-205, the department of agriculture is charged to issue licenses for suppliers and retailers of HDC products; oversee supplier compliance for product labeling, testing, and transportation; and inspect HDC product sales locations for compliance with the HDC act.

Under T.C.A. § 43-27-207, the department must promulgate rules specifying pass/fail action levels for full-panel testing of active cannabinoid molecules.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

This rule affects manufacturers, distributors, retailers, and consumers of hemp-derived cannabinoid (HDC) products, including raw flower, vapes, pre-rolls, etc., which are reported by industry to comprise more than 70% of the cannabis product market in Tennessee. The rule also affects third-party laboratories that provide testing services within the cannabis market.

Those persons and entities are not expected to object to this rule where this rule only establishes the HDC product program for purposes of licensing and enforcement of express statutory requirements.

Re other portions of this rule that are not enforceable under the rule prior to January 1, 2025, (e.g., product testing requirements), most persons and entities generally support regulation of the HDC product market and most testing standards contemplated under this rule. However, there is a deep divide of persons re inclusion of any testing standard that accounts for THCa concentrations within the statutorily defined limits for THC in hemp products. Generally, manufacturers, distributors, retailers, and consumers oppose the measure; health and safety advocates, law enforcement, and Farm Bureau support the measure. Hemp growers support application of one standard for THC/THCa limits that applies equally to both hemp growers and HDC product stakeholders, which is accomplished by standards contemplated under this rule. Nonetheless, the divide is not germane to this filing where testing standards are not enforceable under this rule.

(D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

Upon review of attorney general opinions and binding decisions of state and federal law, the department did not identify any opinions directly related to the rule or the necessity to promulgate the rule for licensing requirements. There is, however, ongoing litigation in other states regarding hemp-derived cannabinoid products and the validity of state laws that attempt to regulate them, e.g., *Bio Gen, LLC v Sanders*, No. 4:23-CV-00718-BRW, 2023 WL 5804185 (E.D. Ark. Sept. 7, 2023).

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

Under T.C.A. §§ 43-27-201, et seq., the Department is required to establish a new regulatory program for oversight of a hemp-derived cannabinoid (HDC) products program. Although development of that program is anticipated to increase state government revenues and expenditures, those items are not anticipated to increase or decrease compared to projections/fiscal notes already considered by the legislature in passage of the enabling statute. I.e., an increase or decrease in state revenues or expenditures for the program are not resulting from promulgation of this rule.

(F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Jay Miller, General Counsel

(G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Jay Miller, General Counsel

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Jay Miller, PO Box 40627, Nashville, TN 37204; (615) 837-5341; jay.miller@tn.gov

(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

None.

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Last Effective Day: ____________

Redline

Emergency rules are effective from date of filing, unless otherwise stated in the rule, for a period of up to 180 days.

Agency/Board/Commission: Department of Agriculture
Division: Consumer & Industry Services
Contact Person: Annie Balghiti
Address: Post Office Box 40627, Nashville, Tennessee
Zip: 37204
Phone: 615.253.5828
Email: tda.rulemaking@tn.gov

Revision Type (check all that apply):
_x_ Amendment
_x_ New
___ Repeal

Statement of Necessity:
Under this rule set, and pursuant to Tenn. Code Ann. § 4-5-208(a)(5), the department seeks to establish the process for the licensing program required by statute to be in place by July 1, 2024, of which the public has had notice since codification of the act in July 2023. Generally, the following items will be the subject of outreach, education, and enforcement as necessary regarding hemp-derived cannabinoid (HDC) products, beginning July 1, 2024:

- License requirements for retail, manufacturing, and distribution of HDC products. T.C.A. §§ 43-27-203(a)(1); 43-27-206.
- HDC products offered for sale by unlicensed entity subject to forfeiture. T.C.A. § 43-27-203(a)(2).
- Proof of age requirements at retail. T.C.A. § 43-27-203(b)(1).
- Under 21 sales restrictions at retail. T.C.A. § 43-27-203(b)(2)-(4).
- Sample distribution prohibited on public streets, sidewalks, and parks. T.C.A. § 43-27-203(c).
- HDC product behind counter at retail. T.C.A. § 43-27-204(b).
- Third party testing and provision of certificates of analysis. T.C.A. § 43-27-207(b)(1), (c).
- Product label must be consistent with product potency. T.C.A. § 43-27-207(a)(2).
- Label requirements for ingredients, allergens, amount of cannabinoid per serving, total hemp-derived cannabinoid per package in milligrams, product net weight, QR code, and expiration date. T.C.A. § 43-27-209(a)(2).
- Label prohibition of imagery appealing to persons under 21. T.C.A. § 43-27-209(c).
- Total milligrams limit for hemp-derived cannabinoids per serving. T.C.A. § 43-27-209(d)(1).
- Product shape prohibitions. T.C.A. § 43-27-209(d)(2).
- Transportation requirements for proof of: licensed hemp grower origin (T.C.A. § 43-27-208(a)(1)(A)); satisfaction of statutory limits on hemp-derived cannabinoids (T.C.A. § 43-27-208(a)(1)(B)); and bills of lading (T.C.A. § 43-27-208(a)(2)).
- Child-resistant safety for HDC products sold at retail. T.C.A. § 43-27-209(a)(1).
- Storage of product in original packaging at retail. T.C.A. § 43-27-209(b).

Under this rule the department also provides notification of regulatory requirements that are anticipated if the current statute continues past expiration of this emergency rule set. The requirements below, e.g., will not be effective prior to January 1, 2025.

- Labeling except as detailed under statute. Tenn. Comp. R. & Regs. 0080-10-01-.06.
- Product testing except as to required potency testing. Tenn. Comp. R. & Regs. 0080-10-01-.05.
- Transportation except as detailed under statute. Tenn. Comp. R. & Regs. 0080-10-01-.07.
- Recordkeeping requirements except as detailed under statute. Tenn. Comp. R. & Regs. 0080-10-01-.08.

Despite these requirements not being enforceable prior to January 1, 2025, the department will conduct inspection surveys with licensed firms for all provisions under statute and these rules, including product testing, for purposes of education and outreach re all potential future HDC product requirements.

Rule(s) Revised (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. 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**
0080-10-01	Hemp-derived Cannabinoid Products - Manufacturing and Distribution
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	Manufacturing
0080-10-01-.05	Sampling and Testing Requirements
0080-10-01-.06	Labels
0080-10-01-.07	Transportation Requirements
0080-10-01-.08	Records
0080-10-01-.09	Inspections
0080-10-01-.10	Violations

Chapter Number	**Chapter Title**
0080-10-02	Hemp-derived Cannabinoid Products - Retail Sale
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	Manner of Sale
0080-10-02-.05	Records
0080-10-02-.06	Inspections and Testing
0080-10-02-.07	Violations

New

Division 0080-10 Hemp is created.

Authority: T.C.A. §4-3-203.

RULES
OF
TENNESSEEE DEPARTMENT OF AGRICULTURE
HEMP

CHAPTER 0080-10-01
HEMP-DERIVED CANNABINOID PRODUCTS - MANUFACTURING AND DISTRIBUTION

TABLE OF CONTENTS

0080-10-01-.01 Scope.

(1) This chapter applies to any person who manufactures or distributes in commerce any HDC product. For purposes of enforcement, all statutory requirements under the Act will be effective beginning July 1, 2024. All requirements under rules 0080-10-01-.04 through .08 will not be effective prior to January 1, 2025.

(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.

0080-10-01-.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" and "COA" mean 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;

(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) "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 in 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 demonstrated by calculation of 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.

0080-10-01-.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) 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 product 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. However, 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 nationwide criminal background check, facilitated through the Tennessee Bureau of Investigation, for the person identified as legally responsible for applicant's operations.

(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.

0080-10-01-.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 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 are used as solvents, the solvent must be documented on its COA as at least 99 percent purity.

(b) 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 under 21 CFR Part 174.

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

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

(1) Tolerances. HDC product manufacturers must cause each batch of HDC product they manufacture to be sampled and tested. Prior to transport of any HDC product in commerce, HDC product manufacturers must confirm conformance of the batch to all testing requirements under this rule.

(a) For raw hemp products in commerce post-harvest (e.g., flower), pre-harvest COAs for the products are presumptively valid for subsequent holders in commerce, provided that:

1. The hemp product was grown by a hemp producer licensed by the department;

2. The holder maintains a copy of the COA for the harvest that produced the product, showing pre-harvest compliance of the product's crop with all testing requirements under this rule; and,

3. The product has not been subjected to physical or chemical alteration post-harvest and has only been filtered, cleaned, or trimmed to isolate particular parts of the hemp plant.

4. This subparagraph shall not limit the department's authority to test raw cannabis products for compliance with the Act and this chapter.

(b) Tolerances for each required testing 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.

1. For all HDC products:

(i) 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 product licensee (post-decarboxylation THC value ≤ 5%);

II. HDC products in commerce to any person who is not an HDC product licensee (post-decarboxylation THC value ≤ 0.3%);

(ii) Microbial contaminants:

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

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

(iii) 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);

(iv) 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

(v) Heavy metals:

(I) Arsenic (≤ 0.4 ppm);

(II) Cadmium (≤ 0.4 ppm);

(III) Lead (≤ 1 ppm);

(IV) Mercury (≤ 1.2 ppm);

(vi) 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.		

(c) 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).

(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) 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);

(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 COA requirements 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 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;

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

(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.

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 (ND).

(c) Failed testing.

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

(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 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) 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 batch is under immediate transport to a licensed HDC product manufacturer for purposes of diluting the batch and the batch and remediation plan are reported to the department prior to transport; or,

(III) The batch is rendered unusable.

(iii) 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.

0080-10-01-.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 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 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+ 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.

0080-10-01-.07 Transportation Requirements.

(1) In addition to transportation requirements under the Act, for transportation of any HDC product in commerce, including raw product, HDC product licensees must ensure that COAs for the product accompany the shipment.

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

0080-10-01-.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.

0080-10-01-.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, 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.

0080-10-01-.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 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 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, imposition of civil penalties, or pursuit of criminal charges against the violator.

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

RULES
OF
TENNESSEEE DEPARTMENT OF AGRICULTURE
HEMP

CHAPTER 0080-10-02
HEMP-DERIVED CANNABINOID PRODUCTS - RETAIL SALE

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0080-10-02-.01 Scope.

(1) This chapter applies to any person who sells or offers to sell at retail any HDC product. For purposes of enforcement, all statutory requirements under the Act will be effective beginning July 1, 2024. All requirements under rules 0080-10-02-.04 through .06 will not be effective prior to January 1, 2025.

(2) Persons who sell or offer to sell 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 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.

0080-10-02-.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" and "COA" means a written document from a laboratory approved by the department for testing samples under Tenn. Comp R. & Regs. 0080-10-01, 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;

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

(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) "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 in 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 demonstrated by calculation of 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 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; and,

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

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

0080-10-02-.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 at retail. 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) 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) 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;

(h) A nationwide criminal background check, facilitated through the Tennessee 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 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 $25 per each full calendar month remaining in the license period, provided the total fee not exceed $250. 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 nationwide criminal background check, facilitated through the Tennessee Bureau of Investigation, for the person identified as legally responsible for applicant's operations.

(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 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. 0080-10-01.

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

(a) The product is pre-packaged in conformance with Tenn. R. & Regs. 0080-10-01; 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. 0080-10-01;

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.

0080-10-02-.05 Records.

(1) For each HDC product offered for sale, HDC retail licensees shall maintain for two years and readily produce upon departmental 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.

0080-10-02-.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.

(a) 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. 0080-10-01-.04 and .05. Any test result exceeding allowable limits of those rules is grounds for destruction of the batch of HDC product represented by the sample.

(b) A sample collected and tested according to departmental protocols is deemed representative of the HDC product batch from which the sample was obtained.

(c) For raw hemp products at retail (e.g., flower) for which the holder has a pre-harvest COA under Tenn. Comp. R. & Regs. 0080-10-01-.05(1)(a), any test failure of requirements under this rule may be remedied either by rendering the product and its batch in inventory unusable or by shipment of the product and its batch in inventory to an HDC product licensee for manufacturing or further processing and retesting of its resulting product.

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

0080-10-02-.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. 0080-10-01-.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. 0080-10-01;

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

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

(e) Violate any departmental order issued under the Act or this chapter, including but not limited to orders to hold or dispose of HDC product; or,

(f) Violate any workplace safety or environmental protection standard enforced by state or federal authorities.

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

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

Amendments

**RULES
OF
TENNESSEEE DEPARTMENT OF AGRICULTURE
FOOD**

**CHAPTER 0080-04-09
RETAIL FOOD STORE SANITATION**

TABLE OF CONTENTS

Rule 0080-04-09-.01 Definitions is amended by inserting the following as a newly captioned paragraph (56) and renumbering all subsequent paragraphs of the rule such that the rule contains 122 paragraphs.

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

(5~~6~~7) "Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

(5~~7~~8) "Highly susceptible population" means persons who are more likely than other people in the general population to experience foodborne disease because they are:

(a) Immunocompromised; preschool age children, or older adults; and

(b) Obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

(5~~8~~9) "Imminent health hazard" means any condition, deficiency, or practice that, if not corrected, is very likely to result in illness, injury, or loss of life to any person.

(~~59~~60) "Injected" means manipulating meat to which a solution has been introduced into its interior by processes that are referred to as "injecting," "pump marinating," or "stitch pumping."

(6~~0~~1) Juice.

(a) "Juice" means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or purée.

(b) "Juice" does not include, for purposes of HACCP, liquids, purées, or concentrates that are not used as beverages or ingredients of beverages.

(6~~1~~2) "Kitchenware" means food preparation and storage utensils.

(6~~2~~3) "Law" means applicable local, state, and federal statutes, regulations, and ordinances.

(6~~3~~4) "Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.

(6~~4~~5) Major Food Allergen.

(a) "Major food allergen" means:

1. Milk, egg, fish (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

2. A food ingredient that contains protein derived from a food, as specified in part (a)1 of this definition.

(b) "Major food allergen" does not include:

1. Any highly refined oil derived from a food specified in part (a)1 of this definition and any ingredient derived from such highly refined oil; or

2. Any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282).

(6~~5~~6) "Meat" means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goat, other edible animals except fish, poultry, and wild game animals as specified under 0080-04-09-.03(2)(a)7(i)(III), (IV).

(6~~6~~7) Mechanically Tenderized.

(a) "Mechanically tenderized" means manipulating meat with deep penetration by processes which may be referred to as "blade tenderizing," "jaccarding," "pinning," "needling," or using blades, pins, needles or any mechanical device.

(b) "Mechanically tenderized" does not include processes by which solutions are injected into meat.

(6~~7~~8) "mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

(6~~8~~9) "Mobile food unit" means a food establishment designed to be readily moved and vend food.

(~~69~~70) "Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

(7~~0~~1) Non-Continuous Cooking.

(a) "Non-continuous cooking" means the cooking of food in a food establishment using a process in which the initial heating of the food is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service.

(b) "Non-continuous cooking" does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

(7~~1~~2) Packaged.

(a) "Packaged" means bottled, canned, cartoned, securely bagged, or securely wrapped, whether packaged in a food establishment or a food processing plant.

(b) "Packaged" does not include a wrapper, carry-out box, or other nondurable container used to containerize food with the purpose of facilitating food protection during service and receipt of the food by the consumer.

(7~~2~~3) "Permit" means the document issued by the department that authorizes a person to operate a food establishment.

(7~~3~~4) "Permit holder" means the entity that:

(a) Is legally responsible for the operation of the food establishment such as the owner, the owner's agent, or other person; and

(b) Possesses a valid permit to operate a food establishment.

(7~~4~~5) "Person" means any individual, partnership, firm, corporation, agency, municipality, state or political subdivision, or the federal government and its agencies and departments.

(7~~5~~6) "Person in charge" means an individual present at a food establishment who is responsible for the operation at the time of inspection. A person in charge shall be present at the establishment during food preparation and handling, and may put instructions in place for cleaning and preparing the establishment prior to the preparation of any food or beverage.

(7~~6~~7) Personal Care Items.

(a) "Personal care items" means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a person's health, hygiene, or appearance.

(b) "Personal care items" include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

(7~~7~~8) "pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.

(7~~8~~9) "Physical facilities" means the structure and interior surfaces of a food establishment including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

(~~79~~80) "Plumbing fixture" means a receptacle or device that:

(a) Is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system; or

(b) Discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

(8~~0~~1) "Plumbing system" means the water supply and distribution pipes; plumbing fixtures and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the premises; and water-treating equipment.

(8~~1~~2) "Poisonous or toxic materials" means substances that are not intended for ingestion and are included in four categories:

(a) Cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

(b) Pesticides, except sanitizers, which include substances such as insecticides and rodenticides;

(c) Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and personal care items that may be deleterious to health; and

(d) Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

(8~~2~~3) "Poultry" means:

(a) Any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or squabs), whether live or dead, as defined in 9 CFR 381.1 Poultry Products Inspection Regulations Definitions, Poultry, and

(b) Any migratory waterfowl or game bird, pheasant, partridge, quail, grouse, or pigeon, whether live or dead, as defined in 9 CFR 362.1 Voluntary Poultry Inspection Regulations, Definitions.

(8~~3~~4) "Premises" means:

(a) The physical facility, its contents, and the contiguous land or property under the control of the permit holder; or

(b) The physical facility, its contents, and the land or property not described in subparagraph (a) of this definition if its facilities and contents are under the control of the permit holder and may impact food establishment personnel, facilities, or operations, and a food establishment is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

(8~~4~~5) "Primal cut" means a basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank, or veal breast.

(8~~5~~6) Priority Item.

(a) "Priority item" means a provision in this chapter whose application contributes directly to the elimination, prevention or reduction to an acceptable level, hazards associated with foodborne illness or injury and there is no other provision that more directly controls the hazard.

(b) "Priority item" includes items with a quantifiable measure to show control of hazards such as cooking, reheating, cooling, handwashing; and

(c) "Priority item" is an item that is denoted in this chapter with (P).

(8~~6~~7) Priority Foundation Item.

(a) "Priority foundation item" means a provision in this chapter whose application supports, facilitates or enables one or more priority items.

(b) "Priority foundation item" includes an item that requires the purposeful incorporation of specific actions, equipment or procedures by industry management to attain control of risk factors that contribute to foodborne illness or injury such as personnel training, infrastructure or necessary equipment, HACCP plans, documentation or record keeping, and labeling; and

(c) "Priority foundation item" is an item that is denoted in this chapter with (Pf).

(8~~7~~8) "Public water system" has the meaning stated in 40 CFR 141 National Primary Drinking Water Regulations.

(8~~8~~9) "Ratite" means a flightless bird such as an emu, ostrich, or rhea.

(~~89~~90) "Ready-to-Eat-Food" means food that:

(a) Is in a form that is edible without additional preparation to achieve food safety, as specified under one of the following 0080-04-09-.03(4)(a)1(i) or (ii), 0080-04-09-.03(4)(a)2, or 0080-04-09-.03(4)(b)1 or as specified in 0080-04-09-.03(4)(a)1(iii); or

(b) Is a raw or partially cooked animal food and the consumer is advised as specified in 0080-04-09-.03(4)(a)1(iv)(I) and (III); or

(c) Is prepared in accordance with a variance that is granted as specified in 0080-04-09-.03(4)(a)1(iv)(IV); and

(d) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

(e) "Ready-to-eat food" includes:

1. Raw animal food that is cooked as specified under 0080-04-09-.03(4)(a), or frozen as specified under 0080-04-09-.03(4)(b);

2. Raw fruits and vegetables that are washed as specified under 0080-04-09-.03(3)(b)5;

3. Fruits and vegetables that are cooked for hot holding, as specified under 0080-04-09-.03(4)(a)3;

4. All time/temperature control for safety food that is cooked to the temperature and time required for the specific food under 0080-04-09-.03(4) and cooled as specified under 0080-04-09-.03(5)(a)4;

5. Plant food for which further washing, cooking, or other processing is not required for food safety, and from which rinds, peels, husks, or shells, if naturally present are removed;

6. Substances derived from plants such as spices, seasonings, and sugar;

7. A bakery item such as bread, cakes, pies, fillings, or icing for which further cooking is not required for food safety;

8. The following products that are produced in accordance with USDA guidelines and that have received a lethality treatment for pathogens: dry, fermented sausages, such as dry salami or pepperoni; salt-cured meat and poultry products, such as prosciutto ham, country cured ham, and Parma ham; and dried meat and poultry products, such as jerky or beef sticks; and

9. Food manufactured as specified in 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers.

(9~~0~~1) Reduced Oxygen Packaging.

(a) "Reduced oxygen packaging" means:

1. The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and

2. A process as specified in part (a)(1) of this definition that involves a food for which the hazards Clostridium botulinum or Listeria monocytogenes require control in the final packaged form.

(b) "Reduced oxygen packaging" includes:

1. Vacuum packing, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package;

2. Modified atmosphere packaging, in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen;

3. Controlled atmosphere packaging, in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and

impermeable packaging material;

4. Cook chill packaging, in which cooked food is hot filled into impermeable bags that have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

5. Sous vide packaging, in which raw or partially cooked food is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

(9~~1~~2) "Refuse" means solid waste not carried by water through the sewage system.

(9~~2~~3) "Reminder" means a written statement concerning the health risk of consuming animal food raw, undercooked, or without otherwise being processed to eliminate pathogens.

(9~~3~~4) "Re-service" means the transfer of food that is unused and returned by a consumer after being served or sold and in the possession of the consumer, to another person.

(9~~4~~5) "Restrict" means to limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not work with exposed food, clean equipment, utensils, linens, or unwrapped single-service or single-use articles.

(9~~5~~6) "Restricted egg" means any check, dirty egg, incubator reject, inedible, leaker, or loss as defined in 9 CFR 590.

(9~~6~~7) "Restricted use pesticide" means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 Pesticides classified for restricted use, and that is limited to use by or under the direct supervision of a certified applicator.

(9~~7~~8) Retail food store.

(a) "Retail food store" means any establishment or a section of an establishment where food and food products are offered to the consumer and intended for off-premise consumption;

(b) "Retail food store" does not include:

(i) Establishments that handle only prepackaged, non-time/temperature control for safety food, as defined by department rules and regulations;

(ii) Roadside markets that offer only fresh fruits and fresh vegetables;

(iii) Food and beverage vending machines;

(iv) Food service establishments not located within a retail food store; or

(v) A person who makes infrequent casual sales of honey or who packs or sells less than one hundred fifty gallons (150 gals.) of honey per year.

(9~~8~~9) "Risk" means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

(~~99~~100) "Safe material" means:

(a) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food;

(b) An additive that is used as specified in § 409 of the Federal Food, Drug, and Cosmetic Act; or

(c) Other materials that are not additives and that are used in conformity with applicable regulations of the Food and Drug Administration.

(10~~0~~1) "Sanitization" means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

(10~~1~~2) "Sealed" means free of cracks or other openings that allow the entry or passage of moisture.

(10~~2~~3) "Service animal" means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to an individual with a disability.

(10~~3~~4) "Servicing area" means an operating base location to which a mobile food establishment or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding food.

(10~~4~~5) "Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

(10~~5~~6) "Shellfish control authority" means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce.

(10~~6~~7) "Shellstock" means raw, in-shell molluscan shellfish.

(10~~7~~8) "Shiga toxin-producing Escherichia coli (STEC)" means any E. coli capable of producing Shiga toxins (also called verocytotoxins or "Shiga-like" toxins). Examples of serotypes of STEC include both O157 and non-O157 E. coli. Also see Enterohemorrhagic Escherichia Coli.

(10~~8~~9) "Shucked shellfish" means molluscan shellfish that have one or both shells removed.

(1~~09~~10) "Single-service articles" means tableware, carry-out utensils, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one person use after which they are intended for discard.

(11~~0~~1) Single-Use Articles.

(a) "Single-use articles" means utensils and bulk food containers designed and constructed to be used once and discarded.

(b) "Single-use articles" includes items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength, and cleanability specifications under 0080-04-09-.04-(1)(a), (2)(a), (b) for multiuse utensils.

(11~~1~~2) "Slacking" means the process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -23°C (-10°F) to -4°C (25°F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as shrimp.

(11~~2~~3) "Smooth" means:

(a) A food-contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number 3 stainless steel;

(b) A nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and

(c) A floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

(11~~3~~4) "Tableware" means eating, drinking, and serving utensils for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, and tumblers; and plates.

(11~~4~~5) "Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of food, air, or water.

(11~~5~~6) "Temporary food establishment" means a food establishment that operates at a fixed location in conjunction with an organized temporary event for more than one (1) day and not more than fourteen (14) consecutive days.

(11~~6~~7) Time/Temperature Control for Safety Food.

(a) "Time/temperature control for safety food" means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

(b) "Time/temperature control for safety food" includes:

1. An animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and

2. Except as specified in subpart 3(iv) of this definition, a food that because of the interaction of its A_W and pH values is designated as Product Assessment Required (PA) in Table A or B of this definition:

Table A. Interaction of PH and A_w for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged

A_w values	PH values		
	4.6 or less	> 4.6 - 5.6	> 5.6
≤0.92	non-TCS FOOD*	non-TCS FOOD	non-TCS FOOD
> 0.92 - .95	non-TCS FOOD	non-TCS FOOD	PA**
> 0.95	non-TCS FOOD	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD
** PA means Product Assessment required

Table B. Interaction of PH and A_W for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged				
A_W values	PH values			
	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
< 0.88	non-TCS food*	non-TCS food	non-TCS food	non-TCS food
0.88 – 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
> 0.90 – 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

* TCS FOOD means TIME/TEMPERATURE CONTROL FOR SAFETY FOOD
** PA means Product Assessment required

3. "Time/temperature control for safety food" does not include:

(i) An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard boiled, but has been pasteurized to destroy all viable salmonellae;

(ii) A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;

(iii) A food that because of its pH or Aw value, or interaction of Aw and pH values, is designated as a non TCS food in Table A or B of this definition;

(iv) A food that is designated as Product Assessment Required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:

(I) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients,

(II) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use, or

(III) A combination of intrinsic and extrinsic factors; or

(v) A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the subparts 3(i) – 3(iv) of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

(11~~7~~8) "USDA" means the U.S. Department of Agriculture.

(11~~8~~9) "Utensil" means a food contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multiuse, single-service, or single use, gloves used in contact with food; temperature sensing probes of food temperature measuring devices; and probe-type price or identification tags used in contact with food.

(1~~19~~20) "Variance" means a written document issued by the commissioner that authorizes a modification or waiver of one or more requirements of this chapter if, in the opinion of the commissioner, a health hazard or nuisance will not result from the modification or waiver.

(12~~0~~1) "Warewashing" means the cleaning and sanitizing of utensils sanitizing of utensils and food-contact surfaces of equipment.

(12~~1~~2) "Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

Authority: T.C.A. §§ 4-3-203 and 53-8-~~2~~104.

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

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. 0080-10-02.

Authority: T.C.A. §§ 4-3-203 and 53-8-~~204~~104.

RULES
OF
TENNESSEEE DEPARTMENT OF AGRICULTURE
FOOD

CHAPTER 0080-04-13
FOOD MANUFACTURERS AND WAREHOUSES

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Paragraph 0080-04-13-.02(2) is amended by deleting subparagraphs (f)-(g) and inserting the following language:

~~(f) Food means those articles as defined under the Act and includes dietary supplements; and~~

~~(g) Potentially hazardous food has the same meaning as T.C.A. § 53-1-104(1)(D).~~

(f) Food means those articles as defined under the Act and includes dietary supplements;

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

(h) Potentially hazardous food has the same meaning as T.C.A. § 53-1-104(1)(D).

Authority: T.C.A. §§ 4-3-203 and 53-1-~~207~~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. 0080-10-01.

Authority: T.C.A. §§ 4-3-203 and 53-1-~~207~~202.