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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 continue 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 redueralis. 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.

INTRODUCTION

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 jurisdictions' 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.

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. - NEW YORK
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General

Currently (as of December 2020), New York State's primary body of marijuana law is the New York Compassionate Care Act (NYCCA). The NYCCA regulates New York's medical marijuana programme and provides certified patients with serious medical conditions with employment protections under New York's expansive Human Rights Law.

New York has operated an industrial hemp agricultural research pilot programme since 2015 under the federal 2014 Farm Bill. It will remain in place until the USDA approves a New York hemp cultivation plan under the 2018 Farm Bill (as of 6th July 2020, New York has not submitted a plan). In December 2019, Governor Cuomo signed an amendment to the agriculture and markets law imposing additional regulations on the production and sale of hemp extracts, including CBD. In October 2020, New York published a comprehensive set of draft regulations for the manufacture and sale of hemp-derived CBD.

Under current law, limited protections exist for users of adult-use marijuana in New York. As of August 28, 2019, New York decriminalised possession of small amounts of marijuana statewide, though still punishable as a violation subject to a fine. In New York City, employers are not able to test job applicants for marijuana and THC, outside of certain safety-sensitive jobs. No protections exist for cultivation or sales.

For the past two years New York has tried, and failed, to overhaul its cannabis laws as part of the executive budget process. Governor Cuomo included the Cannabis Regulation and Taxation Act in his draft executive budget. It was stripped out of the budget passed on 31st March 2020, due to the economic impact of COVID-19. If reintroduced next year in similar form, the act will change New York's medical, adult use and hemp laws by centralising their regulation at the newly established Office of Cannabis Management which will "control the manufacture, wholesale, and retail production, distribution, transportation, and sale of cannabis, medical cannabis, and hemp cannabis in the State of New York". It will include multiple new taxes on adult-use marijuana. A similar measure failed in 2019.

New York is also subject to federal law (as covered in the "US – Federal" summary).

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in New York State?

The NYCCA (N.Y. Pub. Health Law §§ 3360 to 3369-E) became law on 5th July 2014 and will expire on 5th July 2021 unless amended or replaced. The law allows medical practitioners to certify patients with serious medical conditions like cancer, HIV, epilepsy or PTSD. Certified patients can obtain a registry card which provides them or their designated caregiver with certain protections. This includes possessing and transporting a 30-day supply of medical marijuana, which cannot be consumed in a public place. Registered patients are recognised as having a disability under New York's Human Rights Law (N.Y. Exec. Law §§ 290 to 301). This entitles patients to certain protection against discrimination, though the law on this has been sparse in New York. However, there is no right to be impaired while at work. The patient's use of medical marijuana may require the employer and employee to work on a reasonable accommodation.

The current law also regulates the sale of medical marijuana, limiting the manufacturing and dispensing of medical marijuana in the state to licensed companies, referred to as registered organisations. These registered organisations are subject to regulations prohibiting them from employing convicted felons, requiring them to manufacture marijuana in an indoor, enclosed, secure facility in New York State, regulating laboratory testing and mandating security measures. Prices are regulated by the Department of Health, though they vary from dispensary to dispensary, and advertising is also regulated (and all but prohibited).

2. What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in New York State?

New York has one of the oldest medical marijuana laws, and no adult-use or recreational marijuana regime. Because of the significant barriers that exist, there are only about 113,000 registered patients in New York, or about 0.5% of the population.

There is also a limited number of registered organisations (it was initially limited to five by regulation, but ultimately expanded to ten). Applications are not currently being accepted, but come with a non-refundable $10,000 fee and a $200,000 registration fee for successful candidates. A registration is valid for two years, is non-transferable and

must be renewed no more than six, and no less than four, months before expiration. Similar fees apply for renewal.

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

See Question 1.

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

In addition to federal-level regulation of CBD (covered in the "US – Federal" section), CBD is regulated under the hemp regulatory framework in New York.

Currently, the only lawful pathway to grow industrial hemp in New York State is through participation in New York's industrial hemp agricultural research pilot programme, which was authorised under the provisions of the 2014 Farm Bill. It is administered by the Department of Agriculture and Markets. New York treats industrial hemp as an agricultural commodity under it Agricultural and Markets Law.

In 2019 New York amended its Agriculture and Markets Law in relation to the cultivation of hemp and regulation of hemp extracts (including CBD). The new law includes a licensing scheme for growers, manufacturers and extractors of cannabinoids, packaging and labelling requirements, and laboratory testing and advertising regulations. The Department is accepting applications from researchers who want to grow industrial hemp for fibre, grain and CBD.

In late 2020 New York published comprehensive proposed regulation for the manufacture, distribution and sale of hemp-derived CBD. Once adopted, these rules will be Part 1005 to Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, to effectuate the provisions of Article 33-B of the New York Public Health Law (PHL). The regulations establish a scheme for licensing manufacturers and retailers of CBD products, with the overall goal of instituting consumer protections and ensuring products are manufactured, tested and labelled to standards comparable to similar products in the dietary supplement, food and cannabis industries.

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

While the Agriculture and Markets Law includes regulations related to the use of CBD, it should be noted that this is in addition to (but not in place of) the FDA's own rulemaking, outlined in the "US – Federal" summary, which is still pending. New York's Department of Agriculture has stated that no food or beverage product may be made or sold in New York State if it contains CBD as a food, a food additive or an ingredient. This is consistent with the FDA's approach.

New York has testing requirement for products intended for human consumption as dietary supplements (discussed in Question 6 below). However, the Department of Agriculture notes in its guidance that this is at odds with the FDA's position, which holds that CBD is not a dietary supplement but an active drug ingredient, and therefore subject to more stringent regulation at the federal level. This is covered in more detail in the "US – Federal" summary.

6. What are the testing specifications in New York 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?

Because New York is not participating in the 2018 Farm Bill programme, due to its reservations about the way the USDA's Interim Final Rule was drafted, hemp and CBD may only be grown and processed for research in New York (the only allowed purpose under the 2014 Farm Bill). New York indicated that it will convert research licences into commercial licences once a plan is adopted under the 2018 Farm Bill. This must occur by the end of 2020, because the 2014 Farm Bill pilot programme sunsets in November 2020.

In addition to federal requirements, in New York State cultivators and producers (known as research partners) making any CBD product intended for human or animal consumption or absorption into the body must ensure that their CBD products are free from chemical, physical and biological contamination. The analytical tests typically used to detect chemical, physical and biological contamination include, for example,

cannabinoid profile (THC and CBD), solvents, pesticides, heavy metals, bacteria and moulds.

The proposed CBD regulations, in addition to various licensing requirements, also impose third-party accredited laboratory testing requirements on all lots of CBD hemp products, testing for cannabinoid profile, heavy metals, microbials, mycotoxins, pesticides and residual solvents. The regulations will hold processors to federally established standards of good manufacturing practices (GMP) at the dietary supplement or food standard depending on the finished product. See §§ 1005.7-1005.8, 1005.10.

In accordance with the Department of Agriculture and Market's CBD processor research partner agreement, any facility manufacturing CBD products intended for human or animal consumption or absorption into the body shall be audited prior to sale or distribution of product to verify compliance with the relevant federal standard. Such audits must be conducted by a qualified, independent third party. The results of such a third-party audit shall be submitted to the Department prior to sale or distribution of the product. The third-party audit must provide evidence that the CBD processor is complying with the following requirements:

- A CBD product developed and/or produced under a research partner agreement, to the extent it is or will be a component of a dietary supplement, must be manufactured, tested and labelled in accordance with this agreement and FDA law and regulations concerning dietary supplements, including, without limitation, 21 CFR 111.403(L) and 21 CFR 101.

- A CBD or other cannabinoid product developed and/or produced under a research partner agreement, to the extent it introduces cannabinoids into or onto the body through topical application or other method for purposes other than as a dietary supplement, must be manufactured and labelled in accordance with 21 CFR 111 and 21 CFR 201 and comply with the provisions set forth in the research partner agreement.

The Department of Agriculture and Markets does not approve or maintain a listing of acceptable laboratories that can detect chemical, physical and biological contamination in CBD products. However, the Department will accept any tests performed by private laboratories accredited by the ISO/IEC 17025:2005,2017 standard.

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

In accordance with the amended Agriculture and Markets Law, industrial hemp used for research in New York (including the production of CBD) may only be sourced from an authorised New York State industrial hemp producer. This is likely to change to some extent once a programme is developed in accordance with the 2018 Farm Bill, which will no longer be for research purposes only.

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