

CHAPTER 300. MANUFACTURE, DISTRIBUTION, AND RETAIL SALE OF CONSUMABLE HEMP PRODUCTS.

SUBCHAPTER A. GENERAL PROVISIONS

Rule §300.001. PURPOSE (a) The rules in this chapter implement Health and Safety Code (HSC), Chapter 443, Regulating the Manufacture, Distribution, and Retail Sale of consumable hemp and consumable hemp products in the state of Texas.

(b) DEFINITIONS. In this chapter:

- (1) "Accredited Laboratory" -- a laboratory accredited in accordance with the International Organization for Standardization ISO/IEC 17025 or a comparable or successor standard.
- (2) "Acceptable Hemp THC level" -- a delta-9 tetrahydrocannabinol content concentration level on a dry weight basis, that, when reported with the laboratory's measurement of uncertainty, produces a distribution or range that includes a result of 0.3% or less.
- (3) "Act" -- Texas House Bill 1325, relating to the production and regulation of hemp in Texas, codified in Chapters 443 of the Health and Safety Code.
- (4) "Analyte" -- a chemical, compound, element, bacteria, yeast, fungus, mold, or toxin identified and measured by accredited laboratory analysis.
- (5) "Approved Hemp Source" -- hemp and hemp products grown for human use and consumption must be produced under a state or a compatible federal, foreign, or Tribal plan, approved by the United States Department of Agriculture under 7 U.S.C. Chapter 38, Subchapter VII, or Chapter 121 of the Texas Agricultural Code, or in a manner that is consistent with federal law and the laws of respective foreign jurisdictions.
- (6) "Cannabidiol" -- otherwise known as CBD; is a phytocannabinoid identified as an extract in cannabis plants.

- (7) "Certificate of Analysis (COA)" -- an official document released by the accredited laboratory to the manufacturer, processor, distributor, or retailer of consumable hemp products, the public, or department, which contains the concentrations of cannabinoid analytes and other measures approved by the department, to also include data on levels of tetrahydrocannabinol (THC) and state whether a sample passed or failed any limits of content analysis.
- (8) "Consumable Hemp Products License" -- a license issued to a person or facility engaged in the act of manufacturing, extracting, processing, or distributing consumable hemp products for human consumption or use.
- (9) "Consumable hemp product" -- any consumable hemp product (CHP), to include drugs, devices, or a cosmetic, as those terms are defined by Section 431.002 of the Health and Safety Code, that contains hemp or one or more hemp-derived cannabinoids, including cannabidiol.
- (10) "Department" -- the Department of State Health Services (DSHS).
- (11) "Delta-9 tetrahydrocannabinol or THC or Delta-9-THC" -- the primary psychoactive component of cannabis. For the purposes of this chapter, the terms delta-9-THC and THC are interchangeable.
- (12) "Distributor" -- a person or facility which distributes consumable hemp products for resale, either through a retail outlet owned by that person or through sales to another retailer. A distributor is required to hold a consumable hemp products license.
- (13) "Executive Commissioner" -- the executive commissioner of the Health and Human Services Commission (HHSC).
- (14) "Facility" --
 - (A) A place of business engaged in manufacturing, processing, or distributing consumable hemp products subject to the requirements of this chapter and Texas Health and Safety Code, Chapter 431.
 - (B) A domestic or foreign facility that is required to register under the Federal Food, Drug, and Cosmetic Act, Section 415

in accordance with the requirements of 21 Code of Federal Regulations Part 1, Subpart H.

- (15) "Federal Act" -- means the Federal Food, Drug and Cosmetic Act (Title 21 U.S.C. 301 et seq.).
- (16) "FDA" -- means the United States Food and Drug Administration.
- (17) "Gas chromatography or GC" -- a type of chromatography in analytical chemistry used to separate, identify, and quantify each component in a mixture. GC relies on heat for separating and analyzing compounds that can be vaporized without decomposition.
- (18) "Good Manufacturing Processes" -- (GMP'S) are procedures identified and implemented to ensure conformance to the sanitary guidelines recommended by the department with respect to the manufacture and sale of consumable hemp and consumable hemp ingredients; including all provisions as identified and defined in Health and Safety Code Chapter 431.
- (19) "Hemp" -- the plant Cannabis Sativa L. and any part of that plant, including the seeds of the plant and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.
- (20) "Hemp Processor" -- a person or facility which processes raw agriculture hemp into consumable hemp products for manufacture, distribution and sale into commerce. A consumable hemp processor is required to hold a consumable hemp products license.
 - (A) A person or facility issued a consumable hemp products license which only engages in the manufacturing, processing and distribution of consumable hemp products is not required to hold a license under Health and Safety Code Chapter 431, Subchapter J.
- (21) "High-performance liquid chromatography or HPLC" -- a type of chromatography technique in analytical chemistry used to separate, identify, and quantify each component in a mixture. HPLC relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid adsorbent material to separate and analyze compounds.

- (22) "License holder" -- the person or facility that is legally responsible for the operation of a consumable hemp manufacturer, processor, distributor, such as the owner, the owner's agent, or other person, and that possesses a valid license.
- (23) "Lot Number" -- a specific quantity of raw or processed hemp product that is uniform and intended to meet specifications for identity, strength, purity, and composition, that shall contain the manufacturer's, processors, or distributor's, number and a sequence to allow for inventory, traceability, and identification of the plant batches used in the production of consumable hemp products.
- (24) "Manufacturing" -- means making, extracting, processing, or distributing consumable hemp product from one or more ingredients; including but not limited to; synthesizing, preparing, treating, modifying or manipulating hemp or hemp crops or ingredients to create a consumable hemp product. For farms and farm mixed-type facilities, manufacturing and processing does not include activities related to growing, harvesting, packing, or holding raw hemp product.
- (25) "Measurement of Uncertainty (MU)" -- the parameter, associated with the results of an analytical measurement, that characterizes the dispersion of the values that could reasonably be attributed to the quantity subjected to testing measurement. For example, if the reported delta-9 tetrahydrocannabinol content concentration level on a dry weight basis is 0.35% and the measurement of uncertainty is +/- 0.06%, the measured delta-9 tetrahydrocannabinol content concentration level on a dry weight basis for this sample ranges from 0.29% to 0.41%. Because 0.3% is within the distribution or range, the sample is within the acceptable hemp THC level for the purpose of plan compliance. This definition of "acceptable hemp THC level" affects neither the statutory definition of hemp, in 7 U.S.C. §1639(1) and Tex. Agric. Code §121.001, nor the definition of "marihuana," in 21 U.S.C. §802(16) and in Tex. Health & Safety Code §481.002(26).
- (26) "Non-Consumable Hemp Processors" -- persons who intend to process hemp products not for human consumption and are registered with the Texas Department of Agriculture.
- (27) "Non-consumable hemp product" -- as defined by Texas Agricultural Code §122.001(8), means a product that contains hemp, other than a consumable hemp product as defined by Texas Health and Safety Code §443.001. The term includes cloth, cordage, fiber, fuel, paint,

paper, particleboard, construction materials, and plastics derived from hemp.

- (28) "Pathogen" -- a microorganism of public health significance; including; molds, yeasts, *Listeria monocytogenes*, *Campylobacter*, *Salmonella*, *E-coli*, *Yersinia*, or *Staphylococcus*.
- (29) "Person" -- means an individual, business, partnership, corporation, or association.
- (30) "Process" -- extraction of a component of hemp, including cannabidiol or another cannabinoid, that is:
 - (A) sold as a consumable hemp product;
 - (B) offered for sale as a consumable hemp product;
 - (C) incorporated into a consumable hemp product; or
 - (D) intended to be incorporated into a consumable hemp product.
- (31) "QR" -- a quick response (QR) machine-readable code that can be read by a camera, consisting of an array of black and white squares used for storing information or directing or leading a user to product information regarding manufacturer data and laboratory certificates of analysis.
- (32) "Registrant" -- an individual on behalf of themselves, or, representing others on their behalf, who submits a complete registration form to the department for purposes of registering their place of business or businesses, selling at retail consumable hemp products to the public.
- (33) "Reverse Distributor" -- means a person registered under the Controlled Substances Act, to acquire controlled substances from another person or entity for return of products to the registered manufacturer or to destroy adulterated or impermissible THC products.
- (34) "Smoking" -- burning or igniting a substance and inhaling the smoke or heating a substance and inhaling the resulting vapor or aerosol.
- (35) "TCS" -- a consumable hemp product that requires time-temperature controls to prevent the growth of microorganisms and production of toxins.
- (36) "Tetrahydrocannabinol" -- (THC) is the main psychoactive part of the

cannabis plant.

- (37) "Texas Department of Agriculture" -- (TDA) the department responsible for regulation of planting, growing, harvesting, and testing of hemp as a raw agricultural product.
- (38) "texas.gov." -- means the on-line registration system for the state of Texas found through the link: www.texas.gov.

Rule §300.002. APPLICABILITY OF OTHER RULES AND REGULATIONS.

(a) Hemp manufacturers, processors, distributors and retailers must comply with all laws and rules applicable to the manufacture, processing, distribution and sale of consumable products including:

- (1) 25 TAC 217, Subchapter C Rules for the Manufacture of Frozen Desserts;
- (2) 25 TAC 229, Subchapter D Regulation of Cosmetics;
- (3) 25 TAC 229, Subchapter F Production, Processing, and Distribution of Bottled and Vended Drinking Water;
- (4) 25 TAC 229, Subchapter G Manufacture, Storage, and Distribution of Ice Sold for Human Consumption, Including Ice Produced at Point of Use;
- (5) 25 TAC 229, Subchapter L Licensure of Food Manufacturers, Food Wholesalers, and Warehouse Operators;
- (6) 25 TAC 229, Subchapter N Current Good Manufacturing Practice and Good Warehousing Practice in Manufacturing, Packaging, Or Holding Human Food;
- (7) 25 TAC 229, Subchapter W Licensing of Wholesale Distributors of Prescription Drugs – Including Good Manufacturing Practices;
- (8) 25 TAC 229, Subchapter X Licensing of Device Distributors and Manufacturers; and
- (9) 25 TAC 229, Subchapter GG Sanitary Transportation of Human Food.

Rule §300.003. INSPECTIONS. (a) Authorized agents or employees of the department may, upon presenting appropriate credentials to the owner, operator, or agent in charge:

- (1) enter the premises of a manufacturer, processor, distributor, or retailer of consumable hemp products under the department's jurisdiction during normal business operating hours to conduct inspections or collect samples to determine compliance with Health and Safety Code, Chapter 443, Health and Safety Code, Chapter 431, these rules, and;
- (2) enter a vehicle being used to transport or hold the consumable hemp product in commerce; or
- (3) inspect at reasonable times, within reasonable limits, and in a reasonable manner, the facility or vehicle and all equipment, finished and unfinished materials, containers, and labeling of any item and obtain samples necessary for the enforcement of this chapter.

(b) The inspection of a facility where consumable hemp products are manufactured, processed, distributed, packed, held or sold, for introduction into commerce will determine if the consumable hemp product is:

- (1) adulterated or misbranded;
- (2) is otherwise manufactured, processed, held, distributed or sold in violation of this chapter.

(c) An inspection of a facility in which a prescription drug or restricted device is being manufactured, processed, packed, or held for introduction into commerce under Subsection (b) may not extend to:

- (1) financial data;
- (2) sales data other than shipment data;
- (3) pricing data;
- (4) personnel data other than data relating to the qualifications of technical and professional personnel performing functions under this chapter; or
- (5) research data other than data;
 - (A) relating to new consumable hemp products; and
 - (B) subject to reporting and inspection under regulations issued under Section 505(i) or (j), 519, or 520(g) of the Federal Act; or

(d) An inspection under Subsection (b) shall be started and completed with reasonable promptness.

Rule §300.004 MANUFACTURE OF SMOKABLE HEMP PRODUCT. (a) The processing, manufacturing, and retail sale of consumable hemp products for smoking is prohibited.

SUBCHAPTER B. MANUFACTURING, PROCESSING AND DISTRIBUTION OF CONSUMABLE HEMP PRODUCTS.

Rule §300.100. APPLICATION; ISSUANCE. (a) In order to engage in the manufacture, processing, or distribution of products containing consumable hemp or hemp derivatives as ingredients; a license issued by the department must be held prior to the manufacture, processing, or distribution of consumable hemp and hemp derived products.

(b) An individual or facility shall apply for a license under this subchapter by submitting an application to the department on a form and in the manner prescribed by the department for each location engaged in the manufacture, processing, or distribution of consumable hemp products. The application must be accompanied by:

- (1) a legal description of each location where the applicant intends to manufacture or process consumable hemp products; and from the point an applicant intends to deliver consumable hemp products to include the global positioning system coordinates for the perimeter of each location;
- (2) written consent from the applicant or the property owner if the applicant is not the property owner allowing the department, the Department of Public Safety, and any other state or local law enforcement agency to enter onto all premises where consumable hemp is manufactured, processed, or delivered to conduct a physical inspection or to ensure compliance with this chapter and rules adopted under this chapter; and
- (3) Each applicant, shall undergo a finger print based criminal background check, at their own expense.
 - (A) The department shall not issue a license under this subchapter if the applicant has been convicted of a felony relating to a controlled substance under federal law or the law of any state within the previous 10 years.

- (B) If the department receives information that a licensee under this subchapter has been convicted of a felony relating to a controlled substance under federal law or the law of any state within the previous 10 years, the department shall revoke the license.
- (4) A governing person of an establishment that holds a license under this subchapter shall undergo a finger print based criminal background check, at their own expense.
 - (A) The department shall not issue a license under this subchapter if a governing person of that establishment has been convicted of a felony relating to a controlled substance under federal law or the law of any state within the previous 10 years.
 - (B) If the department receives information that a governing person of an establishment licensed under this subchapter has been convicted of a felony relating to a controlled substance under federal law or the law of any state within the previous 10 years, the department shall revoke the license.
- (c) Applications must be submitted by the owner, operator, or other authorized person and shall contain the following information:
 - (1) the name under which the business is operated;
 - (2) the mailing address of the facility;
 - (3) street address of the facility;
 - (4) primary business contact telephone number; and
 - (5) email address.
- (d) If an owner, operator, or other authorized person owns or operates two or more facilities, each facility shall license separately by listing the name and address of each facility on separate application forms.
- (e) Texas.Gov. Applicants must submit an application for license request under these sections electronically through www.texas.gov. The department is authorized to collect fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through texas.gov.

(f) All fees required by the department must be submitted with the application.

(g) Any other information required by the department as evidenced and provided upon application forms for manufacturing, processing, or distribution of hemp products licensure and retail hemp registration.

Rule §300.101. TERM; RENEWAL. (a) A manufacturer, processor or distributor of consumable hemp license is valid for one year and may be renewed annually thereafter provided the licensee maintains good standing.

(b) The department shall issue and renew a license if the license holder:

- (1) is not ineligible to hold the license under rule §300.105;
- (2) submits to the department a license renewal fee;
- (3) does not owe any outstanding fees to the department;
- (4) possesses and provides upon department request testing results of consumable hemp products prior to their manufacture, distribution or sale into commerce;
- (5) has not been convicted of a felony relating to a controlled substance under federal law or the law of any state in the previous 10 years; and
- (6) does not have a governing person of the establishment who has been convicted of a felony relating to a controlled substance under federal law or the law of any state in the previous 10 years.

(c) Fees:

- (1) prior to the manufacture, processing or distribution of consumable hemp products, the amount of fee per business location shall be \$250.00; and
 - (A) for each place of business \$250.00 fee for amendment due to a change of ownership; and
 - (B) \$125.00 amendment during the licensure period due to minor changes.
 - (C) Fees are not prorated.

(d) An application for a consumable hemp manufacturer, processor or distributor license is complete when the department has received, reviewed, and found acceptable the application information and fee required by the appropriate sections of this subchapter.

(e) An application for an annual renewal of a license is complete when the department has received, reviewed and found acceptable the application information and fee required by the appropriate section of this subchapter.

(f) An application for an amendment of a license is complete when the department has received, reviewed, and found acceptable the application information and fee required by the appropriate section of this Subchapter.

(g) An application for a license shall be processed in accordance with the following time periods;

(1) the first-time period is 45 business days, which begins on the date the department receives the completed application and ends on the date the license is issued. If an incomplete application is received, the period ends on the date the facility is issued a written notice that the application is incomplete. The written notice shall describe the specific information or fee that is required before the application is considered complete;

(2) the second-time period is 45 business days, which begins on the date the department receives a completed application and ends on the date the license is issued, or the facility is issued a written notice that the application is being proposed for denial; and

(3) if the applicant fails to submit the requested information and/or fee within 135 days of the date the department issued the written notice to the applicant as described in paragraph (1) of this subsection, that the application is incomplete and/or additional fees are owed, the application is considered withdrawn.

(h) Reimbursement of fees;

(1) in the event the application is not processed within the time periods stated in subsection (g) of this section, the applicant has the right to make a written request within 30 days of the end of the second period that the department reimburse in full the fee paid in that application process; and

(2) if the department finds that good cause existed for exceeding the established periods, the request will be denied. The department will

notify the applicant in writing of the denial of the reimbursement within 30 days of the department's decision.

(i) Proof of a license issued by and from the department must be prominently displayed in a conspicuous location.

Rule §300.102. ACCESS TO RECORDS. (a) A person who is required to maintain records under this chapter or Section 519 or 520(g) of the Federal Act or a person who is in charge or custody of those records shall, at the request of the department, permit at all reasonable times, access to and to copy and verify the records, including records that verify that the hemp in a consumable hemp product was produced in accordance with United States Department of Agriculture under 7 U.S.C. Chapter 38, Subchapter VII, or Chapter 121 of the Texas Agricultural Code, or in a manner that is consistent with federal law and the laws of respective foreign jurisdictions.

(b) A person licensed under Chapter 122, Agriculture Code, shall make available to the department upon request; the results of test(s) conducted on samples of hemp or hemp product(s) as evidence that the delta-9 tetrahydrocannabinol concentration of the hemp or hemp product(s) does not exceed 0.3 percent.

(c) Records described in (b) must be maintained for period of no less than three years.

SUBCHAPTER C. TESTING OF CONSUMABLE HEMP PRODUCTS.

Rule §300.106. TESTING REQUIRED. (a) A consumable hemp product must be tested as provided by:

- (1) Subsections (b) and (c); or
- (2) Subsection (d).

(b) All hemp or hemp derivatives used in the manufacture of a consumable hemp product must be tested by a laboratory accredited by an accreditation body in accordance with International Organization for Standardization ISO/IEC 17025 or a comparable or successor standard to determine:

- (1) the concentration of various cannabinoids and THC;
- (2) the presence or quantity of heavy metals and pesticides; and
- (3) the presence of harmful pathogenic microorganisms, including: *Listeria monocytogenes*; *Campylobacter*; *Salmonella*; *E-coli*;

Yersinia; Staphylococcus; yeasts, and molds.

(c) The presence and quantity of:

- (1) any residual solvents used in processing, if applicable; and
- (2) any other substance posing a health risk if consumed as described in §300.108.

(d) Testing to be done by an approved laboratory to determine that the product does not contain a substance described by Subsection (b) or (c).

(e) A Certificate of Analysis (COA) documenting tests conducted in accordance with this subchapter including as a minimum testing performed under rule §300.108 shall:

- (1) be made available to the department upon request in an electronic format prior to manufacture, processing, or distribution into commerce;
- (2) in a format that documents presence and content of CBD, levels of THC, and an analysis as described in rule §300.108(m); and
- (3) includes measurement of uncertainty analysis parameters.

Rule §300.107. SAMPLE ANALYSIS OF CONSUMABLE HEMP AND CERTAIN CANNABINOID OILS. (a) This section does not apply to low-THC cannabis regulated under Chapter 487.

(b) Notwithstanding any other law, a person may not sell, offer for sale, possess, distribute, or transport a consumable hemp product, including cannabidiol oil, in this state:

- (1) if the oil contains any material extracted or derived from the plant Cannabis Sativa L., other than from hemp produced in compliance with 7 U.S.C. Chapter 38, Subchapter VII;
- (2) a sample representing the oil has been tested by a laboratory that is accredited by an independent accreditation body in accordance with International Organization for Standardization ISO/IEC 17025 or a comparable or successor standard and found to have a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent; and
- (3) testing results are provided to the department upon request.

(c) The department will conduct random testing of consumable hemp products, including cannabidiol oil (CBD), at various retail and other facilities that sell, offer for sale, distribute, or use the oil to ensure that product:

- (1) does not contain harmful ingredients;
- (2) is produced in compliance with 7 U.S.C. Chapter 38, Subchapter VII; and
- (3) has a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent.

(d) Representative raw or finished consumable hemp product samples shall be provided by the manufacturer, processor, distributor, or retailer of consumable hemp products to the department upon request.

(e) Representative raw or finished consumable hemp product samples shall be provided to the department at owner, licensee or registrant expense.

Rule §300.108. PROVISIONS RELATED TO TESTING. (a) A consumable hemp product that has a delta-9 tetrahydrocannabinol concentration of more than 0.3 percent or is adulterated in a manner harmful to human consumption may not be sold at retail or otherwise introduced into commerce in this state.

(b) A hemp manufacturer, processor or distributor shall make the results of testing required by rule §300.106 available to the department upon request.

(c) The seller of retail hemp products shall make the testing required under rule §300.106 available to a consumer or to the department upon request.

(d) A license holder may not use an independent testing laboratory unless the license holder has:

- (1) no ownership interest in the laboratory; or
- (2) holds less than a 10 percent ownership interest in the laboratory if the laboratory is a publicly traded company.

(e) A license holder must pay the costs of raw and finished hemp product testing in an amount prescribed by the laboratory selected by the license holder.

(f) The department shall recognize and accept the results of a test performed by an institution of higher education or an independent testing laboratory in accordance with International Organization for Standardization ISO/IEC 17025 or a comparable or successor standard.

(g) The department may require that a copy of the test results be sent by the institution of higher education or independent testing laboratory directly to the department and the license holder.

(h) The department shall notify the license holder of the results of the test not later than the 14th day after the date after testing results are made available to the department.

(i) For testing, extracts should be thoroughly mixed before sampling to ensure homogenization of the sample and collected following distillation prior to processing into products:

- (1) COA's must include an analysis of pesticides, residual solvents, processing chemicals, metals, total yeast and mold as per criteria contained in Table 1:

Table 1 – Process Lot Sampling			
Process Lot Weight		Sample Increments Required (1.0g+/-0.2g)	
Pounds	Kilograms	# of Samples	Reserve Samples
0-0.50	1-0.23	2	1
0.50-1.50	0.24-0.68	4	1
1.51-3.00	0.69-1.36	6	1
3.10-6.0	1.40-2.72	6	1
6.10-10.0	2.77-4.54	10	1
10+	4.58+	15	2

(j) A manufacturer, or distributor of consumable hemp product(s) shall develop and follow written procedures for the sampling of consumable hemp products that require:

- (1) sample collection in a manner that provides analytically sound and representative samples;
- (2) document every sampling event and provide this documentation to the department upon request;
- (3) descriptions of all sampling and testing plans in written procedures that include sampling method, the number of units per lot to be tested, measurement of uncertainties applicable to the test; and
- (4) ensure all random samples from each lot are;

- (A) taken in an amount necessary to conduct applicable testing;
- (B) labeled with the lot number;
- (C) submitted for testing; and
- (D) retain results from the samples for a period of no less than three years.

(k) A manufacturer or processor, of consumable hemp products shall conduct sampling and testing using acceptance criteria that are protective of public health.

(l) A consumable hemp product is not required to be tested under rule §300.106 if each hemp-derived ingredient of the product:

- (1) has been tested in accordance with:
 - (A) Subsections (b) and (c); or
 - (B) Subsection (d).
- (2) results are available upon request from the department prior to distribution or sale; and
- (3) does not have a delta-9 tetrahydrocannabinol concentration of more than 0.3 percent.

(m) Contaminant analysis and pathogen acceptance criteria is as follows in Table 2:

Table 2 – Contaminate Analysis and Acceptance Criteria			
Analyte	Acceptable Limit	Comment	Guideline Source
Metals			
Arsenic	1.5 ppm	Required	FDA Q3D, elemental impurities guidance
Cadmium	0.3ppm	Required	Same as above
Lead	1.0ppm	Required	Same as above
Mercury	0.5ppm	Required	Same as above
Microbial Impurities	Total Aerobic Count	1x10 ³ CFU/g	American Herbal Pharmacopeia
Total combined yeast molds count		1x10 ² CFU/g	Same as above

E-Coli	No Detection	1g	Same as above
Campylobacter	No detection	1g	Same as above
Listeria monocytogenes	No Detection	1g	Same as above
Salmonella	No detection	1g	Same as above
Shiga-Toxin	No detection	1g	Same as above
Staphylococcus	No detection	1g	Same as above
Yersinia	No detection	1g	Same as above
Pesticides	Chemical Abstract Services Number (CAS)	Acceptable Limit	American Chemical Society
Acetamiprid	135410-20-7	0.2ppm	Same as above
Aldicarb	116-06-3	0.4ppm	Same as above
Azoxystrobuin	131860-33-8	0.2ppm	Same as above
Bifenzate	149877-41-8	0.2ppm	Same as above
Boscalid	188425-85-6	0.2ppm	Same as above
Carbaryl	63-25-2	0.5ppm	Same as above
Carbofuran	1563-66-2	0.2ppm	Same as above
Chlorantraniliprole	5000008-45-7	0.2ppm	Same as above
Chloropyrifos	2921-88-2	0.6ppm	Same as above
Cypermethrin	52315-07-8	18ppm	Same as above
Diazinon	333-41-5	2.6ppm	Same as above
Dichlorovos	62-73-7	0.1ppm	Same as above
Ethoprophos	13194-48-4	0.4ppm	Same as above
Etofenprox	80844-071	0.4ppm	Same as above
Fipronil	120068-37-3	1.0ppm	Same as above
Fonicamid	158062-67-0	1.0ppm	Same as above
Glyphosate	1071-83-6	0.2 ppm	Same as above
Imidacloprid	138261-41-3	0.4ppm	Same as above
Metalaxyl	57837-19-1	0.2ppm	Same as above
Methiocarb	2032-65-7	0.4ppm	Same as above
Methomyl	16752-77-5	0.4ppm	Same as above
Methyl parathion	298-00-0	8.5ppm	Same as above
Myclobutanil	88671-89-0	0.3ppm	Same as above
Oxamyl	23135-22-0	1ppm	Same as above
Permethrin I	52465-53-1	1.1ppm	Same as above
Pyridaben	96489-71-3	0.2ppm	Same as above
Spiroxamine I	118134-30-8	2ppm	Same as above
Tebuconazole	80443-41-0	0.4ppm	Same as above
Thiacloprid	111988-49-9	0.2ppm	Same as above
Thiamethoxam	153719-023-4	0.2ppm	Same as above

SUBCHAPTER D. RETAIL SALE OF CONSUMABLE HEMP PRODUCTS.

Rule §300.201. POSSESSION, DISTRIBUTION AND SALE OF CONSUMABLE HEMP PRODUCTS. (a) A person may possess, transport, distribute, sell, or purchase a consumable hemp product processed or manufactured in compliance with this chapter.

Rule §300.202. PACKAGING AND LABELING REQUIREMENTS. (a) Before a consumable hemp product that contains or is marketed as containing cannabinoids may be distributed or sold, the product must be labeled in the manner provided by this section with the following information:

- (1) batch identification number;
- (2) batch date;
- (3) product name;
- (4) a uniform resource locator (URL) that provides or links to a certificate of analysis for the product of each hemp-derived ingredient of the product;
- (5) the name of the product's manufacturer;
- (6) telephone number of manufacturer and email address; and
- (7) a certificate of analysis of analysis that the delta-9 tetrahydrocannabinol concentration of the product or each hemp-derived ingredient of the product is not more than 0.3 percent.
- (8) the label required by Subsection (a) must appear on each unit of the product intended for individual retail sale. If that unit includes inner and outer packaging, the label may appear on any of that packaging.
- (9) the label required by Subsection (a) may be in the form of:
 - (A) a uniform resource locator (URL) for the manufacturer's Internet website that provides or links to the information required by that subsection;
 - (B) a QR code or other bar code that may be scanned and that leads to the information required on the label.
- (10) All consumable hemp products sold as dietary supplements must contain the following statement, "This product has not been evaluated

by the FDA and is not intended to diagnose, treat, cure, or prevent any disease or health condition.”

Rule §300.2063. RETAIL SALE OF OUT-OF-STATE CONSUMABLE HEMP PRODUCTS. (a) Retail sales of consumable hemp products processed or manufactured outside of this state may be sold in this state upon request and submission to the department evidence that the products were processed or manufactured in another state or jurisdiction in compliance with:

- (1) that state or jurisdiction's plan approved by the United States Department of Agriculture under 7 U.S.C. Section 1639p;
- (2) a plan established under 7 U.S.C. Section 1639q if that plan applies to the state or jurisdiction; or
- (3) the laws of that state or jurisdiction if the products are tested in accordance with, rule §300.106.

Rule §300.204. TRANSPORTATION AND EXPORTATION OF CONSUMABLE HEMP PRODUCTS OUT OF STATE. (a) Consumable hemp products may be legally transported across state lines and exported to foreign jurisdictions in a manner that is consistent with federal law and the laws of respective foreign jurisdictions.

SUBCHAPTER E. REGISTRATION FOR RETAILERS OF CONSUMABLE HEMP PRODUCTS.

Rule §300.250. REGISTRATION REQUIRED FOR RETAILERS OF CERTAIN PRODUCTS. (a) This section does not apply to low-THC cannabis regulated under HSC Chapter 487.

(b) A person or business may not sell consumable hemp products containing cannabidiol at retail in this state unless the person or business registers with the department each location owned, operated, or controlled by the person or business at which those products are sold. A person or business is not required to register a location associated with an employee or independent contractor described by Subsection (c).

(c) A person is not required to register with the department under Subsection (b) if the person is:

- (1) an employee of a registrant; or

(2) an independent contractor of a registrant who sells the registrant's products at retail.

(d) Proof of registration from the department must be prominently displayed in a conspicuous location accessible by the public.

Rule 300.251. APPLICATION. (a) a person shall apply for a registration under this subchapter by submitting an application in the manner prescribed by the department.

(b) applications must be submitted by the owner, operator, or other authorized person and shall contain the following information:

- (1) the name under which the business is operated;
- (2) the mailing address of the facility;
- (3) street address of each location;
- (4) primary business contact telephone number;
- (5) phone number for each location; and
- (6) current email address.

(c) A registration is valid for one year and may be renewed annually provided the licensee remains in good standing.

(d) Texas.Gov. Applicants must submit an application for registration request under these sections electronically through www.texas.gov.

(e) The department is authorized to collect fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through texas.gov.

(f) All fees required by the department must be submitted with the application.

- (1) A Retail Hemp registration fee of \$150.00 is required prior to the retail sale of consumable hemp product; and
- (2) the amount of fee per business location shall be \$150.00.

SUBCHAPTER F. ENFORCEMENT.

Rule §300.300 VIOLATION OF DEPARTMENT LICENSE REQUIREMENT. (a) A person commits a violation if the person manufactures, processes, or distributes into commerce a consumable hemp product without a license or registration required by the department under Section §300.100 for the manufacture, processing, or distributing of consumable hemp products and; §300.251 for the retail sale of consumable hemp products.

(b) Each day a violation continues or occurs is a separate violation for purposes of imposing a penalty.

Rule §300.301 PROHIBITED ACTS. (a) The following acts and the causing of the following acts within this state are unlawful and prohibited:

(1) the distribution in commerce of a consumer commodity, if such commodity is contained in a package, or if there is affixed to that commodity a label that does not conform to the provisions of this chapter; and

(2) engaging in the packaging or labeling of such commodities.

Rule §300.302 DETAINED OR EMBARGOED ARTICLE. (a) The department shall affix to an article that is a food, drug, device, cosmetic, or consumer commodity a tag or other appropriate marking that gives notice that the article is, or is suspected of being, adulterated or misbranded and that the article has been detained or embargoed if the department finds or has probable cause to believe that the article:

(1) is adulterated;

(2) is misbranded so that the article is dangerous or fraudulent under this chapter; or

(3) violates Texas health and Safety Code Section [431.084](#), [431.114](#), or [431.115](#).

Rule §300.303 DESTRUCTION OF ARTICLE. (a) The department shall request court ordered destruction of a sampled, detained, or embargoed article if the court finds the article is misbranded or adulterated.

(b) After entry of the court's order, an authorized agent shall supervise the destruction of the article.

(c) The claimant of the article shall pay the cost of the destruction of the article.

(d) If the article is being destroyed in whole or in part due to a THC content that meets the definition of a schedule I drug, the article must be destroyed through a United States Drug Enforcement Agency authorized reverse distributor.

Rule §300.304 CORRECTION BY PROPER LABELING OR PROCESSING. (a) A court may order the delivery of a sampled article or a detained or embargoed article that is adulterated or misbranded to the claimant of the article for labeling or processing under the supervision of the department if:

- (1) the decree has been entered in the suit;
- (2) the costs, fees, and expenses of the suit have been paid;
- (3) the adulteration or misbranding can be corrected by proper labeling or processing;
- (4) a good and sufficient bond, conditioned on the correction of the adulteration or misbranding by proper labeling or processing, has been executed.

(b) The claimant shall pay the costs of department supervision.

Rule §300.305 ADMINISTRATIVE PENALTY. (a) The department may impose an administrative penalty against a person who holds a license or is registered under this chapter and who violates this chapter.

(b) The department shall notify a retailer of consumable hemp products of a potential violation concerning consumable hemp products sold by the retailer and given an opportunity to resolve such violations made unintentionally or negligently within three days of department notification.

(c) The department shall assess administrative penalties based upon one or more of the following criteria:

- (1) the seriousness of the violation, including the nature, circumstances, extent, and gravity of any prohibited acts, and the hazard or potential hazard created to the health, safety, or economic welfare of the public;

- (2) the history of previous violations;
- (3) the amount necessary to deter future violations;
- (4) efforts to correct the violation; and
- (5) any other matter that justice may require.

(d) If the department determines that a violation has occurred, the department shall issue a notice of violation that states the facts on which the determination is based, including an assessment of the penalty.

(e) The notice of violation shall be in writing and sent to the licensee by certified mail. The notice must include a summary of the alleged violation and a statement of the amount of the recommended penalty and must inform the person that the person has a right to a hearing on the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty.

(f) Within 20 days after the date the person receives the notice, the person in writing may accept the determination and recommended penalty of the department or may make a written request for a hearing on the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty.

(g) If the person accepts the determination and recommended penalty, the department by order shall impose the recommended penalty.

(h) If the person charged with the violation does not respond in writing within 20 days after the date the person receives the notice of violation, the department will assess the penalty after determining that a violation occurred and the amount of penalty. The department will issue an order requiring that the person pay the penalty.

(i) If the person requests a hearing, the department shall refer the matter to the State Office of Administrative Hearings.