

TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 300 MANUFACTURE, DISTRIBUTION, AND RETAIL SALE OF
CONSUMABLE HEMP PRODUCTS
SUBCHAPTER A GENERAL PROVISIONS

§300.100. Purpose.

This chapter implements Texas Health and Safety Code Chapter 443, regulating the manufacture, distribution, and retail sale of consumable hemp and consumable hemp products in the State of Texas.

§300.101. Definitions.

The following words and terms, when used in this chapter, have the following meanings unless context clearly indicates otherwise:

(1) Acceptable hemp THC level--A total delta-9 tetrahydrocannabinol content concentration level on a dry weight basis, that, when reported with the accredited laboratory's measurement of uncertainty, produces a distribution or range that includes a result of 0.3% or less.

(2) Accredited laboratory--A laboratory, including at an institution of higher education, accredited in accordance with the International Organization for Standardization ISO/IEC 17025 or a comparable or successor standard.

(3) Act--House Bill 1325, 86th Legislature, Regular Session, 2019, relating to the production and regulation of hemp in Texas, codified in Texas Health and Safety Code Chapter 443.

(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 for human use and consumption must be grown under a state or compatible federal, foreign, or Tribal plan. These plans must be approved by the United States Department of Agriculture under 7 United States Code (U.S.C.) Chapter 38, Subchapter VII, or Texas Agriculture Code Chapter 121. The products must comply with federal law and the laws of respective foreign jurisdictions.

(6) Batch date--The date a product batch was made, used for tracking and quality control. This is also called the lot date.

(7) Batch ID number--A number that identifies a specific amount of raw or processed hemp product that meets standards for identity, strength, purity, and composition. Each batch ID number must include the manufacturer's, processor's, or distributor's number and a sequence for inventory, traceability, and identification

of the plant batches used in making consumable hemp products. This is also called the lot number.

(8) Cannabis--A type of flowering plant in the Cannabaceae family. Any plants or plant matters from plants in the genus Cannabis Sativa L.

(9) Cannabidiol (CBD)--A phytocannabinoid produced by cannabis.

(10) Certificate of Analysis (COA)--An official document from an accredited laboratory available to the manufacturer, processor, distributor, retailer, public, or department. The COA shows the concentrations of cannabinoid analytes and other measurements required by the department, including data on THC levels, and states whether a sample passed or failed content analysis limits.

(11) Consumable hemp product (CHP)--Any product processed or manufactured for consumption that contains hemp, including food, a drug, a device, and a cosmetic, as defined by Texas Health and Safety Code §431.002. The definition excludes any hemp product containing a hemp seed or hemp seed-derived ingredient that the FDA has designated as Generally Recognized as Safe (GRAS).

(12) Consumable hemp products license--A license issued to a person or facility engaged in the act of manufacturing, extracting, or processing consumable hemp products for human consumption or use.

(13) Decarboxylation--The removal or elimination of a carboxyl group from a molecule or organic compound.

(14) Delta-9 tetrahydrocannabinol (d-9 THC)--A tetrahydrocannabinol isomer known as the primary psychoactive component of cannabis.

(15) Department--The Texas Department of State Health Services.

(16) Distributor--A person who 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 wholesaler license per Texas Health and Safety Code Chapter 431.

(17) Facility--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. A facility includes a domestic or foreign facility 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.

(18) FDA--The United States Food and Drug Administration or its successor agency.

(19) Federal Act--Federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. 301 et seq.).

(20) 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.

(21) Hemp-derived cannabinoid product--Any intermediate or final product derived from hemp (other than industrial hemp), that:

(A) contains cannabinoids in any form; and

(B) is intended for human or animal use through any means of application or administration, such as inhalation, ingestion, or topical application.

(22) Independent contractor--A person or entity contracted to perform work or sales for a registrant.

(23) License holder--The person who is legally responsible for the operation as a consumable hemp manufacturer or processor and possesses a valid license.

(24) Manufacturer--A person who makes, mixes, extracts, processes, packages, or repackages consumable hemp product from one or more ingredients. The definition includes synthesizing, preparing, treating, modifying, or manipulating hemp, hemp crops, or ingredients to create a consumable hemp product. It also includes private-labeling. For farmers and persons with farm mixed-type facilities, manufacturing and processing do not include activities related to growing, harvesting, packing, or holding raw hemp product. Manufacturers may only distribute products they manufactured.

(25) Measurement of uncertainty--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 total d-9 THC content concentration level on a dry weight basis is 0.35% and the measurement of uncertainty is +/- 0.06%, the measured total d-9 THC 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.

(26) Minor--A person under 21 years of age.

(27) Non-consumable hemp processor--A person who intends to process hemp products not for human consumption and who is registered with the Texas Department of Agriculture.

(28) Non-consumable hemp product--As defined by Texas Agriculture 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.

(29) Pathogen--A microorganism of public health significance, including molds, yeasts, *Listeria monocytogenes*, *Campylobacter*, *Salmonella*, *E. coli*, *Yersinia*, or *Staphylococcus*.

(30) Person--An individual, business, partnership, corporation, or association.

(31) Private labeling--When a person or manufacturer labels a CHP with the person's name and address, thereby representing itself as responsible for the purity and labeling of a CHP.

(32) Process--Extraction of a component of hemp, including CBD 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 for incorporation into a consumable hemp product.

(33) Processor--A person who operates a facility that processes raw agriculture hemp into consumable hemp products for manufacture, distribution, and sale. A hemp processor is required to hold a consumable hemp products license.

(34) QR code--A quick response 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 a user to product information regarding manufacturer or processor data and accredited laboratory COA.

(35) Raw hemp--An unprocessed hemp plant, or any part of the plant, in its natural state.

(36) Registrant--A person who sells consumable hemp products directly to consumers, and who submits a complete registration form to the department for purposes of registering the place of business to sell consumable hemp products at retail to the public.

(37) Reverse distributor--A person registered with the federal Drug Enforcement Agency as a reverse distributor that receives controlled substances from another person or entity for return of the products to the registered manufacturer or to destroy adulterated or impermissible THC products.

(38) Smoking--Burning or igniting a substance and inhaling the resultant smoke or heating a substance and inhaling the resulting vapor or aerosol.

(39) Supplier--A person or entity that manufactures or processes a material used in the processing or manufacturing of hemp. This term also includes a person or entity that manufactures hemp-derived cannabinoids or sells products containing hemp-derived cannabinoids to retailers.

(40) Tetrahydrocannabinol (THC)--A cannabinoid found in cannabis and considered the primary psychoactive component of the cannabis plant.

(41) Tetrahydrocannabinolic acid (THCA)--A precursor to all tetrahydrocannabinols (THC).

(42) Texas Department of Agriculture--The state agency responsible for regulation of planting, growing, harvesting, and testing of hemp as a raw agricultural product.

(43) Texas.gov--The online registration system for the State of Texas found at <https://www.texas.gov>.

(44) Total THC--The value determined after the process of decarboxylation, or the application of a conversion factor if the testing methodology does not include decarboxylation, that expresses the potential total tetrahydrocannabinol content derived from the sum of all THC isomers and THCA content and reported on a dry weight basis. This technique requires the use of the following conversion: $[\text{Total THC} = (0.877 \times \text{THCA}) + \text{THC}]$, which calculates the potential total THC in a given sample.

(45) Total delta-9 THC--The value is determined after decarboxylation or by applying a conversion factor if the testing method does not include decarboxylation. This shows the potential total delta-9 THC content from the sum of delta-9 THC and THCA, reported on a dry weight basis. The post-decarboxylation value of delta-9 THC can be calculated using a chromatograph technique with heat, like gas chromatography, which converts THCA. This test calculates the potential total delta-9 THC in a sample. The total delta-9 THC can also be calculated using a liquid chromatograph technique, which keeps THCA intact. This technique uses the conversion: $[\text{Total delta-9 THC} = (0.877 \times \text{THCA}) + \text{delta-9 THC}]$. This test calculates the potential total delta-9 THC in a sample.

§300.102. Applicability of Other Rules and Regulations.

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

(1) Chapter 217, Subchapter C of this title (relating to Rules for the Manufacture of Frozen Desserts);

(2) Chapter 229, Subchapter D of this title (relating to Regulation of Cosmetics);

(3) Chapter 229, Subchapter F of this title (relating to Production, Processing, and Distribution of Bottled and Vended Drinking Water);

(4) Chapter 229, Subchapter G of this title (relating to Manufacture, Storage, and Distribution of Ice Sold for Human Consumption, Including Ice Produced at Point of Use);

(5) Chapter 229, Subchapter L of this title (relating to Licensure of Food Manufacturers, Food Wholesalers, and Warehouse Operators);

(6) Chapter 229, Subchapter N of this title (relating to Current Good Manufacturing Practice and Good Warehousing Practice In Manufacturing, Packing, Or Holding Human Food);

(7) Chapter 229, Subchapter O of this title (relating to Licensing of Wholesale Distributors of Nonprescription Drugs--Including Good Manufacturing Practices);

(8) Chapter 229, Subchapter W of this title (relating to Licensing of Wholesale Distributors of Prescription Drugs--Including Good Manufacturing Practices);

(9) Chapter 229, Subchapter X of this title (relating to Licensing of Device Distributors and Manufacturers); and

(10) Chapter 229, Subchapter GG of this title (relating to Sanitary Transportation of Human Foods).

§300.103. Inspections.

(a) Authorized employees of the department or the Texas Alcoholic Beverage Commission, after showing proper credentials to the owner, operator, or person in charge, may:

(1) enter the premises at reasonable times, conduct inspections, collect samples, and take photographs to determine compliance with this chapter and Texas Health and Safety Code (HSC) Chapters 431 and 443;

(2) enter a vehicle being used to transport or hold a 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, repackaged, sold, or held, for introduction into commerce must undergo inspection to determine if the consumable hemp product is:

(1) adulterated or misbranded; or

(2) manufactured, processed, held, distributed, packed, or sold in violation of this chapter or HSC Chapters 431 and 443.

(c) An inspection of a facility where a consumable hemp product is being manufactured, processed, packed, or held for introduction into commerce under subsection (b) of this section must 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 21 United States Code (U.S.C.) §§355, 360i, or 360j.

(d) The inspector must start and complete the inspection under subsection (b) of this section with reasonable promptness.

§ 300.104. Manufacturing and Processing of Hemp Products for Smoking

The manufacturing and processing of consumable hemp products for smoking is prohibited.

Source Note: The provisions of this §300.104 adopted to be effective August 2, 2020, 45 TexReg 5195; amended to be effective July 5, 2023, 48 TexReg 3504

TITLE 25	HEALTH SERVICES
PART 1	DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 300	MANUFACTURE, DISTRIBUTION, AND RETAIL SALE OF CONSUMABLE HEMP PRODUCTS
SUBCHAPTER B	MANUFACTURE, PROCESSING, AND DISTRIBUTION OF CONSUMABLE HEMP PRODUCTS

§300.201. Application for License or Renewal.

(a) A person must hold a consumable hemp products license issued by the department before engaging in manufacturing or processing of consumable hemp products. A person must hold a wholesaler license per Texas Health and Safety Code (HSC) Chapter 431 before engaging in the distribution of consumable hemp products.

(b) A person must apply for a consumable hemp products license by submitting an application to the department for each location engaged in manufacturing or processing consumable hemp products. The application must include:

(1) a legal description of each location, including the global positioning system coordinates for the perimeter of each location:

(A) where the applicant intends to manufacture or process consumable hemp products; and

(B) where the applicant intends to store consumable hemp products;

(2) written consent from the applicant or property owner, if the applicant is not the property owner, for the department, the Department of Public Safety, Texas Alcoholic Beverage Commission, and any other state or local law enforcement agencies to enter all premises where consumable hemp is manufactured, processed, or delivered for physical inspection or to ensure compliance with this chapter; and

(3) a fingerprint-based criminal background check from each applicant at the applicant's expense.

(c) If the applicant has been convicted of a felony relating to a controlled substance under federal law or the law of any state within 10 years before the date of application, the department must not issue a consumable hemp products license under this subchapter.

(d) If the department receives information that a license holder has been convicted of a felony relating to a controlled substance under federal law or the law of any state within 10 years before the license was issued, the department must revoke the consumable hemp products license.

(e) A person holding a consumable hemp products license under this subchapter must undergo a fingerprint-based criminal background check at the person's own expense.

(f) Applications must contain the following information:

(1) the name of the license applicant;

(2) the business name, if different from the applicant's name, and any other names under which the firm does business, if applicable;

(3) the mailing address of the business;

(4) the street address of the facility;

(5) the primary business contact telephone number;

(6) the personal email address of the applicant; and

(7) the email address of the business, if different than the applicant's email address.

(g) If a person owns or operates two or more facilities, each facility must have a separate license with its own application form, listing the name and address of each facility.

(h) Applicants must submit an application for a consumable hemp products license request under this subchapter electronically through www.Texas.gov. The department is authorized to collect fees to recover costs associated with application and renewal application processing through www.Texas.gov.

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

(j) Applicants must provide any additional information required by the department, as specified on the application forms.

(k) The facility must display the consumable hemp products license issued by the department in an obvious and conspicuous public location.

§300.202. License Term and Fees.

(a) A consumable hemp product license is valid for one year from the date displayed on the license and must be renewed annually. An expired license is not current or valid. A person must not process hemp or manufacture a consumable hemp product without a valid license.

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

(1) is eligible to obtain a license under §300.201 of this subchapter (relating to Application for License or Renewal);

(2) submits a license fee to the department;

(3) does not owe outstanding fees to the department;

(4) possesses testing results of consumable hemp products before manufacture, distribution, or sale into commerce, and provides those testing results upon department request;

(5) has not been convicted of a felony relating to a controlled substance under federal law or the law of any state in the 10 years before the date of renewal of the license;

(6) submits a complete application; and

(7) has not had a consumable hemp products license revoked for sale to a minor in the preceding five years from the date on which an application is submitted to the department.

(c) Fees.

(1) Before manufacturing or processing consumable hemp products, a license holder must pay a fee of \$10,000 per facility. License renewal fees are \$10,000 per facility.

(2) For each facility, a license holder must pay:

(A) a \$10,000 fee for an amendment to a new license due to a change of ownership of the licensed facility; or

(B) a \$125.00 fee for any amendment during the licensure period due to minor changes, such as change of location, change of name, or change of address.

(3) Fees are not prorated.

(4) A person who files a renewal application after the expiration date of the current license must pay an additional delinquency fee of \$1,000.

(d) An application for an amendment of a consumable hemp product license is complete when the department has received, reviewed, and found acceptable the application information and fee required by subsection (c) of this section.

(e) An initial and renewal application for a consumable hemp product license must be processed in the following time periods:

(1) the first time period of 45 calendar days begins on the date the department receives a completed application. If the department receives an incomplete application, the period ends on the date the department issues a written notice that the application is incomplete. The department must issue the written notice within 60 calendar days after receiving the incomplete application and describe the specific information or fee required before the application is considered complete;

(2) the second time period of 45 calendar days begins on the date the department receives a completed application and ends on the date the department issues the license or issues a written notice that the application is being proposed for denial; and

(3) the third time period of 135 calendar days begins on the date the department issues the written notice to the applicant as described in paragraph (1) of this subsection. If the applicant fails to submit the requested information or fee within this period, the department considers the application withdrawn.

(f) Reimbursement of fees:

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

(2) if the department finds that good cause does not exist for exceeding the established periods, the request shall be approved, and the department shall notify the applicant in writing of the approval of the reimbursement within 30 business days after the department's decision.

§300.203. Access to Records.

(a) A person who is required to maintain records under this chapter or 21 United States Code (U.S.C.) §360i or §360j must maintain records on site for immediate inspection. Upon request by the department or the Texas Alcoholic Beverage Commission, the person must provide access to records for review or copying to verify that consumable hemp products are being produced in accordance with United States Department of Agriculture under 7 U.S.C. Chapter 38, Subchapter VII, or Texas Agriculture Code Chapter 121.

(b) A person regulated under Texas Agriculture Code Chapter 122 must provide the department with test results of hemp or hemp products upon request. These results must show that the total delta-9 tetrahydrocannabinol concentration is not more than 0.3 percent on a dry weight basis.

(c) Records described in this chapter must be maintained for a period of no less than three years after the date the records are created.

(d) A consumable hemp manufacturer or processor must maintain the following records, as applicable:

(1) certificate of analysis (COA) of raw hemp and hemp ingredients in accordance with §300.301(b)(1) - (3) and §300.301(c) of this chapter (relating to Testing Required);

(2) COA of finished hemp products by batch number;

(3) source of ingredients, including:

(A) receiving records with address and contact information from suppliers, distributors, warehouses, or any person engaged in the business of making a consumer product directly or indirectly; or

(B) licensing documentation, if applicable, from the supplier's respective hemp or food regulating authority;

(4) batch production records;

(5) recalled product information;

(6) consumer complaints;

(7) other records required by the department, including corrective action logs, destruction logs, equipment calibration records, or other accurate reproductions of the original records, or electronic records; and

(8) master production records.

(e) Records must contain actual values and observations. Records must be accurate, permanent, legible, and created concurrently with performance of the activity documented. Records can be electronic. Records must be detailed enough to provide a history of work performed, and include:

(1) the name and, if more than one, the location of the plant or facility;

(2) the date and time of the documented activity

(3) the signature or initials of the person performing the activity; and

(4) the identity of the product and the batch number.

§300.204. Master Production Records.

(a) To ensure uniformity from batch to batch, one person must prepare, date, and sign with full handwritten signature, the master production records for each

consumable hemp product, including batch size. A second person must independently check, date, and sign these records. The preparation of master production and control records must be described in a written procedure that the firm must follow.

(b) Master production records must include:

- (1) the name and weight or measure of each ingredient;
- (2) a complete list of ingredients;
- (3) a statement of any calculated excess of a by-product; and
- (4) complete manufacturing instructions and specifications.

§300.205. Batch Production Records.

Batch production records must be prepared for each batch of consumable hemp product produced and must include complete information regarding each batch. These records must include, if applicable:

- (1) the appropriate master product record, checked for accuracy, dated, and signed; and
- (2) documentation that each step in the manufacture, processing, packaging, or holding of the batch was accomplished, including:
 - (A) dates;
 - (B) identity of individual major equipment and lines used;
 - (C) weight and measure of ingredients;
 - (D) in-process results;
 - (E) laboratory control results, if applicable;
 - (F) inspection of the packaging and labeling area before and after use;
 - (G) statement of the actual yield;
 - (H) complete labeling records, including copies of all labeling used;
 - (I) any sampling performed;
 - (J) any investigation conducted;

(K) any destruction of tetrahydrocannabinol;

(L) any rework conducted; and

(M) certificate of analysis of hemp or hemp derivative used in the manufacture of a consumable hemp product.

§300.206. Raw Materials and Ingredients.

(a) All raw materials and ingredients must come from approved sources.

(b) All raw materials and ingredients must be clearly identified to allow for appropriate traceability. Identification includes:

(1) name of raw material or ingredient;

(2) batch or lot number from original package;

(3) date the ingredient was manufactured;

(4) date the ingredient was received at the facility;

(5) expiration, re-test, or use-by date; and

(6) total delta-9 THC content concentration level on a dry weight basis.

(c) Substances containing total delta-9 THC levels above the acceptable hemp THC level may not be transported into Texas for further processing within Texas.

§300.207. Recalls.

(a) Recall Procedures. All facilities engaged in the manufacture, processing, distribution, or retail sale of consumable hemp products must maintain written recall procedures. The recall procedures must describe the steps, assign responsibility, and include at a minimum:

(1) identification of recalled products;

(2) immediate removal and segregation of recalled products from sale and active inventory;

(3) return holding, or disposal of recall products; and

(4) notification to the public about any hazards presented by the product to protect public health.

(b) Recall plan. Manufacturers, distributors, or processors must establish a recall plan. The recall plan must include the following procedures:

(1) directly notify the direct consignees of the hemp product, including how to return or dispose of the affected product;

(2) notify the public about any hazards presented by the product to protect public health;

(3) conduct effectiveness checks to verify that the recall is carried out; and

(4) dispose of recalled product appropriately by reprocessing, reworking, diverting to a safe use, or destroying the product.

§300.208. Complaints.

(a) Each manufacturer or processor must maintain complaint files relating to product safety. Each manufacturer or processor must establish and maintain procedures for receiving, reviewing, and evaluating complaints. The procedures must ensure that:

(1) all complaints are processed in a uniform and timely manner;

(2) oral complaints are documented upon receipt; and

(3) complaints are evaluated to determine whether the complaint represents an event that must be reported to the FDA and the department.

(b) Each manufacturer or processor must review and evaluate all complaints to determine whether an investigation is necessary. All safety-related complaints must be investigated. If no investigation is made, the manufacturer or processor must maintain a record that includes the reason for not investigating and the name of the individual responsible for the decision.

(c) Any complaint about labeling or packaging not meeting specifications must be reviewed, evaluated, and investigated, unless a similar complaint has already been investigated and another investigation is not needed.

(d) The record of the investigation must include:

(1) the name of the product;

(2) the date the complaint was received;

(3) the batch number and batch date of product used;

(4) the name, address, and phone number of the complainant;

- (5) the nature and details of the complaint;
- (6) the dates and results of the investigation;
- (7) any corrective action taken; and
- (8) any reply to the complainant.

TITLE 25	HEALTH SERVICES
PART 1	DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 300	MANUFACTURE, DISTRIBUTION, AND RETAIL SALE OF CONSUMABLE HEMP PRODUCTS
SUBCHAPTER C	TESTING OF CONSUMABLE HEMP PRODUCTS

§300.301. Testing Required.

(a) Before a hemp plant is processed or otherwise used in the manufacture of a consumable hemp product, a representative sample must be tested to determine:

- (1) the concentration and identity of the cannabinoids, including all acids in the plant;
- (2) the presence and quantity of heavy metals, pesticides, microbial contamination, and other substances prescribed by the department;
- (3) the presence and concentration of d-9 THC, total d-9 THC, and total THC; and
- (4) a total delta-9 tetrahydrocannabinol concentration of 0.3% or less on a dry weight basis.

(b) Before a consumable hemp product, including hemp-derived ingredients used for further processing into another consumable hemp product, is sold at retail, distributed, or otherwise introduced into commerce in this state, a representative sample must be tested to determine:

- (1) the presence, concentration, and identity of cannabinoids;
- (2) the presence and concentration of d-9 THC, total d-9 THC, and total THC;
- (3) the presence and quantity of residual solvents, heavy metals, pesticides, and harmful pathogens; and
- (4) the total delta-9 tetrahydrocannabinol concentration is 0.3% or less on a dry weight basis.

(c) A certificate of analysis (COA) documenting tests conducted under this subchapter must:

- (1) be made available to the department upon request in an electronic format before manufacture, processing, or distribution into commerce; and
- (2) include measurement of uncertainty analysis parameters.

(d) The COA must contain, at a minimum, the following information:

- (1) laboratory name, address, and contact information;
- (2) hemp cultivator, hemp processor, or hemp manufacturer's name and address;
- (3) sampler identification;
- (4) sample identifying information, including matrix type;
- (5) lot identification number of sample;
- (6) sample received date and the dates of sample analyses and corresponding testing results;
- (7) units of measure;
- (8) analytical methods, analytical instrumentation used, and corresponding limits of detection (LOD) and limits of quantitation (LOQ);
- (9) expiration date;
- (10) QR code on the COA verifying the authenticity of testing conducted at an accredited laboratory;
- (11) measurement of uncertainty analysis parameters; and
- (12) results of all requested analyses performed for the sample, including percentage of delta-9 THC, total delta-9 THC, and total THC per container.

(e) It is a violation if a person forges, falsifies, or alters the results of a laboratory test authorized or required by this chapter. Consumable hemp products found in violation of this subsection must be retested and are subject to detention or embargo under Texas Health and Safety Code §431.048.

(f) Expired COAs are not valid. Consumable hemp products with expired COAs must be retested and are subject to detention or embargo under Texas Health and Safety Code §431.048.

§300.302. Sample Analysis of Consumable Hemp Products.

(a) This chapter does not apply to low-THC cannabis regulated under Texas Health and Safety Code Chapter 487.

(b) Regardless of any other law, a person must not sell, offer for sale, possess, distribute, or transport a consumable hemp product in this state if the consumable hemp product contains any material extracted or derived from the plant Cannabis

sativa L., other than from hemp produced in compliance with 7 United States Code (U.S.C.) Chapter 38, Subchapter VII, and:

(1) a representative sample of the consumable hemp product has been tested by an accredited laboratory and found to have a total delta-9 THC concentration of 0.3% or less on a dry weight basis, that, when reported with the accredited laboratory's measurement of uncertainty, produces a distribution or range that includes a result of 0.3% or less; and

(2) testing results are provided to the department upon request.

(c) The department must conduct random testing of consumable hemp products at various retail and other facilities that sell or distribute products to ensure the products:

(1) do not contain harmful ingredients;

(2) are produced in compliance with 7 U.S.C. Chapter 38, Subchapter VII; and

(3) have a total delta-9 THC content concentration level on a dry weight basis, that, when reported with the accredited laboratory's measurement of uncertainty, produces a distribution or range that includes a result of 0.3% or less.

(d) Upon request by the department, the manufacturer, processor, distributor, or retailer of consumable hemp products must provide representative raw or finished consumable hemp product samples to the department. These samples must be provided at the licensee's or registrant's expense.

§300.303. Provisions Related to Testing.

(a) A consumable hemp product that exceeds the acceptable hemp THC level or is adulterated in a manner harmful to human consumption must not be sold at retail or otherwise introduced into commerce in this state.

(b) A hemp manufacturer, processor, distributor, and retailer must provide the results of testing required by §300.301 of this subchapter (relating to Testing Required) to the consumer, the Texas Alcoholic Beverage Commission, and department upon request.

(c) A license holder must not use an independent testing accredited laboratory unless the license holder:

(1) has no ownership interest in the accredited laboratory; or

(2) holds 10 percent or less ownership interest in the accredited laboratory if the accredited laboratory is a publicly traded company.

(d) A manufacturer, processor, or retailer must pay the costs of raw and finished hemp product testing in an amount prescribed by the accredited laboratory selected by the license holder.

(e) The department may require that a copy of the test results be sent directly to the department.

(f) A manufacturer, processor, and retailer must retain results from samples for at least three years from the date that testing results are received.

(g) A manufacturer and processor of consumable hemp products must conduct sampling and testing using acceptance criteria determined by the department.

(h) A manufacturer, processor, and retailer must ensure all products are tested for the most current list of analytes maintained by the department.

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SUBCHAPTER D	RETAIL SALE OF CONSUMABLE HEMP PRODUCTS

§300.402. Packaging and Labeling Requirements.

(a) All consumable hemp products marketed as containing cannabinoids must, in addition to the requirements of §300.102 of this chapter (relating to Applicability of Other Rules and Regulations), be labeled in the manner provided by this section with the following information:

- (1) batch number;
- (2) batch date;
- (3) product name;
- (4) name of the product's manufacturer or processor;
- (5) telephone number and email address of manufacturer or processor;

(6) a uniform resource locator (URL) that provides or links to a certificate of analysis (COA) for the product or each hemp-derived ingredient of the product, including the amount of cannabinoid in each serving or unit of the product, the amount of total THC, and total delta-9 THC. The URL must:

(A) be conspicuously marked; and

(B) directly link to a webpage where the required COA may be found in three or fewer steps; and

- (7) recommended serving size in milligrams and servings per container.

(b) Labels must include the following specific warnings:

(1) keep out of reach of children;

(2) product may contain tetrahydrocannabinol (THC) and can cause a user to fail a drug test;

(3) all THCs have psychoactive properties;

(4) pregnant or nursing women should consult a healthcare provider before use; and

(5) this product has not been evaluated by the FDA.

(c) The label required by this section must appear on the outer packaging of each product intended for individual retail sale.

§300.403. Retail Sale of Out-Of-State Consumable Hemp Products.

A person selling consumable hemp products in Texas, that are processed or manufactured outside of Texas must comply with this chapter, and upon request, submit to the department evidence that the products were processed or manufactured in another state or a foreign jurisdiction in compliance with:

(1) a state or tribal or jurisdiction's plan approved by the United States Department of Agriculture under 7 United States Code (U.S.C.) §1639p;

(2) a plan established under 7 U.S.C. §1639q if that plan applies to the state or jurisdiction; or

(3) the laws of a foreign jurisdiction if the products are tested in accordance with §300.301 of this chapter (relating to Testing Required), comply with acceptable hemp THC levels, and comply with federal regulations.

§300.404. Transportation and Exportation of Consumable Hemp Products Out of State.

Consumable hemp products may be legally transported across state lines and exported to foreign jurisdictions in a manner consistent with federal law and the laws of respective foreign jurisdictions. Substances containing total delta-9 THC levels above the acceptable hemp THC level may not be transported into Texas for further processing within Texas.

§300.405. Packaging Requirements.

Before selling or distributing a consumable hemp product, the product must be prepackaged or, at the time of sale, placed in packaging or a container that is:

(1) tamper-evident;

(2) child resistant; and

(3) resealable, if the product contains multiple servings or includes multiple products purchased in one transaction, while keeping the child-resistant mechanism intact.

§300.406. Packaging and Labeling Control.

(a) There must be clear written procedures describing in sufficient detail the process for receipt, identification, storage, handling, and examination of labeling and packaging materials.

(b) Labeling and packaging materials must be examined upon receipt and before use in packaging or labeling of a consumable hemp product. All labels and packaging material meeting appropriate written criteria must be approved by a qualified individual as defined in 25 TAC §229.211(54) (relating to Definitions) and released for use. Any labeling or packaging materials that do not meet such criteria must be rejected to prevent use in unsuitable operations.

(c) Records must be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination, and whether accepted or rejected.

(d) Obsolete or rejected labeling and other packaging must be destroyed.

(e) Labeling materials issued for a batch must be carefully examined for identity and conformity to the labeling specified in the master production records.

(f) Labeling not currently being applied must be stored in a manner to prevent mix-ups with active labeling and ensure appropriate use.

§300.407. Misleading Consumable Hemp Packaging.

A person must not sell or offer for sale a consumable hemp product that contains or is marketed as containing hemp-derived cannabinoids in a package that depicts any statement, artwork, or design that would likely mislead a person to believe:

- (1) the package does not contain a hemp-derived cannabinoid; or
- (2) the product is intended for medical use.

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SUBCHAPTER E	REGISTRATION FOR RETAILERS OF CONSUMABLE HEMP PRODUCTS

§300.501. Registration Required for Retailers of Certain Products.

(a) This chapter does not apply to:

(1) low-THC cannabis regulated under Texas Health and Safety Code Chapter 487; or

(2) products approved by the FDA, or recognized by the FDA under 21 Code of Federal Regulations Part 182, Substances Generally Recognized as Safe (GRAS).

(b) A person must not sell consumable hemp products at retail in Texas unless the person registers each location with the department. This includes any location owned, operated, or controlled by the person where consumable hemp products are sold.

(c) A person is not required to register with the department under subsection (b) of this section 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.

§300.502. Application.

(a) A person must register under this subchapter by submitting an application in the manner prescribed by the department.

(b) The owner, operator, or owner designee must submit an application that contains the following information:

(1) the name under which the business is operated;

(2) the mailing address of the facility;

(3) the street address of each location;

(4) the primary business contact telephone number;

(5) the phone number for each location;

(6) the primary business email address; and

(7) the written consent from the applicant or property owner, if the applicant is not the property owner, for the department, Department of Public Safety, Texas Alcoholic Beverage Commission, and other state or local law enforcement agencies to enter all premises where consumable hemp is manufactured, processed, sold, or delivered for physical inspection or to ensure compliance with this chapter.

(c) A retail hemp registration is valid for one year from the date displayed on the registration and must be renewed annually. An expired registration is not current or valid. A person must not sell at retail or offer to sell a consumable hemp product without a valid registration.

(d) An initial and renewal application for a retail hemp registration must be processed in the following time periods.

(1) The first time period of 45 calendar days begins on the date the department receives a completed application. If the department receives an incomplete application, the period ends on the date the department issues a written notice that the application is incomplete. The department must issue the written notice within 60 calendar days after receiving the incomplete application and describe the specific information or fee required before the application is considered complete.

(2) The second time period of 45 calendar days begins on the date the department receives a completed application and ends on the date the department issues the license or issues a written notice that the application is being proposed for denial.

(3) The third time period of 135 calendar days begins on the date the department issues the written notice to the applicant as described in paragraph (1) of this subsection. If the applicant fails to submit the requested information or fee within this period, the department considers the application withdrawn.

(e) Proof of registration from the department must be prominently displayed in a conspicuous location visible to the public.

(f) Applicants must submit an application for registration electronically through www.Texas.gov.

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

(1) A retail hemp registration or renewal fee of \$5,000 for each location is required before the sale of consumable hemp product.

(2) A person who files a renewal application after the expiration date of the current registration must pay an additional delinquency fee of \$1,000.

(3) A \$125 fee is required for any amendment during the registration period due to minor changes, such as change of location, change of name, or change of address.

(4) Fees are not prorated.

(h) Reimbursement of fees:

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

(2) if the department finds that good cause does not exist for exceeding the established periods, the request shall be approved, and the department shall notify the applicant in writing of the approval of the reimbursement within 30 business days after the department's decision.

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SUBCHAPTER F ENFORCEMENT

§300.601. Violation of Department License or Registration Requirement.

(a) A person commits a violation if the person manufactures, processes, distributes, sells, or otherwise introduces a consumable hemp product into commerce without a license or registration required by the department under:

(1) §300.201 of this chapter (relating to Application for License or Renewal) for manufacturing, processing, or distribution of consumable hemp products; or

(2) §300.502 of this chapter (relating to Application) for the retail sale of consumable hemp products.

(b) Each day a violation continues or occurs counts as a separate violation when calculating an administrative penalty.

§300.602. Prohibited Acts.

The following acts, and the causing of the following acts, within Texas are unlawful and prohibited:

(1) introducing hemp-derived cannabinoids into commerce that do not conform to the provisions of this chapter;

(2) engaging in the packaging or labeling of packaged consumable hemp products if there is affixed to the consumable hemp product a label that does not conform to the provisions of this chapter;

(3) refusing to permit the following:

(A) entry or inspection;

(B) taking of a sample;

(C) access to or copying of any record as authorized by Texas Health and Safety Code §431 and this chapter; or

(D) photography for inspection purposes; and

(4) refusing to permit inspection, which includes impeding the inspection, aggressive behaviors, using foul language, or exhibiting threatening behavior.

§300.603. Detained or Embargoed Article.

The department must attach a tag or other appropriate marking to an article that is a food, drug, device, cosmetic, or consumer commodity that gives notice that the article is, or is suspected of being, adulterated or misbranded. The department tags or marks any detained or embargoed article if the department finds or has probable cause to believe the article:

(1) is adulterated;

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

(3) is in violation of Texas Health and Safety Code §431.084, §431.114, or §431.115.

§300.604. Destruction of Article.

(a) The department may request court-ordered destruction of a sampled, detained, or embargoed consumable hemp product if the department finds the article is misbranded or adulterated.

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

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

(d) If the article is being destroyed in whole or in part due to THC content that meets the definition of a controlled substance, the department may refer to the appropriate law enforcement agency. The article must be destroyed per department specifications and documented as such, unless law enforcement communicates an intent to use the article for evidence.

§300.605. 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; and

(3) the adulteration or misbranding can be corrected by proper labeling or processing.

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

§300.606. Administrative Penalty.

(a) The department may impose an administrative penalty against a person who violates this chapter.

(b) The department must notify a retailer of consumable hemp products of a potential violation and provide the registrant an opportunity to resolve unintentional or negligent violations after being notified by the department.

(c) The department assesses 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) the efforts to correct the violation; and

(5) any other matter that justice may require in relation to the violation.

(d) If the department determines that a violation has occurred, the department must issue a notice of violation. The notice must state the facts on which the determination is based. The notice must include an assessment of the penalty.

(e) The notice of violation must be in writing and be sent to the license holder or registrant 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 of 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 business days after the date the person receives the notice of violation, 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 issues an order imposing the recommended penalty.

(h) If the person charged with the violation does not respond in writing within 20 business days after the date the person receives the notice of violation, the

department may determine that a violation occurred and assesses the penalty. The department must issue an order requiring that the person pay the penalty.

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

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SUBCHAPTER G RESTRICTIONS ON SALE TO MINORS

§300.701. Restriction on Sale to Minors.

(a) A person is prohibited from delivering, selling, or offering to sell a consumable hemp product to a minor.

(b) A person who sells CHP must verify each purchaser's age by reviewing a valid proof of identification before completing the sale of any CHP.

(c) A valid proof of identification may include a driver's license issued by Texas or another state, a passport, or an identification card issued by a state or government agency. A valid proof of identification must meet the following criteria:

(1) include a physical description and a photograph that matches the person's appearance;

(2) provide the individual's date of birth;

(3) be issued by a government agency; and

(4) is not expired.

§300.702. Grounds for Consumable Hemp License or Retail Hemp Registration Revocation.

(a) The department may, after providing an opportunity for a hearing, revoke a consumable hemp license or retail hemp registration after determining the license or registration holder, or an employee, sold, served, or delivered a consumable hemp product to a minor.

(b) An exception to subsection (a) of this section exists where the minor falsely represents to be at least 21 years of age by displaying an apparently valid proof of identification.

(c) The department may impose penalties and pursue additional enforcement actions as provided under Texas Health and Safety Code Chapters 431 and 443.