

AN OVERVIEW OF REGULATORY CHALLENGES FOR CANNABINOID HEMP

Following the federal legalization of hemp in 2018, a national industry has rapidly emerged to manufacture and sell consumable products that contain cannabinoids derived from hemp. The relative lack of federal regulation or enforcement of these products presents several challenges with implications for public health and safety and the ability of consumers to make informed choices about the products they consume. As a result, some states have stepped in to regulate hemp and hemp-derived products and others have followed federal agencies' lead. This has created a state-by-state patchwork of regulations that are often difficult for the industry, government bodies, and consumers to navigate.

LACK OF ENFORCEMENT OF FDA REGULATIONS

The 2018 Farm Bill placed the regulation of foods, beverages, dietary supplements, and cosmetics containing hemp, or substances like cannabidiol (CBD) that are derived from hemp, under the US Food & Drug Administration (FDA) through the FDA's enforcement of the federal Food Drugs, and Cosmetic Act (FDCA). The FDA has stated that CBD and tetrahydrocannabinol (THC) cannot be added to any food that is sold in interstate commerce and that CBD and THC cannot be marketed as dietary supplements, even if they are derived from hemp.

In addition to CBD and THC, there are dozens of cannabinoids present in the hemp plant, and even more that can be manufactured synthetically from hemp extracts. If the compounds are not excluded as drugs, it may be possible to use these other cannabinoids in FDA-regulated products if they go through an appropriate notification or approval process. However, to date, there are no records of any such hemp-derived products having completed the process to be allowed for use in foods, beverages, or dietary supplements.

A wide variety of hemp-derived foods, beverages, and dietary supplements containing CBD, THC, or other cannabinoids that are not in compliance with FDA regulations are being sold online and in traditional brick-and-mortar retail stores. To date, the FDA has taken minimal enforcement action, issuing warning letters to a small number of the manufacturers or sellers of hemp-derived products when there are health claims that put the product into the category of an unapproved drug.

Vape products and smokable hemp flower products such as "buds" and pre-rolls are outside the scope of the FDCA. Unless these products contain added nicotine, which is regulated by the FDA, these hemp vaping and smoking products are not subject to any federal regulation or oversight, which presents consumer safety issues.

PRODUCTS WITH INTOXICATING AMOUNTS OF DELTA-9-THC

"Low THC" is a relative term depending on the type of product. Under federal law, all hemp products are limited to no more than 0.3% delta-9-THC by weight. In dried plant material, this is a very small amount of THC compared with cannabis. But in foods and beverages, which weigh more than dried plant matter, 0.3% can be a lot of THC. The National Institute on Drug Abuse (NIDA) has established a "standard dose" of THC as 5 mg. With that dose in mind, at 0.3% THC by weight:

- Approximately one teaspoon of liquid (5.7 g) contains **more than three doses of THC (17 mg)**
- A "snack size" pack of fruit snacks (20 g) contains **12 doses of THC (60 mg)**
- A typical chocolate bar (50 g) contains **30 doses of THC (150 mg)**

Hemp-derived products are currently being sold that contain 100 mg, 200 mg, or even 400 mg of delta-9-THC, while still complying with the federal limit of 0.3% delta-9-THC by weight. These products sometimes contain more THC than states allow in their adult use cannabis programs, where the maximum serving size for an edible is typically 10 mg THC, with a maximum package size of 100 mg THC.

SEMI-SYNTHETIC DERIVATIVES

"Semi-synthetic cannabinoid" refers to certain types of substances that are produced by converting a cannabis extract into a different substance through chemical reactions. This type of process is commonly used to convert CBD, which is extracted

from hemp and alone is not intoxicating, into THC or other substances such as THC-O-acetates or hexahydrocannabinol (HHC). Semi-synthetic cannabinoids differ from naturally occurring cannabinoids in that they are manufactured via a chemical reaction. Some cannabinoids that are manufactured semi-synthetically also occur naturally in hemp, but typically in much smaller concentrations that are not cost effective to extract directly from the plant.

Semi-synthetic cannabinoids have proliferated in the market for a variety of reasons, including:

- **Perceived legality:** Federal law defines hemp as follows.

7 USC § 1639o (1) HEMP

The term “hemp” means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof 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.

Because this definition includes “all derivatives,” manufacturers of semi-synthetic cannabinoids argue that they are allowed to perform chemical reactions to convert CBD or other hemp-extracted substances into semi-synthetic cannabinoids if the final product contains no more than 0.3% delta-9-THC. This reasoning was supported by a recent decision in the Ninth Circuit relating to delta-8-THC products.

- **Tax, Testing, and Regulation Avoidance:** Semi-synthetic hemp-derived products are produced with little to no regulatory oversight. Most states with a regulatory system for hemp products have not addressed the hazards that can be introduced by the chemicals and processes used to manufacture semi-synthetic cannabinoids, and compliance with existing regulations remains low. State-regulated cannabis products, on the other hand, are subjected to a range of regulations put in place to protect consumer safety and public health, including testing and labeling requirements. Additionally, hemp plants and products are not subjected to the same taxes as cannabis in state-regulated programs. Between the savings from not needing to comply with testing and other regulatory requirements, and products not being subject to the same taxes as similar adult-use cannabis products, intoxicating semi-synthetic cannabinoids can be produced at a lower cost than regulated cannabis products.
- **Access and Market Restrictions:** In states where marijuana is illegal or difficult to obtain legally, semi-synthetic cannabinoids like delta-8-THC are popular among people that want to get “high.” States with established legal cannabis programs are also seeing a surge in intoxicating, hemp-derived products because these intoxicating hemp-derived products are being sold online and at traditional retailers (gas stations, grocery stores, etc.) with little to no regulation, as opposed to state-legal cannabis products which can only be sold at specific adult-only licensed cannabis retailers.

Common semi-synthetic cannabinoids currently being sold include: delta-8-THC, delta-9-THC, delta-10-THC, THC-O-acetates, THCV, THCP, HHC, HHC-O-acetate, HHCP, and CBN.

YOUTH ACCESS AND LACK OF AGE RESTRICTIONS

Federal legalization of hemp focuses primarily on crop production, not end-products. The federal regulations did not impose any age restrictions on the purchase of hemp products. Presumably, this was based on the assumption that hemp products would not be intoxicating. The reality is that many businesses are now manufacturing and selling intoxicating hemp-derived products containing significant doses of delta-9-THC or intoxicating semi-synthetic cannabinoids. In response, some states have established age restrictions on the sale of potentially intoxicating hemp derived products, but in most parts of the country these intoxicating products are available for sale to minors. Even in states with age restrictions in place, online sales can occur to underage individuals.

LACK OF PACKAGING AND LABELING STANDARDS

In state-level efforts to legalize cannabis, most state regulatory programs include robust requirements around the packaging and labeling of marijuana products. These requirements typically:

- Inform consumers that the product they are purchasing may be intoxicating.
- Require labeling to show the amount of THC that is in the product, and in many cases, to indicate a dose or serving size.
- Reduce or prohibit packaging and labeling products in a manner that may be attractive to minors.

There are currently no federal standards requiring labels to disclose the THC content of hemp-derived products. As a result, products that may contain a significant amount of THC simply state that the product contains “less than 0.3% THC.” If a CBD product contains 2 mg THC per serving, a consumer who takes one or two doses of the product two or three times per day may be consuming up to 12 mg THC over the course of the day, or more than two “standard doses” of THC as defined by NIDA.

Many consumers may be subject to drug testing, for example through their job or as ordered by a court as a condition of probation. For these consumers, it is especially important to know the THC content of any hemp products they might consume. Other consumers may work in jobs operating vehicles or heavy machinery, where it could be extremely dangerous for them to become unexpectedly impaired because they did not know the products they were consuming contained potentially impairing doses of THC or other cannabinoids.

LACK OF TESTING REQUIREMENTS

State-legal cannabis programs also typically establish robust testing requirements for marijuana products. These vary between states, but typically include:

- Potency testing to establish THC content of products.
- Pesticide testing to look for residues of pesticides, especially prohibited pesticides.
- Solvent testing to look for residual solvents from extraction processes.
- Mycotoxin or microbiological contaminant testing to look for potentially harmful contaminants.
- Heavy metal testing, since cannabis has the potential to accumulate significant amounts of potentially harmful metals from the environment.

At the federal level, hemp testing requirements are only established at the crop level, to confirm that a crop is hemp rather than cannabis. While hemp products are limited to no more than 0.3% delta-9-THC, there are no requirements or standards for finished product potency testing, or for testing for other harmful contaminants. Some individual hemp businesses choose to conduct potency or safety testing on their products, but there is no industry-wide requirement.

WHERE TO GET MORE INFORMATION?

For more information about hemp-derived products in your state, including state-specific programs, regulations, and initiatives, please reach out to your state cannabis regulator. If you don’t know who your state cannabis regulator is, the Cannabis Regulators Association (CANNRA) can connect you. Please contact: info@cann-ra.org.