



# Cannabis Products - What is the Risk?

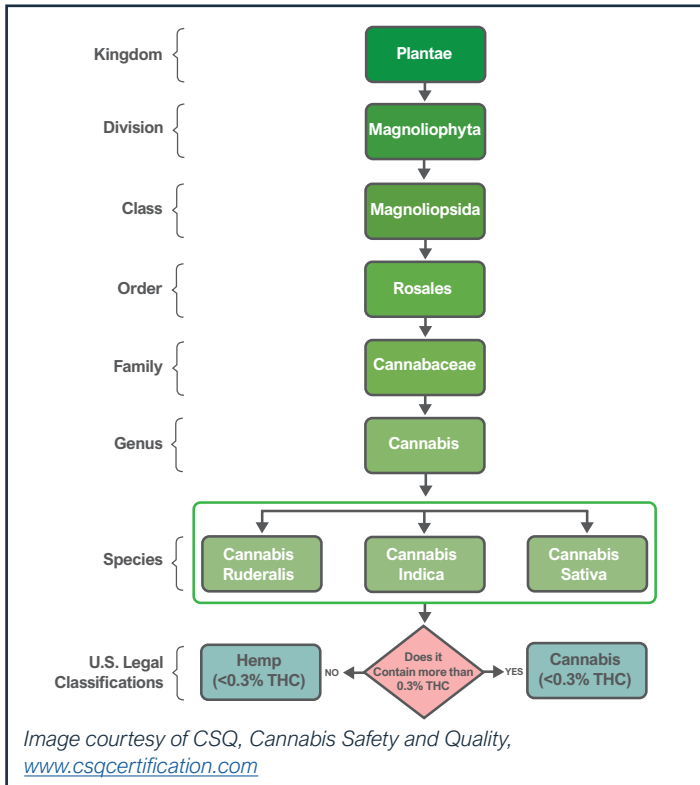
## \\ Cannabis: An Emerging \$61 Billion Worldwide Market

The legalization and regulation of cannabis products are trending across the globe. In the last decade, several U.S. states and countries around the world have either loosened regulations or established legal and government-regulated cannabis industries.

As with every new and emerging industry, the cannabis industry has unique risks and regulatory grey areas. However, this does not hinder its growth. Arcview Market Research and BDS Analytics forecast the global cannabis industry to jump from \$35 billion in 2022 to \$61 billion by 2026<sup>1</sup>.

<sup>1</sup> BDSA Cannabis Market Forecast 2022 Update, March 2022, Volume 5, Issue 2 <https://bdsa.com/wp-content/uploads/2022/03/BDSA-Cannabis-Market-Forecast-Spring-2022-Update-6-15-22-1.pdf>

# Cannabis, Hemp, or Marijuana – What’s the difference?



Cannabis, hemp, and marijuana are all terms for the same plant genus under the cannabaceae family. However, there are botanical, cultural, and political differences between these terms. Cannabis is the taxonomic term (or the “scientific” term), referring

to a genus of flowering plants that are members of the cannabaceae family. The cannabis genus is further divided into three species – Cannabis sativa, Cannabis indica, and Cannabis ruderalis. Hemp is more so a legal definition rather than a scientific definition or classification. In the United States, the 2018 Farm Bill defines hemp as “the plant species Cannabis sativa L. and any part of that plant, including seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol [THC] concentration of not more than 0.3% on a dry weight basis... THC, is the primary intoxicating component of cannabis.”<sup>2</sup>

The term marijuana is often used interchangeably with the term cannabis. It is often used to separate hemp products (i.e., cannabis and cannabis-derived products with less than 0.3% THC) from products that contain more than 0.3% THC found in various U.S. state-regulated medical or adult use markets.

## The Cannabinoid Conundrum

Cannabinoids are naturally occurring chemical compounds that contribute to the variety of effects cannabis consumers experience when consuming cannabis products. Cannabinoids can be categorized into three groups:

- **Phytocannabinoids found in cannabis and other plants**
- **Endocannabinoids found in the bodies of humans and other mammals**
- **Synthetic cannabinoids, which are formulated artificially in a lab**

While cannabis plants produce phytocannabinoids, it does not directly produce cannabinoids. Instead, it produces cannabinoid acids such

as CBDA (cannabidiolic acid) and THCA (tetrahydrocannabinolic acid), which must be activated through a process called decarboxylation to convert CBDA and THCA to CBD (cannabidiol) and THC, respectively.

While over 100+ known phytocannabinoids are found in cannabis plants, the two major cannabinoids are CBD and THC. This is because both cannabinoids occur in much higher concentrations than other minor cannabinoids present in the plant. Some examples of minor cannabinoids include CBG, CBN, and THCV. All of which are being studied for their therapeutic properties; however, researchers have only scratched the surface.

<sup>2</sup> Establishment of a Domestic Hemp Production Program, 7 CFR § 990, Department of Agriculture, Federal Register, October 2019 <https://www.govinfo.gov/content/pkg/FR-2019-10-31/pdf/2019-23749.pdf>

## A Regulatory Grey Area

What do shared electric vehicle companies (i.e., Lime and Bird), food delivery apps (i.e., Door Dash and Uber Eats), and the cannabis industry have in common? They are all relatively new and emerging markets, and like most new and emerging markets, regulations are trailing behind. This lag in the development of sensible regulations often creates a regulatory grey area where businesses must toe the line with what is legal today and what might be illegal for them tomorrow.

Currently, cannabis products that contain over the 0.3% THC limit are federally illegal in the United States. This means there are no federal regulations regarding the growing, harvesting, manufacturing, packaging, storing, or shipping of cannabis products not classified as hemp. However, even in the case of hemp, only the growing and harvesting of hemp plants is regulated by the USDA. That being said, the USDA's primary concern within the regulations is not producing hemp products over the 0.3% THC limit. The regulations do not establish requirements such as current Good Agricultural Practices (GAP) we see in similar industries, such as produce, even though cannabis is being put into food and beverages, dietary supplements, and other similar products. Furthermore, the U.S. FDA has not established ANY regulations regarding cannabis products, including hemp. This means that the manufacturing, packaging, storing, and shipping of hemp products are not regulated at the federal level.

While cannabis over 0.3% THC is still illegal federally, several states have opted to legalize cannabis for either medicinal use, recreational use, or both. As of September 2022, 39 states have legalized cannabis for medicinal use, while 19 states have legalized cannabis for recreational use. Again, this creates a regulatory grey area. While on the one hand, cannabis businesses are operating illegally according to federal regulations, they are operating legally according to local and state regulations. If you are a multi-state operator

(MSO), this creates a marketplace that is difficult to navigate, with regulations varying from state to state.



To further complicate matters, the cannabis industry touches so many other highly regulated industries, which further increases the complexity of cannabis regulations or lack thereof. For example, one cannabis organization might produce edible products (i.e., THC-infused confectionery products and beverages), dietary supplements (i.e., CBD and melatonin capsules), cosmetics (i.e., hemp-infused body lotion), and pharmaceuticals (i.e., FDA approved drug with CBD isolate). While all of these product groups are under the authority of the FDA, the FDA does not allow cannabis to be infused into these products. The only exception to that is pharmaceuticals. To date, the FDA has approved four pharmaceutical products (Epidiolex, Marinol, Syndros, and Cesamet) that contain cannabinoids found in cannabis plants.

Although the FDA may not have regulations in place for cannabis and cannabis-infused products, it doesn't mean that they are not punishing cannabis organizations that explicitly break the laws. While the FDA is not going after cannabis businesses operating legally within their state, they are sending warning letters to bad actors who illegally market their cannabis products to treat diseases or adulterated products, such as products contaminated with mold or heavy metals, sold across state lines.

## A Quick Word on Canada

Unlike the United States, Canada has legalized cannabis on a federal level. In October of 2018 the Cannabis Act came into force with three primary goals:

- To keep cannabis out of the hands of youth
- To keep profits out of the pockets of criminals
- And to protect public health and safety

While territories and provinces have jurisdiction over some things such as stricter minimum age and possession limits, the federal government

enforces strict requirements for producers who grow and manufacture cannabis and develop industry-wide rules and standards including:

- Types of cannabis products available for sale
- Packaging and labeling requirements
- Standardized serving sizes and potency
- Prohibitions on the use of certain ingredients
- Good production practices
- Traceability requirements from seed-to-sale
- Restrictions on promotional activities

## Reliance on Self-Regulation

Due to the lack of federal regulations in the U.S. and the patchwork of state regulations, forward-thinking cannabis businesses are starting to self-regulate by adopting global standards and third-party certifications. Initially, cannabis businesses were obtaining certification to food safety, dietary supplement, or pharmaceutical industry standards. However, cannabis-specific industry standards such as Cannabis Safety & Quality (CSQ) are on the rise. In fact, four states (Florida, New York, Michigan, and Maryland) require third-party certification. Florida and New York require sites to be certified before obtaining a license to operate, while Michigan and Maryland only require it for specific products.

We can compare the cannabis industry today to where the U.S. food industry was 20+ years ago. Minimal robust regulations and consumers pushing for safer and higher quality products. The difference is that the cannabis industry appears more willing to adapt to change and many of the top brands are pushing for industry standardization and federal regulations. This had not always been the case in the U.S. food industry.





## Is the Cannabis Industry Riskier than Similar Industries?

Often the cannabis industry is seen as too high risk for financial service providers such as banks and insurers. However, this is not necessarily the case.

Let's look at one of the largest multi-state operators (MSO) in the United States, Curaleaf. In 2021, Curaleaf Florida recalled two lots of cannabis flower for contamination with *Aspergillus*. According to the Florida Department of Health's Office of Medical Marijuana (OMMU), there were no reported illnesses, hospitalizations, or deaths<sup>3</sup>. The key takeaway is that legal cannabis operations can only distribute products within the state borders of which they operate. This not only reduces the number of products produced in each batch or lot but also reduces the number of consumers at risk if something goes wrong; a key risk factor when considering potential cost and scale of recalls.

As with food products, there have been recalls of cannabis products due to labelling issues. For example, where the ratio of THC to CBD has been incorrectly shown on the label. This is an issue that relates to current Good Manufacturing Practices

(cGMP) and common food safety controls rather than being specific to the cannabis industry.

While there are cases where recalls of cannabis products have caused severe injuries to consumers, they are rare. This can primarily be attributed to every legalized state requiring finished product testing on every lot or batch of products. However, the industry has been known to rely too heavily on finished product testing and not preventative measures such as current Good Manufacturing Practices (GMPs). That, combined with the lack of federal cannabis testing standards, does allow for bad actors to falsify or manipulate test results for economic gain, which is something that should not be overlooked.

Another risk factor to consider for the cannabis industry is the target market for some products on the market. For example, medicinal cannabis products are often marketed to and purchased by the elderly and immunocompromised individuals looking for substitutions to pharmaceutical painkillers or sleeping pills. This presents its own issue as those individuals are more at risk of experiencing serious injury or worse.

<sup>3</sup> Florida Health, Office of Medical Marijuana Use Enforcement: Curaleaf, November 2021 <https://www.floridahealth.gov/newsroom/2021/11/20211108-ommu-curaleaf.pr.html#:~:text=The%20OMMU%20required%20Curaleaf%20to,that%20lives%20indoors%20and%20outdoors>

## Summary

The cannabis industry is a new, exciting, and emerging industry that shows no signs of slowing down as more states and countries loosen cannabis regulations or legalize cannabis products completely. As with any new industry, there are inherent risks and very little regulatory oversight. However, the legal landscape is changing for the better, with the emergence of global cannabis industry standards, such as CSQ, and an industry push for better regulations and more focus on preventative measures in conjunction with finished product testing.

The cannabis industry, while still taboo for some, has shown its legitimacy over the years, going from an illicit underground market with people making edibles in their kitchens to enormous state-of-the-art facilities. Today we see large food and beverage companies such as Nestle, Kraft

Heinz, Molson Coors, Seneca Foods, and Carl's Jr. entering the cannabis space through one-off products or through investment into other cannabis businesses.

The key to identifying a good risk is identifying companies that are leading the way with high standards of production and product safety and separating them from those who still see themselves as part of an underground movement.

**If you need assistance with cannabis quality assurance or if you are interested in understanding risk in the cannabis products industry please email [contact@rqa-group.com](mailto:contact@rqa-group.com)**

RQA Group, December 2022

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