



LEGALINK

INTERNATIONAL BUT PERSONAL

CANNABIS REGULATION
AND CANNABIS
DERIVED PRODUCTS



INTRODUCTION

As more jurisdictions around the world move to legalize various forms of cannabis, including hemp and CBD products, recreational marijuana, and medical marijuana, the global cannabis industry continues to blaze forward. But changing and even inconsistent laws and an evolving regulatory environment have created legal uncertainties and tensions in the development of the industry and marketplace. This booklet aims to provide practitioners a summary reference for cannabis laws and regulations in various jurisdictions across the globe. Practitioners should note that because cannabis laws are quickly evolving, through the legislative process, ballot initiatives and regulatory rule implementations and changes, each jurisdiction's most recent cannabis laws and regulations should be reviewed and assessed.

A QUICK PRIMER ON CANNABIS BASICS

Cannabis vs. Marijuana vs. Hemp

Cannabis refers to a genus of plants that has three species - indica, sativa, and ruderalis. Marijuana and hemp are both cannabis. Despite popular misconception, marijuana and hemp are not different species of cannabis.

Marijuana, in the common parlance, is cannabis that, when consumed, results in a "high." The "high" in marijuana is produced as a result of high tetrahydrocannabinol or THC content. Hemp, again in common usage, does not cause intoxication because it has low levels of THC.

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Some jurisdictions around the world still do not distinguish between marijuana and hemp. For example, for decades, the federal government in the U.S. did not distinguish between hemp and marijuana or the level of THC content in either – both were illegal cannabis and a controlled “Schedule I” drug.

As cannabis laws and policy have changed over the years, now, in the U.S. and, as applicable, in other jurisdictions, the legal difference between marijuana and hemp is often based upon THC content level. In the U.S., again by way of further example, the Agriculture Improvement Act of 2018 defines legal hemp as “Plant Cannabis sativa L. and any part of that plant, including cannabinoids with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” Thus, under federal law in the U.S., cannabis that has no more than 0.3% THC is legal hemp, but cannabis that contains more than 0.3% remains illegal marijuana. Each jurisdiction’s definitions for each should, of course, be consulted to determine whether hemp and marijuana are distinguished from one another and where the lines of cannabis legality or illegality are drawn.

THC vs. CBD

THC and CBD are both cannabinoids found in cannabis. A cannabinoid is a naturally occurring compound that reacts with cannabinoid receptors found in our nervous system that are part of our endocannabinoid system, involved in appetite, mood, and sensing pain.

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As noted, THC is a psychoactive cannabinoid in marijuana that produces a “high.” CBD, or cannabidiol, is a non-psychoactive cannabinoid that may have some health benefits. But more studies are needed. CBD can be derived or extracted from hemp and marijuana. Many CBD products are derived from hemp, containing low levels of THC and higher levels of CBD. Whether CBD or CBD products are legal in any particular jurisdiction will be driven by legal definitions and parameters established by applicable regulatory authorities.

U.S.A. - TEXAS BELL NUNNALLY

General

Although marijuana remains illegal in Texas, Texas cannabis laws continue to slowly evolve. Texas has an extremely limited “medical marijuana” law under the Texas Compassionate Use Act, originally enacted in 2015 and expanded in 2019 to cover additional (but still very restricted) medical conditions, amongst other things. The Texas Compassionate Use Act permits the regulated prescription of low-THC cannabis containing not more than 0.5% THC for the treatment of only epilepsy, seizure disorders, multiple sclerosis, spasticity, amyotrophic lateral sclerosis, autism, terminal cancer or an incurable neurodegenerative disease.

Recreational marijuana remains outlawed in the Lone Star State, but Texas legalised industrial hemp in 2019, following the passage of the Agriculture Improvement Act of 2018, commonly known as the 2018 Farm Bill, at the federal level, which paved the way for state-implemented hemp programmes in the United States. Legal hemp in Texas is essentially defined as cannabis with no more than 0.3% THC. Likewise, a robust and still developing regulatory system surrounds Texas’s hemp programme, which covers the cultivation, manufacturing and sale of hemp and hemp derivatives like CBD and related products.

1. [What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in Texas?](#)

Marijuana, recreational or otherwise, in Texas remains illegal, with a very limited exception for low-THC cannabis under the Texas Compassionate Use Act.

The Texas Compassionate Use Act permits limited prescriptions of low-THC cannabis containing no more than 0.5% THC by qualified, licensed, registered physicians to registered patients for the treatment of only epilepsy, seizure disorders, multiple sclerosis, spasticity, amyotrophic lateral sclerosis, autism, terminal cancer or an incurable neurodegenerative disease. The Texas Compassionate Use Act is codified in Chapter 487 of the Texas Health and Safety Code and in Chapter 169 of the Texas Occupations Code.



The Texas Department of Public Safety (DPS) administers the Act and the Compassionate Use Programme (CUP) in Texas. See Texas Administrative Code, Title 37, Part 1, Chapter 12. The DPS maintains a detailed FAQs page regarding the CUP on its website. Notably, dispensary licensing has been limited, with only three licensed dispensary companies in Texas.

On 10th June 2019, Texas Governor Abbott signed House Bill (HB) 1325 into law in Texas. HB 1325 authorises the production, manufacture, inspection and retail sale of hemp crops and products, including CBD, in Texas, subject to statutory and regulatory requirements. HB 1325 adopted the federal 2018 Farm Bill's definition of hemp:

“Plant *Cannabis sativa* L. and any part of that plant, including ... cannabinoids ... with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”

See Tex. Agricultural Code. § 121.001.

Although hemp and marijuana are both strains of cannabis, legal hemp in Texas, and federally, may not exceed a concentration of 0.3% of tetrahydrocannabinol (THC). Under federal and Texas law, legal hemp is now effectively carved out of the definitions of marijuana, which remains an illegal controlled substance in Texas and under federal law.

A consumable hemp product in Texas is a food, drug, device or cosmetic that contains industrial hemp or hemp-derived cannabinoids, such as CBD, and must not contain more than 0.3% THC concentration to be legal. See Tex. Health & Safety Code § 443.001(1). Significantly, low-THC cannabis is not a consumable hemp product. Retailers of consumable hemp products, including CBD, must be registered in accordance with Texas law and comply with all Texas Department of State Health Services (DSHS) adopted hemp programme rules and regulations, which were enacted earlier in 2020 and became effective as of 2nd August 2020. Manufacturers, processors and distributors must be licensed in accordance with DSHS rules. See Tex. Health & Safety Code §§ 443.101-443.105. DSHS has implemented rules for random testing to ensure compliance with required THC limits. See Tex. Health & Safety Code §§ 443.101.151-443.152. Retailers may possess, transport or sell a consumable hemp product that becomes part of their inventory, but must be registered as required. See Tex. Health & Safety Code §§ 443.201-443.207. Applicable DSHS rules are found in the Texas Administrative Code, Title 25, Part 1, Chapter 300.



The FDA (at the federal level) has a different stance on CBD in food products, determining that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food to which THC or CBD has been added.

HB 1325 establishes a framework for a hemp growing programme in Texas, pursuant to the 2018 Farm Bill, which authorised states to develop plans for the commercial production of hemp. The Texas Department of Agriculture (TDA) developed such a hemp plan for Texas, and the USDA approved it in January 2020. The TDA launched the permit application and licensing process for hemp cultivation in March 2020 and began issuing licences soon thereafter.

The TDA's adopted rules, found in the Texas Administrative Code, Title 4, Part 1, Chapter 24, for the Texas hemp programme may be accessed on the TDA's website, along with detailed FAQs covering various aspects of the programme and rules. The TDA is charged with administering the Texas hemp programme pursuant to Chapter 122 of the Texas Agriculture Code, which codifies certain portions of HB 1325 related to the cultivation of hemp in Texas. The Texas Agricultural Code and the TDA rules provide for inspections and testing to ensure compliance with acceptable levels of THC. See Chapter 122, Subchapter D, of the Texas Agricultural Code; Texas Administrative Code, Title 4, Part 1, Chapter 24, Subchapter D and Subchapter E.

2. [What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in Texas?](#)

Recreational marijuana remains illegal in Texas.

The Texas Compassionate Use Act only permits the prescription of low-THC cannabis for specific medical conditions that the Texas legislature wrote into the Act, restraining patients and their doctors from utilising cannabis to treat conditions not enumerated by the Texas legislature. Dispensary licensing is also limited under the CUP in Texas, with currently only three licensed dispensary companies state-wide.

Smokable hemp products have recently become an industry flashpoint in Texas.



Section 122.301(b) of the Texas Agriculture Code and Section 443.204(4) of the Texas Health & Safety Code ban the processing and manufacture of hemp products for smoking in Texas.

Section 122.301(b) of the Texas Agricultural Code provides that “A state agency may not authorize a person to manufacture a product containing hemp for smoking, as defined by Section 443.001, Health and Safety Code.” Section 443.001(11) of the Health and Safety Code defines “smoking” as “burning or igniting a substance and inhaling the smoke or heating a substance and inhaling the resulting vapor or aerosol.”

Section 443.204(4) of the Health and Safety Code further provides that “Rules adopted . . . regulating the sale of consumable hemp products must to the extent allowable by federal law reflect the following principles: . . . (4) the processing or manufacturing of a consumable hemp product for smoking is prohibited.”

DSHS rule 300.104 provides that “The manufacture, processing, distribution, or retail sale of consumable hemp products for smoking is prohibited.” 25 Tex. Administrative Code 300.104. Rule 300.104 became effective in early August 2020, after a public comment period. Many in the industry were opposed to this rule because of the stifling impact it would have on the smokable hemp product market in Texas. Additionally, critics also note that the rule goes beyond the statutory prohibition of “processing or manufacturing” of consumable hemp products for smoking found in Section 443.204(4). Section 443.204(4) does not itemize a prohibition on retail sales or distribution of smokable hemp products.

Thus, in August 2020, a group of hemp companies that sell smokable hemp products in Texas filed a lawsuit against DSHS and its Commissioner seeking a declaration that Rule 300.104 is invalid and exceeds statutory authority, a declaration that Section 443.204(4), and Section 122.301(b) unconstitutional under the Texas Constitution and injunctive relief against the enforcement of these provisions. See Cause No. D-1-GN-20-004053, Crown Distributing LLC, America Juice Co. LLC, Custom Botanical Dispensary, LLC, and 1937 Apothecary, LLC v. Texas Department of State Health Services and John Hellerstedt, in his official capacity as Commissioner of the Texas DSHS, before the 345th Judicial District Court, Travis County, Texas. The plaintiffs secured entry of a temporary restraining order against DSHS in August 2020; a temporary injunction will be considered next in the case.



3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in Texas?

See Question 1.

4. Which body is responsible for legislative controls relating to CBD?

See Question 1. DSHS has regulatory authority over consumable hemp products, including CBD. TDA administers the Texas hemp cultivation programme and related rules. DPS administers rules and regulations related to the Texas Compassionate Use Act.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in Texas?

See Question 1. At the federal level, the Food and Drug Administration governs approval of ingestible products like food, as well as medicinal products. The Food and Drug Administration has not yet permitted commercialisation of CBD-containing products in the United States other than prescription drug Epidiolex, which is used to treat seizures.

6. What are the testing specifications in Texas for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Section 443.151 of the Health and Safety Code governs testing of consumable hemp products, including CBD products. Section 443.151(b) provides:

“Before a hemp plant is processed or otherwise used in the manufacture of a consumable hemp product, a sample representing the plant must be tested, as required by the executive commissioner, to determine:

- (1) the concentration of various cannabinoids; and
- (2) the presence or quantity of heavy metals, pesticides, and any other substance prescribed by the department.”



Section 443.151(c) provides:

“Before material extracted from hemp by processing is sold as, offered for sale as, or incorporated into a consumable hemp product, the material must be tested, as required by the executive commissioner, to determine:

- (1) the presence of harmful microorganisms; and
- (2) the presence or quantity of:
 - (A) any residual solvents used in processing, if applicable; and
 - (B) any other substance prescribed by the department.”

As per Section 443.151(d), required testing must be conducted by a laboratory that is accredited by an accreditation body in accordance with International Organization for Standardization ISO/IEC 17025 or a comparable or successor standard to determine the delta-9 tetrahydrocannabinol concentration of the product. A consumable hemp product is not required to be tested as provided above if each hemp-derived ingredient has been tested as specified and does not have a delta-9 tetrahydrocannabinol concentration of more than 0.3%. Health & Safety Code § 443.151(e).

DSHS rules 300.301 – 300.303 further address testing requirements of the department. Rule 300.301 requires:

“(a) All hemp or hemp derivatives used in the manufacture of a consumable hemp product must be tested as appropriate for the product and process by an accredited laboratory to determine:

- (1) the presence and concentration of cannabinoids;
- (2) the presence and concentration of THC; and
- (3) the presence or quantity of residual solvents, heavy metals, pesticides, and harmful pathogens.

(b) A Certificate of Analysis documenting tests conducted under this subchapter shall:

- (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.”



Relevant to CBD oils and other CBD products that may be imported into Texas for retail sale, DSHS rule 300.302(b) mandates:

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

(1) a representative sample of the oil has been tested by an accredited laboratory and found to have a 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 percent or less; and

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

Of special note and concern to all retailers (but equally applicable to Texas manufacturers, processors and distributors) of consumable hemp products, including CBD products, in Texas, whether processed or manufactured in the state of Texas or out of state, DSHS rule 300.302(c) provides for random product testing by DSHS to ensure the products do not contain harmful ingredients, are produced in compliance with the 2018 Farm Bill, and have a 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.

Upon request by the department, the manufacturer, processor, distributor or retailer of consumable hemp products shall provide representative raw or finished consumable hemp product samples to the department, which must be provided at the owner, licence holder, and/or registrant expense. Rules 300.301(d), (e). Upon request by the department, test results are to be provided to the department by manufacturers, processors and distributors. Rule 300.303(b). Registrants (e.g., retailers) are to provide test results upon request of the department or consumers. Rule 300.303(c). Test results are to be maintained for at least three years from the date the results are made available to a licence holder. Rule 300.303(i).



The foregoing answer focuses on CBD as a consumable hemp product only. The TDA has a robust regulatory regime for testing non-consumable hemp in Texas. See Chapter 122, Subchapter D, of the Texas Agricultural Code; Texas Administrative Code, Title 4, Part 1, Chapter 24, Subchapter D and Subchapter E.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Retail sales of consumable hemp products processed or manufactured out of state are governed by Section 443.204 of the Health and Safety Code as well as DSHS rule 300.403. There are no limits on quantity of such out-of-state products, but as per Section 443.204 and rule 300.403, such products must be 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, or in a manner similar to, Section 443.151.

The foregoing answer focuses on CBD as a consumable hemp product only. The TDA has its own rules and regulations governing the sale of out-of-state non-consumable hemp in Texas. See Chapter 122 of the Texas Agriculture Code; Texas Administrative Code, Title 4, Part 1, Chapter 24.

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