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The current state of delta-8 THC

Delta-9 tetrahydrocannabinol (THC) is the main pharmacologically active ingredient of the Cannabis plant and is responsible for the clinical effects associated with the use of this substance. While possession and/or use of cannabis has been legalized in many states, it is still currently illegal to use, sell, or possess cannabis, according to the federal government of the United States.

The United States Agriculture Improvement Act of 2018 ("2018 Farm Bill") was passed with the purpose of supporting agricultural programs in the United States. Legislation included in the 2018 Farm Bill approved the legalization of hemp products. Hemp is a variety of the *Cannabis sativa* plant that is grown specifically for industrial use, including the manufacture of textiles, biodegradable plastics, and paint [1]. Prior to incorporation of the 2018 Farm Bill, the growth and cultivation of hemp was allowed only under state-sanctioned programs [2]. The 2018 Farm Bill removed hemp from the federal list of controlled substances, thereby allowing for the commercial sale and use of hemp-derived products, with the strict definition that hemp cannot contain more than 0.3% delta-9 THC [2]. The 2018 Farm Bill does not specifically address the possession, use, or sale of products that can be derived from hemp, including other biologically active cannabinoids such as delta-8 THC.

Delta-8 THC is a naturally occurring cannabinoid and close structural analog of delta-9 THC; it is present in low concentrations in most Cannabis plants [3]. Like delta-9 THC, delta-8 THC acts at cannabinoid and serotonergic receptors, and its use can result in psychoactive clinical effects similar to those induced by use of delta-9 THC [4,5]. The clinical effects associated with delta-8 THC use include euphoria, visual and time distortion, relaxation, difficulty in thinking, speaking, and reading, and a dream-like state [5]. The dose required to achieve these clinical effects is unclear, as dose-response studies of delta-8 THC in humans have been limited. Delta-8 THC is known to be less potent than delta-9 THC, but a standard human dose has not been identified. In one study, delta-8 THC was found to have two-thirds the potency of delta-9 THC; in another study of habitual cannabis smokers, ingestion of delta-8 THC 75 mg did not result in significant physiologic effects [5,6]. Pediatric exposure to delta-8 THC was reported in one study in which the

antiemetic potential of delta-8 THC was explored [7]. In this study, 8 children with hematologic malignancies (age range 3.5 months to 13 years) were administered oral delta-8 THC at a dose of 18 mg/m², 2 h prior to chemotherapy and repeated every 6 h for a single day. Adverse events were reported in 2 children, and included euphoria and slight irritability.

Because it is not specifically addressed in the 2018 Farm Bill, the legal status of delta-8 THC in the United States remains nebulous on the federal level. As of June 2021, several states have banned or restricted delta-8 THC products, but in other jurisdictions delta-8 THC remains legal and available for sale to individuals of all ages. In states where the sale of delta-8 THC is not restricted, the product is often available at tobacco shops and convenience stores in various formulations including vape cartridges, dried plant or "flower", and gummies (Fig. 1).

Due to the lack of federal regulation regarding the marketing of delta-8 THC, products may be packaged in brightly-colored containers featuring cartoon characters, sweet or fruity flavors and candy-themed images that may be attractive to young children and adolescents. Delta-8 THC products are also not required to have child-resistant packaging, further increasing the potential for exploratory exposure and toxicity in the pediatric population. An additional consequence of the minimal regulation of delta-8 THC products relates to purity and standardization. The actual product contents may differ from what is listed on the package label, with the added potential for contamination with other drugs or substances.

As the awareness and popularity of delta-8 THC expands, it is likely medical providers will encounter increasing numbers of patients who are under the influence of this substance. There is no specific antidote for delta-8 THC intoxication, and supportive care is currently the mainstay of treatment for patients with adverse effects related to use of this product. Toxicology screening assays for delta-8 THC are not readily available in most medical facilities, but may be obtained from a reference laboratory. Both consumers and physicians should be aware of the potential for intoxication or adverse events after use of delta-8 THC products. As with all potentially toxic substances, delta-8 THC products should be kept well out of reach of young children, especially considering the lack of uniform child-resistant packaging in delta-8 THC products. Given its psychoactive clinical effects, further discussion is warranted at the state and federal level regarding the legal status of delta-8 THC as well as whether it should be labeled as a controlled substance.



Fig. 1. Delta-8 THC products.

Funding

None.

Prior presentation

None.

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5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC



Español (<https://www.fda.gov/consumers/articulos-en-espanol/5-cosas-que-debe-saber-sobre-el-delta-8-tetrahydrocannabinol-delta-8-thc>)

Delta-8 tetrahydrocannabinol, also known as delta-8 THC, is a psychoactive substance found in the *Cannabis sativa* plant, of which marijuana and hemp are two varieties. Delta-8 THC is one of over 100 cannabinoids produced naturally by the cannabis plant but is not found in significant amounts in the cannabis plant. As a result, concentrated amounts of delta-8 THC are typically manufactured from hemp-derived cannabidiol (CBD).

It is important for consumers to be aware that delta-8 THC products have not been evaluated or approved by the FDA for safe use in any context. They may be marketed in ways that put the public health at risk and should especially be kept out of reach of children and pets.

Here are 5 things you should know about delta-8 THC to keep you and those you care for safe from products that may pose serious health risks:

1. Delta-8 THC products have not been evaluated or approved by the FDA for safe use and may be marketed in ways that put the public health at risk.

The FDA is aware of the growing concerns surrounding delta-8 THC products currently being sold online and in stores. These products have not been evaluated or approved by the FDA for safe use in any context. Some concerns include variability in product formulations and product labeling, other cannabinoid and terpene content, and variable delta-8 THC concentrations. Additionally, some of these products may be labeled simply as “hemp products,” which may mislead consumers who associate “hemp” with “non-psychoactive.” Furthermore, the FDA is concerned by the proliferation of products that contain delta-8 THC and are marketed for therapeutic or medical uses, although they have not been approved by the FDA. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of federal law,

but also can put consumers at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments raises significant public health concerns because patients and other consumers may use them instead of approved therapies to treat serious and even fatal diseases.

2. The FDA has received adverse event reports involving delta-8 THC-containing products.

From December 2020 through July 2021, the FDA received adverse event reports from both consumers and law enforcement describing 22 patients who consumed delta-8 THC products; of these, 14 presented to a hospital or emergency room for treatment following the ingestion. Of the 22 patients, 19 experienced adverse events after ingesting delta-8 THC-containing food products (e.g., brownies, gummies). Adverse events included vomiting, hallucinations, trouble standing, and loss of consciousness.

National poison control centers received 661 exposure cases of delta-8 THC products between January 2018 and July 31, 2021, 660 of which occurred between January 1, 2021, and July 31, 2021. Of the 661 exposure cases:

- 41% involved unintentional exposure to delta-8 THC and 77% of these unintentional exposures affected pediatric patients less than 18 years of age.
- 39% involved pediatric patients less than 18 years of age
- 18% required hospitalizations, including children who required intensive care unit (ICU) admission following exposure to these products.

3. Delta-8 THC has psychoactive and intoxicating effects.

Delta-8 THC has psychoactive and intoxicating effects, similar to delta-9 THC (i.e., the component responsible for the “high” people may experience from using cannabis). The FDA is aware of media reports of delta-8 THC products getting consumers “high.” The FDA is also concerned that delta-8 THC products likely expose consumers to much higher levels of the substance than are naturally occurring in hemp cannabis raw extracts. Thus, historical use of cannabis cannot be relied upon in establishing a level of safety for these products in humans.

4. Delta-8 THC products often involve use of potentially harmful chemicals to create the concentrations of delta-8 THC claimed in the marketplace.

The natural amount of delta-8 THC in hemp is very low, and additional chemicals are needed to convert other cannabinoids in hemp, like CBD, into delta-8 THC (i.e., synthetic conversion). Concerns with this process include:

- Some manufacturers may use potentially unsafe household chemicals to make delta-8 THC through this chemical synthesis process. Additional chemicals may be used to change the color of the final product. The final delta-8 THC product may have potentially harmful by-products (contaminants) due to the chemicals used in the process, and there is uncertainty with respect to other potential contaminants that may be present or produced depending on the composition of the starting raw material. If consumed or inhaled, these chemicals, including some used to make (synthesize) delta-8 THC and the by-products created during synthesis, can be harmful.
- Manufacturing of delta-8 THC products may occur in uncontrolled or unsanitary settings, which may lead to the presence of unsafe contaminants or other potentially harmful substances.

5. Delta-8 THC products should be kept out of the reach of children and pets.

Manufacturers are packaging and labeling these products in ways that may appeal to children (gummies, chocolates, cookies, candies, etc.). These products may be purchased online, as well as at a variety of retailers, including convenience stores and gas stations, where there may not be age limits on who can purchase these products. As discussed above, there have been numerous poison control center alerts involving pediatric patients who were exposed to delta-8 THC-containing products. Additionally, animal poison control centers have indicated a sharp overall increase in accidental exposure of pets to these products. Keep these products out of reach of children and pets.

Why is the FDA notifying the public about delta-8 THC?

A combination of factors has led the FDA to provide consumers with this information. These factors include:

- An uptick in adverse event reports to the FDA and the nation's poison control centers.
- Marketing, including online marketing of products, that is appealing to children.
- Concerns regarding contamination due to methods of manufacturing that may in some cases be used to produce marketed delta-8 THC products.

The FDA is actively working with federal and state partners to further address the concerns related to these products and monitoring the market for product complaints, adverse events, and other emerging cannabis-derived products of potential concern. The FDA will warn consumers about public health and safety issues and take action, when necessary, when FDA-regulated products violate the law.

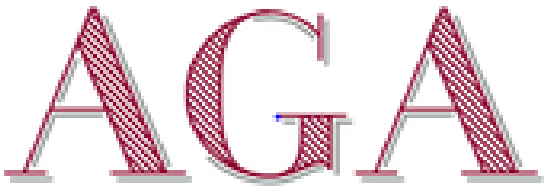
How to report complaints and cases of accidental exposure or adverse events:

If you think you are having a serious side effect that is an immediate danger to your health, call 9-1-1 or go to your local emergency room. Health care professionals and patients are encouraged to report complaints and cases of accidental exposure and adverse events to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Call an FDA [Consumer Complaint Coordinator \(/safety/report-problem-fda/consumer-complaint-coordinators\)](/safety/report-problem-fda/consumer-complaint-coordinators) if you wish to speak directly to a person about your problem.
- Complete an [electronic Voluntary MedWatch form \(https://www.accessdata.fda.gov/scripts/medwatch/\)](https://www.accessdata.fda.gov/scripts/medwatch/) online or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form, or submit by fax to 1-800-FDA-0178.
- Complete a [paper Voluntary MedWatch form \(https://www.fda.gov/media/85598/download\)](https://www.fda.gov/media/85598/download) and mail it to the FDA.
- To report adverse events in animals to the FDA's Center for Veterinary Medicine, please download and submit Form FDA 1932a found at: [www.fda.gov/ReportAnimalAE \(/animal-veterinary/report-problem/how-report-animal-drug-and-device-side-effects-and-product-problems\)](http://www.fda.gov/ReportAnimalAE/).

For more information about Delta-8 THC: [CDC HEALTH ALERT NETWORK \(HAN\) \(https://emergency.cdc.gov/han/2021/han00451.asp\)](https://emergency.cdc.gov/han/2021/han00451.asp).

The American Association of Poison Control Centers (AAPCC) maintains the National Poison Data System (NPDS), which houses de-identified case records of self-reported information collected from callers during exposure management and poison information calls managed by the country's poison control centers (PCCs). NPDS data do not reflect the entire universe of exposures to a particular substance as additional exposures may go unreported to PCCs; accordingly, NPDS data should not be construed to represent the complete incidence of U.S. exposures to any substance(s). Exposures do not necessarily represent a poisoning or overdose and AAPCC is not able to completely verify the accuracy of every report. Findings based on NPDS data do not necessarily reflect the opinions of AAPCC.



Hemp-Derived THC:

A Discussion on Public Health, Policy, and Enforcement

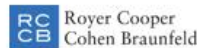
Presenters:

Gary S. Kaminsky; Neil M. Willner; Rod Kight; Dr. Corey Burchman



Agenda:

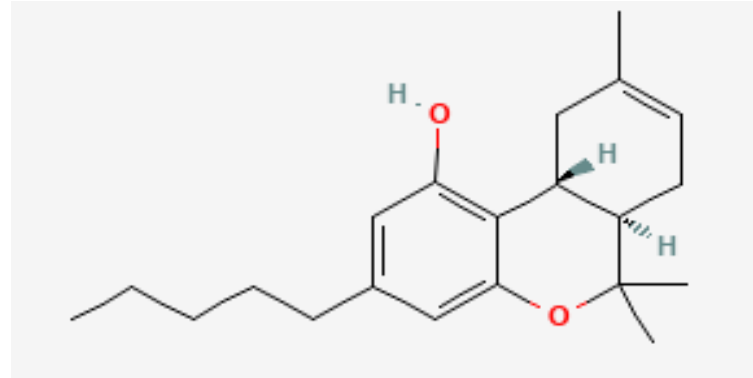
- 1. Introduction;**
- 2. Scientific Overview of Delta-8 THC;**
- 3. Legal Overview of Delta-8 THC; and**
- 4. Policy and Enforcement Issues and Solutions**



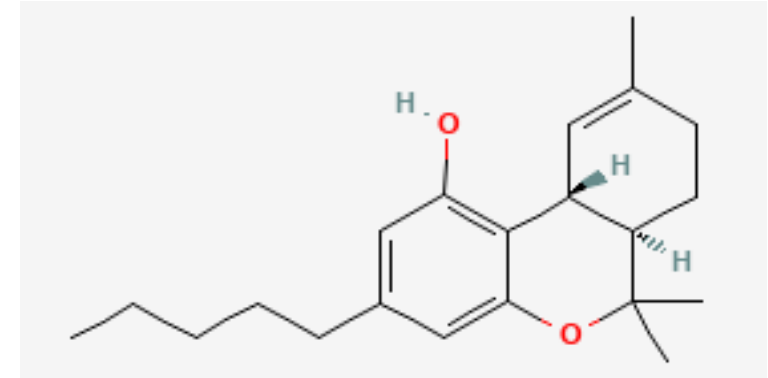
Scientific Overview of Delta-8 THC

- ❑ One of over 100 cannabinoids produced naturally by the cannabis plant;
- ❑ Not found in significant amounts in the cannabis plant;
- ❑ As such, concentrated amounts of delta-8 THC are typically manufactured from hemp-derived cannabidiol (CBD); and
- ❑ **Not** evaluated by FDA for safe use, in any context.

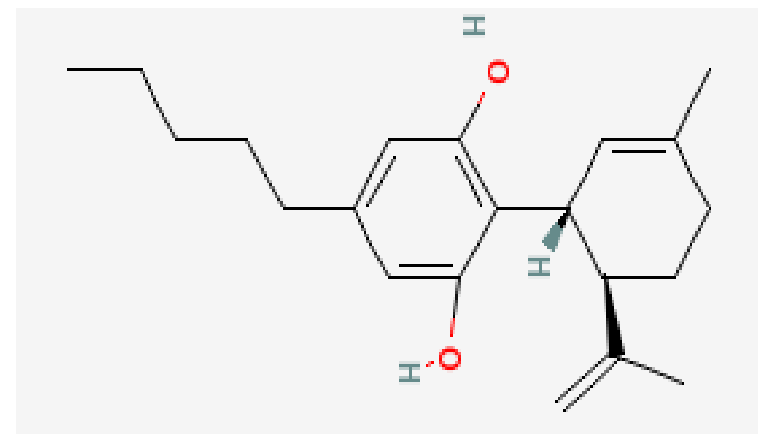
Delta-8 THC



Delta-9 THC

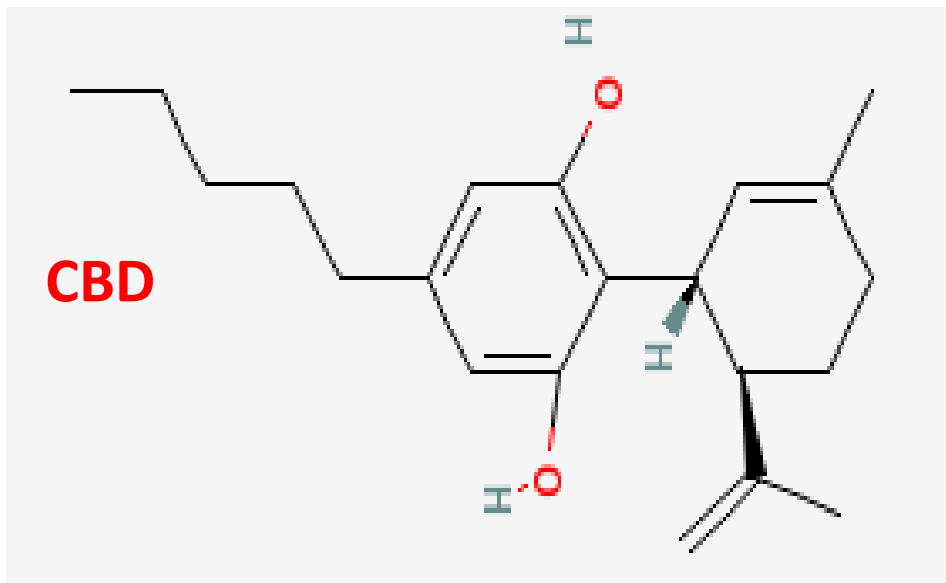


CBD

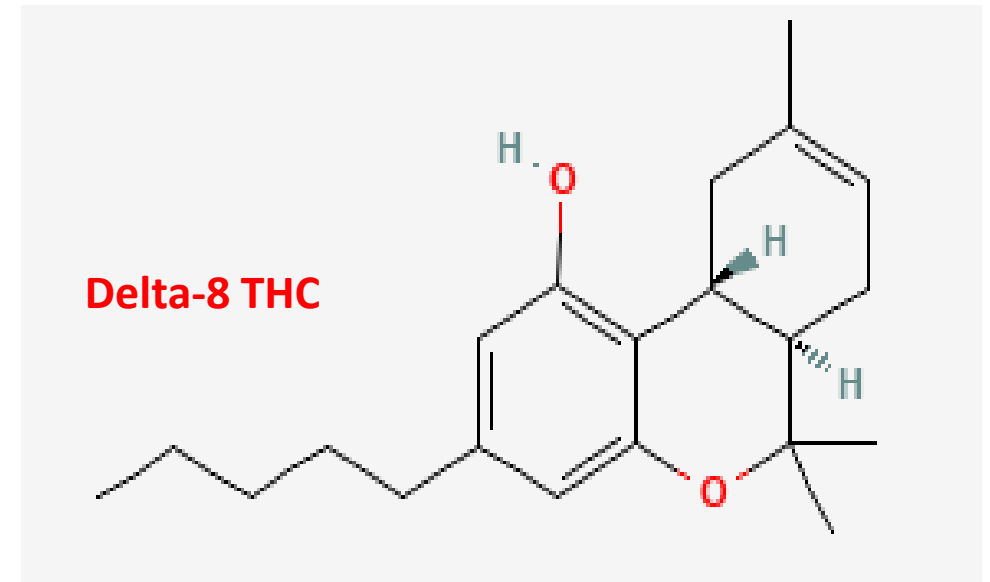


Scientific Overview of Delta-8 THC

- ❑ FDA has received adverse event reports
- ❑ Delta-8 THC manufacturers may use potentially harmful household chemicals to synthesize it
- ❑ The final product may have potentially harmful by-products related to chemicals used in the process
- ❑ Manufacturing may occur in unregulated conditions, resulting in presence of unsafe contaminants



Acid catalyst,
Solvent, Heat



Why are we Concerned?

- ☐ Increase in ADR's to FDA and nation's poison control centers
- ☐ Contamination/manufacturing concerns
- ☐ Variability in formulations and labeling
- ☐ Other cannabinoid and terpene content
- ☐ Variable delta-8 concentrations
- ☐ If labeled as "hemp products," consumers may assume non-psychoactive
- ☐ Concern @ marketing for therapeutic uses
 - ☐ Violation of federal law
 - ☐ Puts consumers at risk, as products have not been proven as safe or effective
 - ☐ Patients may use in lieu of approved therapies to treat disease



Increases in Availability of Cannabis Products Containing Delta-8 THC and Reported Cases of Adverse Events



Is Delta-8 THC Legal?

Yes

- ❑ Delta-8 THC is a cannabinoid naturally occurring in the hemp plant as defined in the 2018 Farm Bill;
- ❑ Delta-8 THC is also a double bond isomer of delta-9 THC which is produced by the hemp plant;
- ❑ The 2018 Farm Bill legalizes isomers that do not contain delta-9 THC concentrations that exceed 0.3% on a dry-weight basis;
- ❑ Delta-8 THC is not a controlled substance under the Federal Analogue Act because THC's found in hemp are excepted from the CSA by virtue of the 2018 Farm Bill.
- ❑ Moreover, the effects of delta-8 THC on the central nervous system are not substantially similar to those of delta-9 THC.

No

- ❑ Delta-8 THC does not naturally occur in commercially viable amounts in the hemp plant;
- ❑ DEA's August 2020 IFR clarified that synthetic THC's still remain schedule I controlled substances;
- ❑ No delta-8 THC on the market is produced via direct extraction from the hemp plant;
- ❑ All delta-8 THC available through unregulated channels is made in a laboratory by converting hemp-derived CBD through a chemical process to delta-8 THC;
- ❑ This conversion is "synthesis", making delta-8 THC produced from CBD a synthetic THC;
- ❑ Delta-8 THC is also a controlled substance analogue under the Federal Analogue Act.

It doesn't matter . . .

This is a Public Safety Issue



Centers for Disease
Control and Prevention

National poison control centers received 661 exposure cases of delta-8 THC products between January 2018 and July 31, 2021, 660 of which occurred between January 1, 2021, and July 31, 2021. Of the 661 exposure cases:

- 41% involved unintentional exposure to delta-8 THC and 77% of these unintentional exposures affected pediatric patients less than 18 years of age.
- 39% involved pediatric patients less than 18 years of age
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This is a Public Safety Issue



All-Natural, Plant Based

Our Delta-8 products are derived from the hemp plant and CBD, which is a cannabinoid found in the hemp plant. The National Cancer Institute defines Delta 8 as "an analogue of tetrahydrocannabinol with... appetite-stimulating, analgesic, and neuroprotective properties".



Enhanced Research & Development

Our advanced history in the Hemp and CBD industries have allowed us to innovate while focusing our priorities on purity, quality and safety.



Lab Tested Extracts

We strive to ensure the quality and purity of every batch by submitting our extracts for third-party lab testing. For more information on our lab testing, feel free to reach out or visit our Lab Results page.

Preventing the “Whack-a-Mole” Approach



Available Products on the Market



THC-O PRODUCTS

Bearly Legal's all new **THC-O-Acetate** also known as **Delta-8-Acetate, DELTA-X, Pur-Infinite** vape tanks and cartridges are absolutely amazing. Similar to delta-8-thc, THC-O Acetate delivers a powerful punch of effects that are quite delightful, but much more potent!

🔥 Stronger & longer lasting than D8 or D10 but fully federally farm bill compliant. Bearly Legal's THCO Tanks are made for the connoisseurs of Delta-THC extracts and rare and exotic cannabinoids.

D8 THC-O typically gives a relaxing & Indica feeling, with a calming warmth and head buzz 🧠 immediately. No VG, PG, PEG, Vitamin E, MCT, or any other cutting agents. This is a pure and very concentrated distillate. Extracts of only the highest quality standards and quality is guaranteed, to be what is advertised or money back guarantee.

Source: <https://www.bearlylegalhemp.com/>

We're all in this Together

Protecting Public Safety



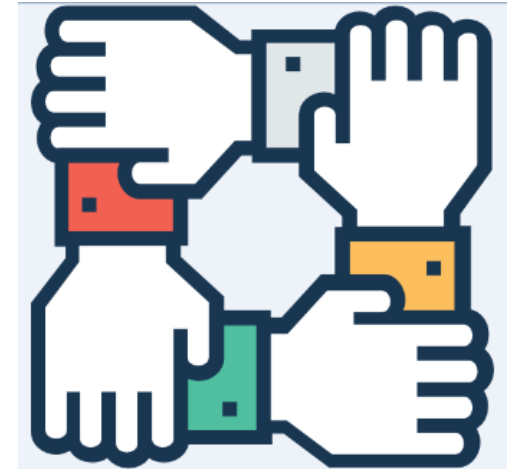
Preventing Youth Access



FACT SHEET Emerging Public Health Concern: Delta-8 THC

- Recently in a nearby state, two cases of severe adverse reactions to delta-8 THC have been reported in children.
 - The children ingested their father's gummies, purchased at a vape shop.
 - They became symptomatic with deep sedation and slowed breathing with initial increased heart rate progressing to slowed heart rate and blood pressure.
 - Both children were admitted to the intensive care unit for further monitoring and oxygen supplementation.

Coordinated Policy



Differing State Approaches

- 1) **Outright Prohibition;**
- 2) **Moving Delta-8 THC into Regulated Marijuana Programs; or**
- 3) **Regulate Within State's Hemp Program.**

Unification Across the States

- Immediate Action
- Attorney General Involvement
- Legislative Fix

Regulatory Tug-of-War



Policy Center
Public Health & Safety



USDA

State Regulators



State Attorneys General

CDC

FDA

Thank You!

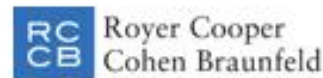
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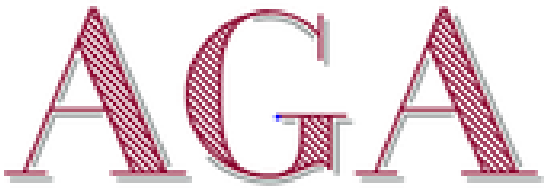
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Hemp-Derived THC:

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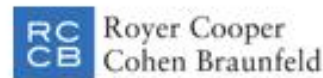
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Colorado

Department of Public Health and Environment
&
Marijuana Enforcement Division



COLORADO

Department of Revenue

Specialized Business Group—Marijuana

May 14, 2021

Re: Industry-Wide Bulletin 21-07 - Industrial Hemp Product (Production/Use of Chemically Modified or Synthetically Derived THC Isomers from Industrial Hemp Precursors)

Dear Stakeholders:

The Marijuana Enforcement Division (Division) is providing clarification to licensees regarding the production or use of chemically modified or synthetically derived tetrahydrocannabinol (THC) isomers (including Delta-8, Delta-9, and Delta-10-THC) originating from Industrial Hemp precursors such as CBD isolate. This is an initial communication in response to numerous inquiries the Division has received. While we acknowledge this communication may not answer all outstanding questions, it is responsive to many inquiries we've received on this subject. We are continuing to gather information and engage with stakeholders to examine these complex matters further. Forums for such discussions include the [Science & Policy Workgroup](#), which the Division facilitates in partnership with the Colorado Department of Public Health & Environment.

Use of Industrial Hemp Product as an Ingredient

Authority:

44-10-503(5)(b)(I), 44-10-603(11)(a), 44-10-503(1)(a) & (2), 44-10-603(1)(a) & (2) C.R.S.

Medical and Retail Marijuana Products Manufacturers are permitted to use Industrial Hemp Product as an ingredient in their medical or retail marijuana product. A Medical and Retail Marijuana Products Manufacturer's Licensed Premises must be used exclusively for the manufacturer and preparation of Medical and Retail Marijuana and Marijuana Products. Medical marijuana product means "a product infused with medical marijuana that is intended for use or consumption other than by smoking, including but not limited to edible products, ointments, and tinctures." 44-10-103(38), C.R.S. Retail marijuana product is "concentrated marijuana products and marijuana products that are comprised of marijuana and other ingredients and are intended for use or consumption, such as, but not limited to, edible products, ointments, and tinctures." 44-10-103(61), C.R.S., and Colo. Const. Art. XVIII, S 16 P(1)(k).

- Industrial Hemp Product is **not permitted** to be further processed or extracted either before or after inclusion in a marijuana product by a Medical or Retail Marijuana Products Manufacturer. This prohibition includes any process that converts an Industrial Hemp Product, such as CBD isolate, into delta-9, delta-8, delta-10-THC, or other tetrahydrocannabinol isomers or functional analogs.
- Before taking possession of the Industrial Hemp Product, the Medical or Retail Marijuana Product Manufacturer must verify the Industrial Hemp Product passed all required tests, including but not limited to potency testing, to ensure the product contains no more than 0.3% delta-9 THC on a dry weight basis. If the Industrial Hemp Product contains more

than 0.3% delta-9 THC on a dry weight basis, it is not an Industrial Hemp Product and is not a permissible ingredient.

Use of Solvents (Rules 5-315, 6-315)

Medical and Retail Marijuana Products Manufacturers are limited to using only the approved solvents in Rule 5-315 and 6-315 when producing a Solvent-Based Concentrate. The approved list includes butane, propane, CO₂, ethanol, isopropanol, acetone, heptane, ethyl acetate, and pentane. The use of any other solvent not approved by the Division is expressly prohibited.

- The use of acids, bases, catalysts, or other unapproved reagents to extract, isolate, or convert cannabidiols, tetrahydrocannabinols, or other cannabinoids is **not permitted**.

As noted in the introductory paragraph of this Bulletin, the Division is aware that this communication may not answer all outstanding questions. We are continuing to engage with stakeholders on this matter. The Division intends to use forums such as the [Science & Policy Workgroup](#) to further explore these and related matters, which may include opportunities to examine potentially compliant methods to produce marijuana-derived Delta-8 THC products, potency testing, and Total THC labeling impacts.



May 14, 2021

Re: Production and/or Use of Chemically Modified or Converted Industrial Hemp Cannabinoids

Dear Stakeholders:

Today, the Marijuana Enforcement Division (MED) provided clarification to licensees regarding the production or use of chemically modified or synthetically derived tetrahydrocannabinol (THC) isomers (including Delta-8, Delta-9, and Delta-10-THC) originating from Industrial Hemp precursors such as CBD isolate. Like MED, we have received numerous inquiries and want to ensure we are responsive to the issues and concerns.

The Division of Environmental Health and Sustainability (“Division”) within the Colorado Department of Public Health and Environment (“Department”) is providing this notice to industrial hemp registrants to clarify that chemically modifying or converting any naturally occurring cannabinoids from industrial hemp is non-compliant with the statutory definition of “industrial hemp product.” This includes any process that converts an industrial hemp cannabinoid, such as CBD isolate, into delta-9, delta-8, delta-10-THC, or other tetrahydrocannabinol isomers or functional analogs.

Additionally, a complete profile of reactionary byproducts has not been established in association with the conversion or creation of delta-9, delta-8, delta-10-THC; therefore, insufficient evidence exists to determine whether or not any toxic or otherwise harmful substances are produced during these reactions and may remain in the regulated industrial hemp products ingested or applied/used by consumers. Therefore, these tetrahydrocannabinol isomers are **not allowed** in food, dietary supplements or cosmetics.

Authority:

Section 25-5-426(1)(g.3) & (g.5) and 25-5-426(4)(d), C.R.S.

The Department and Division is aware that this communication may not answer all outstanding questions. We will host stakeholder conversations on this topic as necessary to provide further clarification.



Florida

Department of Agriculture and Consumer Services

Delta 8:

At this time any hemp product intended for human or animal ingestion or inhalation which is sold in Florida must comply with all Florida statutes and rules.

Any hemp or hemp extract products offered for sale or sold in Florida must comply with all labeling rules and have a certificate of analysis that shows a total THC ($\text{THCA} \times .8777 + \text{THC Delta 9} = \text{total THC}$) content of 0.3% or less. Any hemp or hemp extract product that does not comply with all statutes and rules is subject to enforcement and possible destruction by the Florida Department of Agriculture and Consumer Services.

Please see <https://www.fdacs.gov/Cannabis-Hemp/Hemp-CBD-in-Florida> for more information and direct links to the applicable laws.

Consumer Alert: Delta-8-THC (July 2021)

Florida is one of only a few states that regulates each facet of the hemp industry – from seed to sale. Under the direction of Commissioner Nikki Fried, the Florida Department of Agriculture and Consumer Services (“FDACS”) strives to ensure that food products are safe for consumption. Since standing up the state hemp program in 2019, the department has issued more than 700 licenses to cultivate hemp, and permitted more than 8,000 locations that extract, process (aka manufacture), wholesale/distribute, store, and sell hemp extract. In addition to permitting, the department actively inspects for sanitary operating conditions and tests for label accuracy and contaminants unsafe for human consumption.

The department routinely finds violative products and conducts investigations based on consumer complaints. The FDACS team is on the ground daily working to make sure the rules are being followed and that hemp extract products do not contain contaminants unsafe for human consumption. Over the past year, the department has observed a growing interest in the sale of Delta-8-tetrahydrocannabinol (“Delta-8-THC”) and received numerous inquiries regarding its safety.

Delta-8-THC is one of over 100+ naturally occurring cannabinoids in the cannabis plant. Delta-8-THC, like many other cannabinoids, occurs in relatively low levels in the plant. It is commonly understood that these products are manufactured by converting Cannabidiol (CBD) to Delta-8-THC through a chemical process. As a result, the U.S. Drug Enforcement Agency and several states have issued formal opinions that Delta-8-THC is an illegal synthetic cannabinoid.

Additionally, many states have formally banned the sale of Delta-8-THC. Florida law requires all hemp extract products, including Delta-8 products, to have a COA showing the Total THC ($\text{THC A} \times .8777 + \text{Delta 9} = \text{total THC}$) is 0.3% or less. The Department is conducting regulatory testing to confirm compliance with this standard for consumer protection.

Perhaps more concerning are the unknown chemicals in these products. Often, the chemical conversion from CBD to Delta-8-THC is performed under acidic conditions. Ingesting or inhaling residual acids left over from conversion can result in bodily harm or even death. Until comprehensive, nationwide standards are adopted, consumers have no way of knowing what post-processing steps were taken to ensure the safety of these products.

If you have consumed an unsafe product, call your doctor. If it's an emergency, call 911. If you believe you or someone you know became ill from one of these products, you should report the illness directly to the Florida Department of Health using their online submission form.

Illinois

Department of Agriculture

Division of Cannabis Regulation

State Fairgrounds • P.O. Box 19281 • Springfield, IL 62794-9281 • 217/524-2143 • TDD 866/287-2999 • Fax 217/524-4215

Updated Illinois Department of Agriculture Policy Regarding Hemp and Hemp Derivatives in Medical and Adult-Use Cannabis Products

1. "Cannabis" means marijuana, hashish, and other substances that are identified as including any parts of the plant *Cannabis sativa* and including derivatives or subspecies, such as indica, of all strains of cannabis, whether growing or not; the seeds thereof, the resin extracted from any part of the plant; and any compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or resin, including tetrahydrocannabinol (THC) and all other naturally produced cannabinol derivatives, whether produced directly or indirectly by extraction; however, "cannabis" does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted from it), fiber, oil or cake, or the sterilized seed of the plant that is incapable of germination. *"Cannabis" does not include industrial hemp as defined and authorized under the Industrial Hemp Act.* "Cannabis" also means cannabis flower, concentrate, and cannabis-infused products. (410 ILCS 705/1-10) (emphasis added)
2. "Industrial hemp" means the plant *Cannabis sativa* L. and any part of that plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis that has been cultivated under a license issued under this Act or is otherwise lawfully present in this State, and includes any intermediate or finished product made or derived from industrial hemp." (505 ILCS 89/5)
3. Cannabis business establishments licensed by the Illinois Department of Agriculture for cultivation, growing, processing, manufacturing, and/or infusing of medical and/or adult-use cannabis products pursuant to the Cannabis Regulation and Tax Act and/or the Compassionate Use of Medicinal Cannabis Program Act (hereafter "Cannabis Cultivation Center") may use industrial hemp as an ingredient in cannabis infused products offered for sale at licensed dispensaries in Illinois. Hemp flower may not be sold to dispensaries.
4. All hemp obtained through this policy must be used in extracted form and only in infused cannabis products.
5. Industrial hemp may be procured from third party, licensed growers and/or processors from within the State of Illinois or any other State with a regulated industrial hemp program.
6. All hemp and hemp derivatives must be obtained from a licensed or registered hemp grower or processor, regardless of the grower's or processor's home state. Cannabis producers must provide a copy of the hemp grower's or processor's state-issued license upon demand of the Illinois Department of Agriculture or the Illinois State Police.
7. Any Licensed Cannabis Cultivation Center that intends to use hemp or hemp derivatives must apply for, and be issued, a Hemp Processor's Registration through the Department of Agriculture. Applications for the Registration can be found here: https://agrlicensing.illinois.gov/Industrial_Hemp/
8. Industrial hemp flower and biomass may be purchased and extracted by licensed cannabis cultivation centers.

Division of Cannabis Regulation

State Fairgrounds • P.O. Box 19281 • Springfield, IL 62794-9281 • 217/524-2143 • TDD 866/287-2999 • Fax 217/524-4215

9. Licensed cannabis cultivation centers may procure and/or process industrial hemp in the form of distillate or isolate. All processed hemp derivatives must be accompanied by a certificate of analysis showing potency levels for Delta-9 THC, THCa, CBD, and CBDa.
10. The delta-9 tetrahydrocannabinol contained in the hemp and hemp derivatives may not be concentrated above the allowable 0.3% threshold.
11. Hemp and hemp derivatives may not be used to concentrate or to synthesize intoxicating compounds including delta-9 tetrahydrocannabinol or delta-8 tetrahydrocannabinol.
12. A representative sample of all final products containing industrial hemp or hemp derivatives must undergo testing pursuant to the Compassionate Use of Medical Cannabis Act and the Cannabis Regulation and Tax Act and the applicable administrative rules.
13. This policy is in effect until and through December 31, 2021 and is subject to change at any time.

Please send any questions to agr.hemp@illinois.gov or call Division Manager David Lakeman at 217-524-4190.



David Lakeman – Division Manager

Iowa

Department of Agriculture & Land Stewardship



AGRICULTURE & LAND STEWARDSHIP

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[\(/\)](#)

Iowa's Hemp Law

Farmers can apply for a license to grow hemp in Iowa. Growers are advised to do their research and confirm there is a viable, profitable market for commercial hemp production before they make an investment in seed and equipment. This commercial hemp production program does not legalize the use of cannabidiol (CBD) for human consumption, extraction or processing in Iowa. All questions about applying for a hemp license or seed permit should be directed to hemp@iowaagriculture.gov (<mailto:hemp@iowaagriculture.gov>) or (515) 725-1470.

Iowa Hemp Statute (<https://www.legis.iowa.gov/docs/code/2021/204.pdf>) | December 4, 2020

Iowa Hemp Administrative Rules (<https://www.legis.iowa.gov/docs/iac/chapter/03-11-2020.21.96.pdf>) | March 20, 2020

Advisory Notice in Iowa Administrative Bulletin (<https://www.legis.iowa.gov/docs/aco/bulletin/04-08-2020.pdf>) | April 8, 2020

Comment letter to USDA AMS on the Hemp Production Program interim final rule (</sites/default/files/2020/pdf/Hemp%20Comments.pdf>)

How to Apply for a Hemp License in 2021

Applications for **outdoor planting** are no longer accepted for 2021. The deadline was May 1.

Applications for **indoor planting** are accepted year-round.

To apply, visit hemp.iowaagriculture.gov (<https://hemp.iowaagriculture.gov/landing>).

Tips

1. Click on the "Register" button on the front page and provide a name, email and password. It will take you to page 1 that asks for the authorized representative info.
2. Page 2 asks for the business info. The EIN isn't required. The map will show the business location.
3. At the bottom of page 3, the system asks how many fingerprint cards you'd like to request or how many have been submitted. The system will notify the Iowa Department of Agriculture and Land Stewardship if cards need to be sent to applicants.
4. Page 4 asks if there are any other associates on this license. If so, click "Add Another Person" and fill out their info. The Iowa Department of Agriculture will email a separate set of Acknowledgements for the associate to sign and return.
5. Page 5 is for the crop site location. Asterisked items are required. The map at the bottom of the page shows the business address. Scroll and zoom in/out to locate your crop sites. Use the pencil at left to click on the first corner of your site and then point and click to "fence" your area. If you have an indoor site and outdoor site, you're welcome to draw the "fence" around both if you're willing to pay for the extra unused space. Otherwise, you need to license them separately. Remember that this is for the crop site being licensed and not the individual lots.
6. Read and sign the Acknowledgements on page 6.
7. Complete and submit the payment on page 7. Print a receipt for your records.

License Reporting Forms

of Iowa's licensing and certification requirements. If you have employees and you use pesticides in hemp production, the Worker Protection Standard applies and includes training, notification, personal protective equipment, access to pesticide labeling and other requirements. Visit the Pesticide Bureau's **Applicator Licensing & Certification page** (<https://iowaagriculture.gov/pesticide-bureau/applicator-licensing-certification>) for more information.

Q. Can I apply a pre-plant herbicide prior to planting hemp?

A. No, at this time, no herbicide can be applied to an area where you intend to cultivate hemp. This is subject to change, as per EPA approval of pesticides. For more information on pesticide products and registration, see the Pesticide Bureau's **product list page** (<https://iowaagriculture.gov/pesticide-bureau/pesticide-products>) or call 515-281-8591.

Q. How do the herbicides I applied in the 2019, and even 2020, growing seasons impact acres I may wish to plant to hemp in 2021 and future years?

A. You are required to follow the herbicide label, the label is the law. Because hemp has only recently become a legal commodity crop, herbicide labels do not include rotation/plant-back restrictions for hemp. Hemp would fall under the category of "other crop" and many of those re-plant/plant-back restrictions are for several months — some longer than a year. The herbicides you choose to apply in previous year may preclude you from growing hemp on those acres in 2021 — and possibly beyond — depending on what the label states.

Q. Can I include hemp products in animal feed?

A. The 2018 Farm Bill did not override the FDA's regulatory authority to approve the use of hemp and hemp products in animal feed.

Q. Is crop insurance available for hemp?

A. Yes, The USDA Farm Service Agency (FSA) is offering limited coverage available on the 2021 hemp crop via the Noninsured Crop Disaster Assistance Program (NAP). (https://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/FactSheets/noninsured_crop_disaster_assistance_program-nap-fact_sheet.pdf (https://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdafiles/FactSheets/noninsured_crop_disaster_assistance_program-nap-fact_sheet.pdf)) Hemp raised for commercial grain, seed, fiber, and CBD or other phytocannabinoids may be eligible if all FSA requirements can be met. NOTE: Beginning farmers and socially disadvantaged farmers, including women, etc., may be eligible for reduced premiums. Sign-up deadline: March 15. Talk to your county FSA office for more details, or Amanda Weigel at Amanda.Weigel@usda.gov (<mailto:Amanda.Weigel@usda.gov>) or 515-331-8471.

Q. Are delta-8 hemp products legal in Iowa?

A. Iowa considers delta-8 not legal for possession or manufacture in Iowa.

Q. Do I need an Iowa Agriculture and Vegetable Seed Permit to sell hemp?

A. Yes. All agricultural seed sold and distributed in Iowa requires an **Iowa Agricultural and Vegetable Seed Permit** (<http://iowaagriculture.gov/sites/default/files/department-forms/Application%20for%20Seed%20Permit%202019.pdf>).

Q. Who should I contact if I have questions about hemp production?

A. For more information, contact Robin Puisner at Robin.Puisner@iowaagriculture.gov (<mailto:Robin.Puisner@iowaagriculture.gov>) or 515-725-1465.

Partner Resources

1. **AAFCO (Association of American Feed Control Officials) Guidelines on Hemp in Animal Food** ([/sites/default/files/2020/Hemp/AAFCO%20Hemp%20in%20Animal%20Food%207-2020.pdf](https://iowaagriculture.gov/sites/default/files/2020/Hemp/AAFCO%20Hemp%20in%20Animal%20Food%207-2020.pdf)) (updated July 16, 2020)

Kentucky

Department of Agriculture

Ryan F. Quarles
Commissioner



Kentucky Department of Agriculture

Office of the Commissioner
105 Corporate Drive
Frankfort, KY 40601
Phone: (502) 782-9259

April 19, 2021

Dear Kentucky Hemp License Holder:

In recent weeks the Kentucky Department of Agriculture (KDA) received inquiries from members of the public, including licensees within KDA's Hemp Licensing Program, about the legal status of products containing Delta-8 THC under federal law and state law. In response to these inquiries, I am writing this letter to advise you that Delta-8 THC is a Schedule I controlled substance under federal law and Kentucky law; that distributing products containing this substance is illegal; and distributing such products could lead to your expulsion from the Hemp Licensing Program as well as potential exposure to criminal prosecution.

Let's begin with federal law. As you know, in 2018 Congress created a narrow exemption from the Controlled Substances Act's definition of "marijuana" (DEA numbers 7350 and 7360) for hemp that contains not more than 0.3% total Delta-9 THC. Cannabis with total Delta-9 THC in excess of that threshold remains a Schedule I substance.

There is no equivalent exemption for Delta-8 THC. That being the case, the manufacture and marketing of products containing Delta-8 THC, in any quantity or concentration level, remains prohibited by federal law.

And indeed, the federal Drug Enforcement Administration's [*Controlled Substances List*](#) states that Delta-8 THC and other forms of THC are Schedule I controlled substances. (They are identified with DEA Number 7370.) You can find this specific Schedule I listing on Page 17.

That brings us to state law. Because Delta-8 THC is a Schedule I controlled substance under federal law, it remains a Schedule I controlled substance under state law as well. See 902 KAR 55:015, Section 1(1) (stating that each substance that is scheduled or designated as a Schedule I controlled substance under federal law "shall be scheduled or designated at the state level as a Schedule I controlled substance").

To date, the Kentucky General Assembly has not enacted any law to create an exemption from the Kentucky Controlled Substances Act, KRS Chapter 218A, for products containing Delta-8 THC. Of course, the General Assembly could choose to create such an exemption in the future, as it did in recent years by revising the definition of "marijuana" to create exemptions for four specific categories of products containing cannabidiol (CBD). See KRS 218A.010(28)(c-f).

Because there are no such exemptions for Delta-8 THC in the Kentucky Controlled Substances Act, those substances remain prohibited by state law. For that reason, you should not manufacture, market, or distribute products containing Delta-8 THC. Failure to heed this guidance could result in the revocation of your hemp license and expose you to the risks of prosecution by federal, state, and local law enforcement agencies.

Please do not hesitate to contact me with any questions or concerns you may have about this letter.

Thank you for everything you do to make KDA's Hemp Licensing Program the best in the nation.

Respectfully,

/s/

Joe Bilby
General Counsel

Massachusetts

Department of Agricultural Resources

EMERGENCY ALERTS

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Hemp in Massachusetts: FAQs

The information here should provide answers to frequently asked questions about hemp in Massachusetts, the MA Hemp Program, policies, licensing, testing, and more.

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What is the difference between hemp and marijuana?

EPA Pesticide Registration

(<https://www.epa.gov/pesticide-registration/about-pesticide-registration>)

Will I be allowed to cultivate hemp for food, or manufacture edible products that contain hemp?

The FDA has completed evaluations of three hemp products: hulled hemp seeds, hemp seed protein, and hemp seed oil, and indicated they are Generally Recognized as Safe (GRAS). The use of these hemp or hemp-derived products in food is legal. However, cannabidiol (“CBD”) derived from hemp is still undergoing evaluations for use as a food additive or supplement and a determination has not yet been made relative to its use in products intended for consumption.

Key Actions

CBD in Food Manufactured or Sold in Massachusetts

(</info-details/cbd-in-food-manufactured-or-sold-in-massachusetts>)

FDA CBD Regulations

(<https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>)

Can I sell CBD or other hemp-derived products in MA?

For more information about the sale of CBD or other hemp derived products in the commonwealth, please visit: mass.gov/info-details/faqs-sale-of-hemp-derived-products-in-the-commonwealth

Key Actions

FAQs: Sale of Hemp-Derived Products in the Commonwealth

(</info-details/faqs-sale-of-hemp-derived-products-in-the-commonwealth>)

Is it legal to manufacture delta-8 THC from hemp?

Because delta-8 THC is not naturally occurring in hemp (except for possible trace amounts), to produce delta-8 THC in commercial quantities it must be derived from hemp synthetically. While the Farm Bill did remove hemp from the Controlled Substances Act, it did not impact the control status of synthetically derived cannabinoids, thus delta-8 THC remains a controlled substance, regardless of the source. As a result, we do not allow hemp-derived delta-8 THC products to be processed or sold in Massachusetts.

Michigan

Marijuana Regulatory Agency



**EFFECTIVE
OCTOBER 11, 2021, IT IS
ILLEGAL FOR BUSINESSES
TO SELL DELTA-8 WITHOUT
PROPER LICENSING FROM
THE STATE'S MARIJUANA
REGULATORY AGENCY.**

Delta-8 is a product of the cannabis plant that binds to the body's endocannabinoid system, which causes a user to feel high, similar to “regular THC” marijuana (delta-9). Due to public health concerns and the need for rigorous testing of intoxicating cannabis compounds, the Michigan Legislature recently passed – and Governor Whitmer signed – legislation that categorizes all THC isomers of the cannabis plant, (including delta-8) as marijuana, which is now regulated by the state's Marijuana Regulatory Agency (MRA).

.....

Side effects of delta-8 may be similar to those of “regular THC”, including dry mouth, red eyes, short-term memory, paranoia, and anxiety. Delta-8 hasn't been studied extensively and more research is needed on the effects it has on the mind and body.

Members of the public can report unlicensed commercial production or sale of delta-8 to the MRA by emailing: MRA-Enforcement@michigan.gov

LARA

Marijuana Regulatory Agency

MRA



Delta-8 Information

Delta-8 is a cannabis compound that has become popular because of its similarity to delta-9. Both delta-8 and delta-9 are cannabinoids and are similar in both their names and their chemical structures. THC is the part of the marijuana plant that produces the "high" associated with marijuana; the scientific name for THC is delta-9-tetrahydrocannabinol, or delta-9 THC, or just delta-9. Delta-8 is short for delta-8-tetrahydrocannabinol, or delta-8 THC. Delta-8 causes effects for users similar to regular delta-9.

Delta-8 occurs naturally in small quantities in cannabis, however most of the commercially available delta-8 has been synthesized through a conversion process that uses a variety of chemicals to convert hemp-derived CBD into delta-8.

Delta-8 - like delta-9 (regular THC) - binds to the body's endocannabinoid system, which causes a user to feel high. Chemically, delta-8 and delta-9 are similar in that they both have a double bond in their structures. Both cannabinoids have a chain of carbon atoms, but delta-8 has the double bond on the eighth carbon, whereas delta-9 has it on the ninth carbon. This double bond is thought to produce the intoxicating effects that make the user feel high. Delta-8 binds to the endocannabinoid system in a slightly different fashion because of the location of its double bond. This is what is thought to make delta-8 much less potent than regular THC. However, more research needs to be done on delta-8 and how it interacts with the body.

It is important to note that delta-9 is naturally occurring in relatively high concentrations in marijuana flower while delta-8 is naturally occurring in marijuana flower but in very low concentrations. When you see a delta-9 concentrate product, the cannabinoids in that product were likely extracted directly from the cannabis plant (marijuana) and concentrated. However, when you see a delta-8 concentrate product, the cannabinoids in that product were likely synthesized and concentrated through a chemical process. Nearly all delta-8 THC is derived from CBD which has been extracted from federally legal hemp, not cannabis, which is why it is currently sold in many states where

cannabis is illegal.

Delta-9 marijuana products are produced from cannabinoids found in the cannabis plant and are strictly regulated and subject to stringent testing standards. Conversely, delta-8 products are created using unregulated, chemically synthesized cannabinoids that are, often, entirely untested. Because of this clandestine synthesis process, delta-8 products can contain harmful additives and byproducts.

Side effects of delta-8 may be similar to those of delta-9, including dry mouth, red eyes, getting the munchies, short-term memory, paranoia, or anxiety. Delta-8 hasn't been studied extensively and more research is needed on the effects it has on the mind and body.

The federal Drug Enforcement Administration has - in a proposed rule that is not yet final - indirectly classified delta-8 as a Schedule 1 controlled substance, which would make it federally illegal. The state of Michigan recently passed legislation that classified delta-8 as marijuana and therefore the production, distribution, and sale of delta-8 will now be regulated by the state's Marijuana Regulatory Agency (MRA).

Effective October 11, 2021, it is illegal for businesses to sell delta-8 without proper licensing from the MRA. Members of the public can report unlicensed commercial production or sale of delta-8 to the MRA by emailing **MRA-Enforcement@michigan.gov**.

The MRA has created a one-page document with information about delta-8 and has made it available on the website **here**.



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All THC Products Derived From the Cannabis Plant to Fall Under MRA Regulation Effective October 11, 2021

October 7, 2021 - Effective Monday, October 11, 2021, all THC products derived from the cannabis plant will be covered by state law and regulated by the state's Marijuana Regulatory Agency (MRA). These products - which were previously available for sale to individuals of all ages by businesses that cannot currently sell licensed marijuana products - will only be made available after appropriate approvals, rigorous testing, and commercial standards that currently protect consumer safety in the legal marijuana marketplace.

To ensure public health and safety, the MRA needs to both confirm that these products are safe for consumption and make sure that the production processes are safe. These products will no longer be available in convenience stores, gas stations, and tobacco/smoke shops throughout the state. All intoxicating substances will be reviewed and analyzed to determine if they need to be safety-tested through the MRA's statewide monitoring system and tracked through the state's seed-to-sale tracking system, including delta-8 THC and THC-O-acetate.

"Michigan's approach to cannabis is a model for the nation in regard to protecting its residents and making sure that those who consume these products do so in a safe manner," said MRA Executive Director Andrew Brisbo. "Moving forward, these intoxicating products will be removed from the unregulated marketplace and placed in a well-regulated and licensed system, restricted to adults, and monitored for safety."

Effective October 11, 2021, it is illegal for businesses to manufacture, possess, transfer, inventory, sell, or give away delta-8 THC or THC-O-acetate without proper licensing and approval from the MRA. Unlicensed commercial production or sale of delta-8 THC or THC-O-acetate can be reported to the MRA by emailing MRA-Enforcement@michigan.gov. The MRA has created a one-page document with information about delta-8 THC and has made it available [here](#).

In addition, effective October 11, 2021:

- Licensees are officially prohibited from selling or transferring marijuana to a minor or to a person who is visibly intoxicated at the time of the sale. Individuals who suffer

damage or are personally injured by a minor or a visibly intoxicated person are now permitted to take action against the licensee who sold or transferred the marijuana.

- Marijuana retailers and marijuana microbusiness licensees are required to have and maintain marijuana liability insurance. The insurance must be provided by a licensed and admitted insurance company in Michigan in a minimum amount of \$50,000. Marijuana retailer and marijuana microbusiness licensees authorized to sell marijuana at a temporary marijuana event must also obtain marijuana liability insurance, which covers sales or transfers of marijuana that will occur at the temporary marijuana event. Failure to hold and maintain the required marijuana liability insurance or provide it to the MRA in a timely fashion, may result in disciplinary action against the licensee. Full details are available in the **Marijuana Liability Insurance MRA bulletin** published on August 27, 2021.
- Telemedicine is now allowed for Michigan residents participating in the Michigan Medical Marijuana Program, a state registry program that administers the Michigan Medical Marijuana Act as approved by Michigan voters on November 4, 2008.
- Adult-use applicants should visit the MRA website and utilize the most up-to-date application forms.



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Minnesota

Board of Pharmacy



MINNESOTA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Disciplinary Actions

Because of space limitations, information on disciplinary actions is no longer included in the *Minnesota Board of Pharmacy Newsletter*. A document that provides information about recent Board disciplinary actions can be found on the Board's [website](#) under the "Resources/FAQs" menu item.

Board Member Appointments

Effective June 2, 2021, Governor Tim Walz reappointed **Rabih Nahas, RPh**, for a third term as a pharmacist member of the Board. Governor Walz also appointed **Ben Maisenbach, PharmD, RPh**, to the pharmacist member seat that had been occupied by **Andy Behm, PharmD, RPh**. The Board and its staff thank Dr Behm for his service to the public and the Board, congratulate Mr Nahas on his reappointment, and welcome Dr Maisenbach to the Board.

Mr Nahas is a licensed pharmacist with 30 years of experience in hospital pharmacy. He is currently a clinical pharmacist at Abbott Northwestern Hospital in Minneapolis, MN. He earned his bachelor of science degree in pharmacy from Drake University in 1990. Mr Nahas was first appointed to the Board by former Governor Mark Dayton in 2013 and was reappointed by Governor Dayton in 2017.

Dr Maisenbach received his doctor of pharmacy degree from Creighton University in 2014. He completed his postgraduate residency at M Health Fairview Southdale Hospital in 2015. Dr Maisenbach has worked throughout the Twin Cities with both HealthPartners and M Health Fairview in a variety of inpatient pharmacist roles. He is currently practicing as a clinical oncology pharmacist with M Health Fairview in its outpatient infusion clinics.

Staff Changes

Beth Ferguson, PharmD, recently retired from her position as the Board's deputy director, after ably serving the Board and the public since October 2013. Dr Ferguson received a bachelor of science degree in biology from the University of Minnesota in 1982, and a bachelor of science degree in pharmacy (1989) and doctor of pharmacy degree (1990) from the University of Minnesota College of Pharmacy. She had extensive experience working in hospital and home infusion settings before joining the Board's staff. She also served

as the director of medication safety and pharmacy education, and the director of the residency program, for the HealthEast Care System. In those roles, Dr Ferguson was heavily involved in ensuring that HealthEast pharmacies complied with statutes, rules, and standards of practice.

Dr Ferguson was one of the Board's compounding experts, representing the Board at many national compounding meetings conducted by Food and Drug Administration. She also represented the Board on work groups and committees involved with antibiotic stewardship and quality culture assessment tool standards. The Board and its staff wish Dr Ferguson a long and enjoyable retirement.

Jennell Bilek, PharmD, PhD, JD, RPh, was hired to replace Dr Ferguson as deputy director. Dr Bilek is a registered pharmacist, attorney, and serves as adjunct faculty at the University of Minnesota College of Pharmacy. Before starting at the Minnesota Board of Pharmacy, she was an equity partner with the law firm Carlson Caspers and represented pharmaceutical and other health care-focused companies in complex civil litigations involving patents, trademarks, trade secrets, and contract disputes. She has served as litigation counsel in a variety of federal district courts and represented clients in appeals before the United States Court of Appeals for the Federal Circuit. Dr Bilek also assisted life sciences clients with regulatory matters and compliance with federal laws and rules. For the last decade, she has served as a course director for Pharmacy Law in Practice, which is a required course for third-year pharmacy students at the University of Minnesota. Prior to starting at Carlson Caspers, Dr Bilek worked at Walgreens as a community pharmacist and as a consultant for large employers as they implemented drug formularies and the services offered by pharmacy benefit managers.

Dr Bilek received her doctor of pharmacy degree from the University of Minnesota in 2004, her juris doctor degree from Mitchell Hamline College of Law in 2010, and her doctor of philosophy degree in social and administrative pharmacy from the University of Minnesota in 2013.

Barb Carter recently retired from her position as the Controlled Substances Reporting Section (CSRS) director, after ably serving the Board and the public since November 2008. In that position, she managed the activities of the prescription monitoring program (PMP) and the Opiate Product Registration Fee Program. Ms Carter is a nationally recognized prescription drug monitoring program (PDMP) expert. She served as vice president and president of the National Association of State Controlled Substances Authorities (NASCSA) and co-chaired the NASCSA PMP Committee. Ms Carter also served on the NABP PMP InterConnect® Steering Committee and participated in the National Alliance for Model State Drug Laws PMP Resource Group. She was a "Committed Member" of the Office of the National Coordinator's Standards and Interoperability Framework PDMP and Health IT Integration Initiative. She also served as the secretary for the Alliance of States with Prescription Monitoring Programs.

Prior to starting employment with the Board, Ms Carter held positions at the Minnesota Department of Human Services and the Minnesota Department of Health, where she served as the state registrar of vital statistics and was responsible for the statewide system of collection, maintenance, and dissemination of birth and death data. She received her certification in project management from the University of Minnesota and her certification in data processing and applications programming from Hennepin Technical College. The Board and its staff wish Ms Carter a long and enjoyable retirement.

Katrina Howard, PharmD, RPh, was hired to replace Ms Carter as the CSRS director. Dr Howard previously served as the Board's PMP consultant pharmacist. In that position, she was responsible for pharmacy compliance with reporting and data integrity, as well as the unsolicited notification process for the Minnesota PMP. Dr Howard received her doctor of pharmacy degree from the University of Minnesota College of Pharmacy. She currently chairs the NASCSA PMP Committee.

2021 Legislative Changes

Governor Walz signed legislation that was passed by the Minnesota Legislature, which has several provisions that will affect licensees and registrants of the Board. Only some of the changes are described below. The Board has published a document on its website that provides additional information.

Labeling of Products That Contain Cannabinoids Extracted From Hemp

Minnesota Statutes §151.72 was amended to allow the label of a product that contains a cannabinoid extracted from hemp to use a scannable bar code or QR code that links to the manufacturer's website. **The website must still provide the following information:**

1. the name, location, contact phone number, and website of the manufacturer of the product;
2. the name and address of the independent, accredited laboratory used by the manufacturer to test the product; [and]
3. an accurate statement of the amount or percentage of cannabinoids found in each unit of the product meant to be consumed.

The other requirements of Minnesota Statutes §151.72 remain unchanged, including the testing requirements. Also, only those products containing **nonintoxicating** cannabinoids that are **extracted directly** from hemp can be legally sold in Minnesota (provided that the product is not a food). The Board is aware that products containing delta-8-tetrahydrocannabinol (delta-8-THC) are being sold in Minnesota. Delta-8-THC is intoxicating, and it is the Board's understanding that it cannot be directly extracted from hemp in any significant quantity. Instead, it is produced by conversion from cannabidiol that is extracted from hemp. Consequently, Minnesota Statutes §151.72 does not allow for the sale of products containing delta-8-THC. That section applies to the sale of any product that contains nonintoxicating cannabinoids *extracted* (not indirectly derived) from hemp.

Provisions Related to Medical Gases

The definition of "medical gases" found in **Minnesota Statutes §151.01** was amended and new definitions of medical gas manufacturer, medical gas wholesaler, and medical dispenser were added to that section. Minnesota Statutes §151.191 was added to Chapter 151. It replaces Minnesota Statutes §151.19, subd. 3 and creates licensing requirements for all types of medical gas facilities.

Medication Repository

Minnesota Statutes §151.555 was amended to allow RoundtableRx, Minnesota's medication repository, to accept the donation of over-the-counter (nonprescription) medications that meet the criteria established in that section for donations.

The central repository, as approved by the Board of Pharmacy, may enter into an agreement with another state that has an established drug repository or drug donation program if the other state's program includes regulations to ensure the purity, integrity,

and safety of the drugs and supplies donated, to permit the central repository to offer to another state program inventory that is not needed by a Minnesota resident and to accept inventory from another state program to be distributed to local repositories and dispensed to Minnesota residents in accordance with this program.

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Pharmacy Benefit Manager Gag Clause

Minnesota Statutes §62W.11, which is under the jurisdiction of the Minnesota Department of Commerce, was amended to make the **following changes**:

- (c) A pharmacy benefit manager or health carrier must not prohibit a pharmacist or pharmacy from discussing information regarding the total cost for pharmacy services for a prescription drug, including the patient's co-payment amount and, the pharmacy's own usual and customary price of **for the prescription drug, the pharmacy's acquisition cost for the prescription drug, and the amount the pharmacy is being reimbursed by the pharmacy benefit manager or health carrier for the prescription drug.**
- (d) **A pharmacy benefit manager must not prohibit a pharmacist or pharmacy from discussing with a health carrier the amount the pharmacy is being paid or reimbursed for a prescription drug by the pharmacy benefit manager or the pharmacy's acquisition cost for a prescription drug.**

The Minnesota Board of Pharmacy News is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Amy Sanchez - Publications and Editorial Manager

Nevada

Proposed Amendment to SB 49

NRS 453.096 “Marijuana” defined.

1. “Marijuana” means:
 - (a) All parts of any plant of the genus *Cannabis*, whether growing or not;
 - (b) The seeds thereof;
 - (c) The resin extracted from any part of the plant, including concentrated cannabis; ~~and;~~
 - (d) Every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin; ~~;~~
 - (e) Any commodity or product made using hemp which the THC exceeds the Acceptable Hemp THC Level as defined in NAC 557; and*
 - (f) Any commodity or product made using hemp which exceeds the allowable limit of THC per package as defined in NAC 453.*
2. “Marijuana” does not include:
 - (a) Hemp, as defined in NRS 557.160, which is grown or cultivated pursuant to the provisions of chapter 557 of ~~NRS or any commodity or product made using such hemp which does not exceed 0.3% THC as defined in NRS 453.139; or~~
 - (b) The mature ~~stems stalks~~ of the plant, fiber produced from the ~~stems stalks~~, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature ~~stems stalks~~ (except the resin extracted therefrom), fiber, oil or cake, or the sterilized seed of the plant which is incapable of germination; ~~;~~
or
 - (c) Any commodity or product made using hemp which the THC does not exceed the THC Acceptable Hemp THC Level as defined in NAC 557*

NRS 678A.085 “Cannabis” defined. [Effective July 1, 2020.] “Cannabis” has the meaning ascribed to the term “marijuana” in NRS 453.096.

(Added to NRS by 2019, 3771, effective July 1, 2020)

NRS 453.139 “THC” defined. “THC” means *Delta-9-tetrahydrocannabinol, along with any structural, optical and/or geometric isomers of tetrahydrocannabinol, unless exempted by NAC 453, including but not limited to:*

1. Delta-~~9~~7-tetrahydrocannabinol;
2. Delta-8-tetrahydrocannabinol; and
3. ~~The optical isomers of such substances~~ *Delta-10-tetrahydrocannabinol.*

NRS 557.160 “Hemp” defined.

1. “Hemp” means any plant of the genus *Cannabis sativa* L. and any part of such a plant, including, without limitation, the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts and salts of isomers, whether growing or not, with a THC concentration that does not exceed *the Acceptable Hemp THC Level as defined by the Department.* ~~the maximum THC concentration established by federal law for hemp.~~
2. “Hemp” does not include any commodity or product made using hemp.

New Statute

NRS XXX.XXX “Synthetic cannabinoid” defined.

1. “Synthetic cannabinoid” means a cannabinoid that is:

- (a) Produced artificially, whether from chemicals or from recombinant biological agents including but not limited to yeast and algae; and*
- (b) Not derived from the genus cannabis, including biosynthetic cannabinoids.*

2. Synthetic cannabinoids are not permitted to be used in hemp, cannabis, or any other commodity produced or sold within the state of Nevada.

New York

Department of Health

Frequently Asked Questions Cannabinoid Hemp Program

General Questions

1. What is Cannabinoid Hemp?

Cannabinoid hemp is any product processed or derived from hemp, that is used for human consumption including for topical application for its cannabinoid content, that does not contain more than 0.3% THC. Cannabidiol or "CBD" products are an example of cannabinoid hemp products and can come in a variety of different forms including but not limited to tinctures (CBD oil), pills, capsules, balms, lotions and food or beverage products. Other hemp-derived products such as hemp seeds or hemp seed oil, which do not contain cannabinoids, are regulated as foods and not under the scope of this program.

2. Is Hemp the same as Marijuana?

Hemp and Marijuana are different classifications of the Cannabis plant. "Hemp" is used to classify varieties of Cannabis that contain 0.3% or less THC content (by dry weight). "Marijuana" is used to classify varieties of Cannabis that contain more than 0.3% THC (by dry weight) and is known for its psychoactive effects (including a feeling of being high).

3. What are cannabinoids?

Cannabinoids are natural compounds found in the cannabis plant that have different effects. Tetrahydrocannabinol (THC) and cannabidiol (CBD) are the most common, but there are more than 100 cannabinoids found in the cannabis plant. THC is known for its psychoactive effects (including a feeling of being high). CBD does not produce a feeling of being high and has anecdotally been found to have a variety of wellness benefits.

4. How do I get a license to process or sell cannabinoid hemp?

The Department of Health is now accepting applications for Cannabinoid Hemp Retail Licenses and Distributor Permits. [Click HERE to apply for a Retail License or Distributor Permit.](#) [Click HERE to apply for a Process License.](#)

5. Trouble creating a New York Business Express (NYBE) account or logging into your existing account on the New York Business Express Website?

Call the NYBE Contact Center at (518)-485-5000, Monday - Friday 8:30 am - 4:30 pm for assistance. When you call the help desk you will hear a list of options, you will want to "Press 4" for the Cannabinoid Hemp Program and then "Press 1" for assistance with NYBE profile login.

6. Is the Cannabinoid Hemp Program transferring to the new Office of Cannabis Management?

The transition process for the Cannabinoid Hemp Program to the Office of Cannabis Management (OCM)

will occur within six months of the Cannabis Control Board being fully appointed. Every effort will be made to ensure the transition from the Department of Health to the OCM for cannabinoid hemp permit holders and licensees will be as seamless as possible. Due to the six-month transition process, no immediate changes are being made to the current Cannabinoid Hemp Program. [You can find more information about this topic here.](#)

7. Will a cannabinoid hemp license allow me to process or sell recreational or adult-use marijuana?

No. This is not a license to sell marijuana. The cannabinoid hemp program only regulates products derived from hemp. If you are interested in the future adult-use marijuana program please visit cannabis.ny.gov or e-mail info@cannabis.ny.gov for more information.

8. Does the Cannabinoid Hemp Program permit the sale of cannabinoid hemp flower products?

The proposed regulations permit the sale of cannabinoid hemp flower; however, cannabinoid hemp flower products may not be labeled or advertised for the purposes of smoking or in the form of a joint, cigarette, cigar or pre-roll. Cannabinoid hemp flower products that are not marketed for smoking may be sold by any cannabinoid hemp retail licensee pursuant to the proposed regulations.

9. Are Delta-8 THC products allowed in the Cannabinoid Hemp Program?

No. Delta-8 THC products are not permitted in the New York State Cannabinoid Hemp Program. Retailers are not permitted to sell Delta-8 THC products and processors are not permitted to manufacture them. The Department has issued proposed regulations clarifying this prohibition which can be viewed here: [Proposed Regulations](#).

Cannabinoid Hemp Processor Licenses

1. What is the difference between the two Cannabinoid Processor Licenses: "Extracting and Manufacturing" and "Manufacturing Only"?

The "Extracting and Manufacturing" license type allows a processor to extract or isolate cannabinoids from hemp to create crude oil, distillate, isolate or other intermediary product to be further refined or manufactured into a final cannabinoid hemp product. This license also permits the manufacturing of final cannabinoid hemp products. The "Manufacturing Only" license type allows a processor to purchase crude oil, distillate, isolate or other intermediary product to manufacture final cannabinoid hemp products.

2. How much does a Cannabinoid Processor License cost?

The Cannabinoid Hemp Processors Extracting and Manufacturing License costs \$1,000 for the application fee and \$3,500 for the license fee. The Cannabinoid Hemp Processor Manufacturing Only License costs \$500 for the application fee and \$1,000 for the license fee. Both licenses are valid for two years from the date of issuance.

3. Is there a paper form of the application available?

No, only online applications are available at this time. Please [click HERE to apply](#).

4. How long is the Cannabinoid Hemp Processor License valid for?

Cannabinoid Hemp Processor licenses are valid for two years from the date of issuance of the license.

5. Why do Cannabinoid Hemp Processors need a Good Manufacturing Practices (GMP) Audit?

Good Manufacturing Practices (GMP) is a quality control system for ensuring that products are consistently produced and controlled in accordance with current federal regulations 21 CFR Parts 111 or 117 established by the Food and Drug Administration (FDA). [You can find more information regarding this requirement, here.](#)

Cannabinoid Hemp Retail Licenses and Distributor Permits

1. What is the difference between a Cannabinoid Hemp Retail License and Distributor Permit?

A Cannabinoid Hemp Retailer is a business, including an internet retailer, that sells cannabinoid hemp products in their final form, to consumers to be used for human consumption or topical application. A Cannabinoid Hemp Distributor is a business, selling or distributing cannabinoid hemp products manufactured outside of New York State at wholesale to licensed Cannabinoid Hemp Retailers. If applicable, a business may need both a Cannabinoid Hemp Retail License and Distributor Permit.

2. How much does a Cannabinoid Hemp Retail License cost?

The Cannabinoid Hemp Retail License costs \$300 per retail location and is valid for a year from the date of issuance.

3. How much does a Cannabinoid Hemp Distributor Permit cost?

The Cannabinoid Hemp Distributor Permit costs \$300 per distributing location and is valid for a year from the date of issuance.

4. If I sell cannabinoid hemp products at multiple retail locations, do I need a license for each location?

Yes, each location offering cannabinoid hemp products for sale is required to obtain a license.

5. Do I need a Cannabinoid Hemp Retail License if I am only selling cannabinoid hemp products online?

Yes, whether in-state or out-of-state, retailers offering cannabinoid hemp products for sale to New York State consumers must obtain a Cannabinoid Hemp Retail License. This ensures that cannabinoid hemp products sold in New York State meet the quality assurance and consumer protection standards required by New York State, regardless of where they are produced.

6. Is there a paper form of the application available?

No, only online applications are available at this time. Please [click HERE to apply](#).

7. How long is the Cannabinoid Hemp Retail License valid for?

Cannabinoid Hemp Retail licenses are valid for one year from the date of issuance of the license.

8. How long is the Cannabinoid Hemp Distributor Permit valid for?

Cannabinoid Hemp Distributor Permits are valid for one year from the date of issuance of the permit.

9. If I have a Cannabinoid Hemp Retail License, do I also need a Distributor Permit?

It depends. If you sell cannabinoid hemp products to consumers in New York State and sell cannabinoid hemp products manufactured out-of-state to cannabinoid hemp retailers in New York State, you would need both a Cannabinoid Hemp Retail License and Distributor Permit.

10. Why is the Distributor Permit only required for products manufactured outside of New York?

The Distributor Permit helps control the quality of cannabinoid hemp products produced out-of-state and sold in New York State. Distributor permittees will be responsible for ensuring that all out-of-state cannabinoid hemp products meet the requirements of the Cannabinoid Hemp Program.

11. If the regulations are not effective yet, are there any restrictions on the type of cannabinoid hemp products I can sell?

Yes. All Cannabinoid Hemp Retail and Distributor Permit applicants are encouraged to read the proposed regulations, available here: [Proposed Regulations](#). The proposed regulatory requirements will not go into effect until the regulations are officially adopted and published in the New York State Register. Upon adoption Cannabinoid Hemp Retail Licensees and Distributor Permit holders must adhere to all of the rules and regulations of the Cannabinoid Hemp Program. The Department will notify all applicants when the regulations are effective.

Questions?

- Call: 866-NYS-HEMP (866-697-4367)
- E-mail: hemp@health.ny.gov
- [FAQs](#)

North Carolina

Department of Agriculture and Consumer Services

Industrial Hemp Pilot Program in North Carolina

Frequently Asked Questions



General Program Questions

What is industrial hemp?

Legally, industrial hemp is *Cannabis sativa L.* with a delta-9 tetrahydrocannabinol content of 0.3% or less. As a plant it is a small seeded, dicot, dioecious, photoperiodic plant. That means it is a broadleaf plant with both male and female plants that generally flowers based on a day length trigger. However, some strains can flower based on a certain amount of days and they are known as auto-flowering strains.

How is industrial hemp cultivated?

Industrial hemp is generally grown for; seed, fiber, or floral materials. Each is produced in a slightly different way. For seed production, plants would generally be seeded at a high plant population similar to a small grain crop. Reported seeding rates are 25 to 40 pounds of seed per acre planted with a grain drill. For fiber, high seeding rates are generally recommended. The reason for high seeding rates and plant population is to limit lateral branching and facilitate harvest. Production of floral materials varies widely from greenhouse production to wider row spacings, which would resemble tobacco or horticultural crop production. Floral buds are harvested, so production systems that promote lateral branching and more numerous flowers per plant would be desirable.

Harvesting methods vary. Industrial hemp for seed can be harvested by a combine, but care must be taken to avoid wrapping of plant stems on combine parts as well as shattering of seed to the ground. Grain (seed) is typically harvested at high moisture levels (~15%) to prevent wrapping and shattering, and then the grain should be dried quickly to 7-10% moisture to prevent spoilage. For fiber, the entire plant is cut close to the ground and a retting process must occur. Retting allows the fiber to be separated from the inner core, or hurd, of the stalk. For floral material, the floral buds are harvested.

What is hemp used for?

Hemp fibers have been used to manufacture hundreds of products that include fiber for injected/molded composite materials, twine, paper, construction materials, carpeting, clothing, and animal bedding. Seeds, on the other hand, have been used in making industrial oils, cosmetics and other personal care products, and medicines. Hemp seed or oil can be found in cooking oil, salad dressings, pasta, and snack products. This crop has also generated great interest among pharmaceutical and medical researchers because of the cannabinoids found in the hair-like structures, called trichomes, found on the floral materials.

How can I participate in the program?

Under state and federal laws, individuals must be issued a license to participate in the industrial hemp pilot program. Growers in North Carolina who wish to cultivate industrial hemp shall apply for a license to the Industrial Hemp Commission, which must be approved by commission members. The Industrial Hemp Commission is responsible for developing rules and applications for participating in the program. As adopted in February of 2017, [Temporary Rules](http://reports.oah.state.nc.us/ncac.asp?folderName=%5CTitle%2002%20-%20Agriculture%20and%20Consumer%20Services%5CChapter%2062%20-%20Industrial%20Hemp%20Commission) (<http://reports.oah.state.nc.us/ncac.asp?folderName=%5CTitle%2002%20-%20Agriculture%20and%20Consumer%20Services%5CChapter%2062%20-%20Industrial%20Hemp%20Commission>) spell out the requirements of the industrial hemp research pilot program. An application (<http://www.ncagr.gov/hemp/application.htm>) to become a licensee is available online as well as [application instructions](http://www.ncagr.gov/hemp/application-instructions.htm) (<http://www.ncagr.gov/hemp/application-instructions.htm>) and an application section in our FAQ page (see below)

How do I obtain a copy of the list of hemp processors or hemp license holders?

The industrial hemp processor list can be found at <https://www.ncagr.gov/hemp/documents/ProcessorListForWeb.pdf> (<https://www.ncagr.gov/hemp/documents/ProcessorListForWeb.pdf>) and you can make a public records request for the hemp license holders list by sending an email to industrialhemprequests@ncagr.gov (<mailto:industrialhemprequests@ncagr.gov>)

Application & Licenses

What kind of requirements do I need to meet in order to get approved for a license?

Most of the application will require little work on your part as an applicant. Many questions only require information that you already know or can easily access like various contact information and GPS coordinates.

There are two sections that will require outside documentation. First, you will need to know who you will be acquiring seed, clones, or transplants from. If you have no idea where to start please navigate to the [Planting Sources](https://hemp.ces.ncsu.edu/seed-sources-for-planting/) link (<https://hemp.ces.ncsu.edu/seed-sources-for-planting/>) under the Forms & Resources section. The provider that you work with will need to provide you with their hemp license information and certificates of analysis for the strains/varieties that you intend to grow and that information will have to be included with your application.

The second portion that will require outside documentation is section 13 of the application, the Bona Fide Farmer Certification section. This will require you to provide 1 of 4 specific sets of tax documents (<http://reports.oah.state.nc.us/ncac/title%2002%20-%20agriculture%20and%20consumer%20services/chapter%2062%20-%20industrial%20hemp%20commission/02%20ncac%2062%20.0107.pdf>) (given in the rules and on the application) to prove that you generated gross income last year from the sale of an agricultural commodity. **There are no exceptions to this requirement and the taxes must be from the previous year NOT the last time that you filed farm income.** As an example, if it is 2020 then you need to provide your 2019 tax information.

Are there any restrictions on the number of acres or greenhouse sq. ft. that I can have?

Assuming you have a license to cultivate industrial hemp you can have as much or as little acreage and greenhouse sq. ft. that you want. Keep in mind that the more acreage and greenhouse sq. ft. that you have the more it will cost to obtain and maintain your license.

Are there any restrictions on where I can legally cultivate hemp?

So long as you can acquire a license to cultivate or are in possession of a valid license, there are few legal restrictions on where you must cultivate. Keep in mind that other laws, such as restrictive covenants and zoning, still apply and may impact your ability to grow in certain areas.

The NCDA does not recommend that anyone cultivate at their home, especially in urban or suburban areas. While there may be no legal restrictions to prevent you from doing so, altercations with neighbors and law enforcement will likely increase if your crop has high visibility.

How long does it take to get approved for a hemp license?

The answer to this question is variable. If you submit an application that is completely correct with an Industrial Hemp Commission meeting scheduled for a week later then the whole process could take as little as a few days. However, applications requiring corrections could take days, weeks, or longer to correct and be approved by the commission. As a general rule, it will take approximately 2-3 weeks to be reviewed, correct your application, and then be approved at an Industrial hemp commission meeting. This timeline can shrink or expand depending on the volume of applications and the frequency of Industrial Hemp Commission meetings.

Does my 3 year license have to be renewed?

Yes. If you acquire a 3 year license you only pay for the first year with your initial invoice. Each year after you must pay an annual renewal fee to keep your license valid for the full 3 year period. Failure to pay your annual renewal can cause your license to expire.

How much does an industrial hemp license cost?

For most, a hemp license costs between \$500 and \$600 dollars but this will vary depending on how many acres and greenhouse sq. ft. you intend to be licensed for. You can visit the [rules page](http://reports.oah.state.nc.us/ncac/title%2002%20-%20agriculture%20and%20consumer%20services/chapter%2062%20-%20industrial%20hemp%20commission/02%20ncac%2062%20.0106.pdf) to read about the fee structure. (<http://reports.oah.state.nc.us/ncac/title%2002%20-%20agriculture%20and%20consumer%20services/chapter%2062%20-%20industrial%20hemp%20commission/02%20ncac%2062%20.0106.pdf>)

Can I change the information on my license?

Yes. We have an [amendment form](#) ([documents/New%20Industrial%20Hemp%20Amendment%20Form.pdf](#)) in place so that you can change just about any part of your license. The form to do that can be found under the Forms & Documents page of our website. Based on the rules of the program you have 30 days to make changes to your license.

Can I be listed on someone else's license or transfer my license to someone else?

No. Hemp license are not transferable to another entity and do not transfer with land. There is no way for you to add an individual to your license or for you to be listed on another's license.

Hemp Processors**How do I register as a hemp processor?**

You can navigate to the [Industrial Hemp Processor page](#) ([ProcessorsInfo.htm](#)) to find the registration form. Fill out this form and submit it back to us according to the instructions at the top of the page.

What is a hemp processor?

A hemp processor can be any number of things including but not limited to: a facility performing extractions and generating crude or distillates from hemp biomass, drying/curing/trimming services, facilities that package or repack hemp/hemp products, facilities that take crude oil or distillate and formulate products ready for

retail, facilities that package or pre-roll smokable hemp products, etc. If you aren't sure if you should register as a hemp processor you can contact us at industrialhemprequests@ncagr.gov (<mailto:industrialhemprequests@ncagr.gov>)

Can I modify my processor registration information?

Yes. You can email us at industrialhemprequests@ncagr.gov (<mailto:industrialhemprequests@ncagr.gov>) with any changes that you need to make.

Selling Hemp & Hemp Products

Do I have to register or get a license to sell hemp or hemp products?

No. There are currently no laws requiring a special license or registration to sell hemp or hemp products (often CBD) in the State of North Carolina. Keep in mind that only an individual with a cultivator's license can be in possession of or sell viable seed or living hemp plants. You will need to establish your business with the state, if you haven't, for tax and other legal purposes.

Are edible hemp/CBD products allowed to be made and sold?

The Federal Food and Drug Administration has stated that CBD cannot be put into foods for human or animal consumption because it is a registered drug. CBD is the active ingredient in a drug called "Epidiolex" and much like you can't put aspirin in food you cannot put CBD into food. In addition to the restrictions on what you can put CBD into, you cannot make medical claims on CBD products or sell CBD as a nutritional supplement because of its status as a registered drug.

Is smokable hemp legal in the State of North Carolina?

At this time, smokable hemp is a legal product in the State of North Carolina. Legislation could be introduced to ban smokable hemp in the General Assembly but until it is passed into law smokable hemp remains legal.

Delta-8 THC

Is Delta-8 THC tested for in hemp in North Carolina?

The North Carolina Industrial Hemp Pilot Program does not regulate or screen for Delta-8 THC when sampling hemp for compliance. Instead, the North Carolina Industrial Hemp Pilot Program samples and tests for the total Delta-9 THC levels, including any potential conversion of THCA into THC. This approach is in-line with USDA's January 19, 2021 Final Rule, titled "Establishment of a Domestic Hemp Production Program." USDA explained that there is no need to screen for Delta-8 THC because the concentration of Delta-8 THC in hemp is basically undetectable and contributes nothing significant to the total THC content.

Are Delta-8 THC products legal in North Carolina?

The threshold factor is whether the Delta-8 THC is derived from hemp or marijuana. If the Delta-8 THC is derived from marijuana, then the product is illegal as a controlled substance under both North Carolina and federal law.

Whether Delta-8 THC derived from hemp is legal or not depends on who you ask. Currently, DEA takes the position that synthetically derived THC is illegal as a controlled substance. Since Delta-8 THC appears at negligible and nondetectable concentrations in hemp, Delta-8 THC is normally derived from chemical conversion from CBD into Delta-8 THC. Therefore, it appears from DEA's August 21, 2020 Interim Final Rule, titled "Implementation of the Agriculture Improvement Act of 2018," that it will treat Delta-8 THC derived from chemical conversion or other synthetic methods as illegal.

How can I keep informed of when the Industrial Hemp Commission will meet next? What if I miss a meeting? Can I get the information I missed from a meeting?

There is a [Meeting Update page \(Meeting-Updates.htm\)](#) that lists the next announced Industrial Hemp Commission meeting. Additionally, you can find meeting agendas and approved minutes from previous meetings. You can also sign up for the mailing list on the [Industrial Hemp Home page \(index.htm\)](#) to get meeting information emailed as it becomes available.

Oregon

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Oregon Liquor Control Commission

Chapter 845

Division 26

ADULT USE CANNABIS AND HEMP CONCENTRATION LIMITS

845-026-0300

Adult Use Cannabis Item

(1) In accordance with ORS 475B.015 as amended by 2021 Oregon House Bill 3000, the Commission must establish the concentration of adult use cannabinoids at which a hemp item qualifies as an adult use cannabis item.

(2) An industrial hemp commodity or product is an adult use cannabis item if it:

(a) Contains 0.5 milligrams or more of any combination of:

(A) Tetrahydrocannabinols or tetrahydrocannabinolic acids, including delta-9-tetrahydrocannabinol or delta-8-tetrahydrocannabinol; or

(B) Any other cannabinoids advertised by the manufacturer or seller as having an intoxicating effect;

(b) Contains any quantity of artificially-derived cannabinoids; or

(c) Has not been demonstrated to contain less than 0.5 milligrams total delta-9-THC when tested in accordance with ORS 571.330 or 571.339.

(3) An adult use cannabis item cannot be sold or delivered to a person under 21 years of age, except by a marijuana retailer that holds a license issued under ORS 475B.105 and that is registered under ORS 475B.146 to sell or deliver marijuana items to a registry identification cardholder who is 18 years of age or older or as allowed under ORS 475B.785 to 475B.949.

Statutory/Other Authority: ORS 475B.025, 475B.015 & 2021 H.B. 3000

Statutes/Other Implemented: ORS 475B.025, 475B.015, 475B.211 & 2021 H.B. 3000

History:

OLCC 8-2021, temporary adopt filed 07/19/2021, effective 07/19/2021 through 12/31/2021

Please use this link to bookmark or link to this rule.

v1.9.2

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South Carolina

Office of the Attorney General



ALAN WILSON
ATTORNEY GENERAL

October 4, 2021

Chief Mark A. Keel
South Carolina Law Enforcement Division
PO Box 21398
Columbia, SC 29221-1398

Dear Chief Keel:

We received your request for an opinion clarifying the application of South Carolina's Hemp Farming Act as it relates to THC and THC variants. This opinion sets out our Office's understanding of your question and our response.

Issue (as quoted from your letter):

In South Carolina, Tetrahydrocannabinol (THC) is a controlled substance listed in Schedule I. . . . As such, it is clear to SLED that the possession, possession with intent to distribute, or distribution of THC is explicitly prohibited by South Carolina law and all existing penalties apply. *See* S.C. Code Ann. § 44-53-370(b)(2). However, South Carolina's Hemp Farming Act, S.C. Code Ann. § 44-56-10 *et seq.*, may authorize certain licensed individuals to cultivate, process, and handle hemp or hemp products in South Carolina. That said, SLED is informed and believes that any authorization provided by the Hemp Farming Act is clearly limited to hemp or hemp products that contain the "federally defined THC level for hemp", which is "a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis" determined by using post-decarboxylation or similarly reliable methods. *See* S.C. Code Ann. § 46-55-10(6), (8), (9).

In that regard, SLED is informed and believes that any and all THC that is not "a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis" is specifically prohibited by the clear and unambiguous language of S.C. Code Ann. § 44-53-190(D)(18). To that end, SLED is informed and believes that this unambiguous language would clearly criminalize the possession, possession with intent to distribute, or distribution of any and all amounts of delta-8 THC, or any other variant of THC, found in South Carolina.

Simply put, delta-8 THC and delta-9 THC are different compounds with different chemical and structural properties and SLED's forensic testing can absolutely differentiate delta-8 THC and delta-9 THC through analytical testing. Accordingly, SLED is informed and believes that the Hemp Farming Act does not apply to delta-8 THC, or any other THC variant, in any way whatsoever because delta-8 THC does not meet the "federally defined THC level for hemp". It also bears noting that Tetrahydrocannabinols are also Schedule I substances prohibited by federal law.

However, SLED would appreciate your opinion on SLED's analysis in this matter.

Law/Analysis:

Section 44-53-190 of the South Carolina Code sets out our State's list of Schedule I controlled substances. Subsection 44-53-190(D) lists, in relevant part:

Any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers, and salts of isomers, unless specifically excepted, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

...

(11) Marijuana

...

(18) Tetrahydrocannabinol (THC)

S.C. Code Ann. § 44-53-190(D)(11) & (18) (2018).

The laws of some other jurisdictions have distinguished between THC contained in cannabis and pure THC, whether extracted or synthetically created. *See, e.g., Aycock v. State*, 246 S.E.2d 489 (Ga. Ct. App. 1978). However, South Carolina law does not, in that section 44-53-190 lists each of them as Schedule I controlled substances "unless specifically excepted." § 44-53-190.

Section 44-53-190 also does not distinguish between various isomers of THC, except to provide that “[a]ny . . . isomers” are included. *Id.* Delta-8 THC is one such isomer, as explained by Georgia Court of Appeals in *Aycock v. State*, 246 S.E.2d 489 (Ga. Ct. App. 1978):

THC is the psychopharmacologically active component of the cannabis plant. Most THC exists in the form of an isomer known as delta-9-THC, but somewhat less than ten percent of naturally occurring THC is of the delta-8 isomer. Both delta-8-THC and delta-9-THC produce a psychological effect. They are found in all cannabis plants, and they are not known to exist elsewhere in nature. Concentrations of THC can be produced in two ways, either by chemically extracting it from the cannabis plant or by synthesizing it in the laboratory.

As noted above, South Carolina law designates all isomers of THC as Schedule I controlled substances “unless specifically excepted.” S.C. Code Ann. § 44-53-190 (2018). The Hemp Farming Act of 2019 is one such exception, as discussed thoroughly in prior opinions of this Office. S.C. Code Ann. § 46-55-10 *et seq.*; *see also Op. S.C. Att’y Gen.*, 2019 WL 3243864 (July 10, 2019). Section 46-55-10 contains several key definitions for purposes of the Hemp Farming Act which we quote here:

(6) “Federally defined THC level for hemp” means a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis, or the THC concentration for hemp defined in 7 U.S.C. SECTION 5940, whichever is greater.

...

(8) “Hemp” or “industrial hemp” means the plant *Cannabis sativa* L. and any part of that plant, including the nonsterilized seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with the federally defined THC level for hemp. Hemp shall be considered an agricultural commodity.

...

(9) “Hemp products” means all products with the federally defined THC level for hemp derived from, or made by, processing hemp plants or hemp plant parts, that are prepared in a form available for commercial sale, including, but not limited to, cosmetics, personal care products, food intended for animal or human consumption, cloth, cordage, fiber, fuel, paint, paper, particleboard, plastics, and

any product containing one or more hemp-derived cannabinoids, such as cannabidiol. Unprocessed or raw plant material, including nonsterilized hemp seeds, is not considered a hemp product.

...

(11) “Marijuana” has the same meaning as in Section 44-53-110 and does not include tetrahydrocannabinol in hemp or hemp products as defined herein.

S.C. Code Ann. § 46-55-10 (Supp. 2020) (emphasis added). We have highlighted throughout this quotation that the lawfulness of hemp and hemp products all hinge on the “federally defined THC level for hemp,” which means “a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis.” §46-55-10(6); *see also* 7 U.S.C. § 5940(a)(2) (“The term ‘industrial hemp’ means the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”).

The Hemp Farming Act does not expressly address delta-8 THC, or any isomer besides delta-9. It does, however, specify application of the Act: “The provisions contained in this chapter do not apply to the possession, handling, transport, or sale of hemp products and extracts, including those containing hemp-derived cannabinoids, including CBD. Nothing in this chapter authorizes any person to violate any federal or state law or regulation.” S.C. Code Ann. § 46-55-30 (Supp. 2020) (emphasis added).

To date, it appears that there are no reported appellate cases in South Carolina construing the Hemp Farming Act. However, our Office has opined previously on the scope and application of the Act. *See, e.g., Op. S.C. Att’y Gen.*, 2019 WL 3243864 (July 10, 2019). This opinion should be read in the context of, and consistent with, those prior opinions.

We turn now to the July 10, 2019 opinion addressed to you where we reasoned that “anything exceeding the 0.3% concentration of THC, as defined [by the Hemp Farming Act], transforms industrial hemp into a controlled substance (marijuana) under federal and state law.” *Op. S.C. Att’y Gen.*, 2019 WL 3243864 (July 10, 2019) (emphasis added). The opinion went on to conclude that “possession or sale of material containing more than delta-9 THC concentration of more than 0.3 percent using post-decarboxylation or similarly reliable methods would likely be deemed to constitute marijuana.” *Id.* Therefore, we concluded, “if material contains more than delta-9 THC concentration of not more than 0.3 percent, based upon the relevant circumstances, possession or retail sale would be ‘punishable by all currently existing South Carolina state and

federal laws prohibiting possession, distribution, possession with intent to distribute and trafficking marijuana.” *Id.* (emphasis added). While that opinion did not expressly consider the question of isomers, this language reflects our view that the General Assembly intended the Hemp Farming Act to create an exception that is narrow. *See id.*

That opinion also emphasized that “[a]ny determination as to whether there has been a violation . . . would have to be determined on a case-by-case basis,” and that “we must defer to law enforcement in this regard.” *Id.* Accordingly, it is beyond the scope of any opinion of this Office to say whether a particular criminal statute is violated in a particular instance. We also observed that “the Hemp Farming Act of 2019 was not drafted with the greatest of clarity and needs legislative or judicial clarification.” *Id.*

Our Office has received and carefully reviewed memoranda prepared by a representative of the hemp industry which posit that delta-8 and other isomers of THC are legal. The essential argument may be summarized as follows: the Hemp Farming Act legalized “all derivatives, extracts, cannabinoids, [and] isomers” with “a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis.” S.C. Code Ann. § 46-55-10. Because delta-9 was the only THC isomer expressly regulated in the Act THC, any other isomer extracted or derived from hemp is lawful – provided the delta-9 concentration remains below 0.3. Therefore, they reason, delta-8 and any isomers of THC other than delta-9 became legal under South Carolina law as a result of the Hemp Farming Act. Moreover, under this construction of the law, any concentration of isomer of THC other than delta-9 also became legal, regardless of psychoactive potential.

In support of their proposed construction, the industry points out that the General Assembly could have defined hemp as having “a THC concentration of not more than 0.3 percent,” without reference to specific isomers. Instead, the General Assembly defined hemp by reference to one specific isomer, delta-9. The industry posits that this choice was deliberate, and was intended to legalize other isomers. They also point out that to the extent that the statutes are in conflict, the Hemp Farming Act was passed later in time and is more specific than section 44-53-190, which categorizes all isomers of THC as Schedule I substances.

We believe that a court ultimately would reject these arguments for the reasons explained hereafter. However, these are arguments that a serious stakeholder can make in good faith, as a result of some of the gaps in the Hemp Farming Act. They highlight the persisting need for legislative clarification, which prior opinions of this Office have identified. *Op. S.C. Att’y Gen.*, 2019 WL 3243864 (July 10, 2019).

Notwithstanding that need for clarification, however, we believe that the application of the law here is relatively straightforward. The basic purpose of the Hemp Farming Act is to create a legal framework for the licensed, regulated production of industrial hemp as defined, and it must be construed consistent with that purpose. Section 44-53-190(D) still categorizes all isomers of THC as Schedule I controlled substances “unless specifically excepted.” S.C. Code Ann. § 44-53-190(D) (2018). The Hemp Farming Act creates such a specific exception in certain circumstances for hemp containing up to a specific level of one specific isomer – that is, delta-9 THC. S.C. Code Ann. § 46-55-10 *et seq.* (Supp. 2020). It does not create an express exception for delta-8 THC, or any other THC isomer. *See id.* Lawful hemp as contemplated by the Hemp Farming Act may contain trace amounts of THC isomers, such as delta-8. *See Aycock v. State*, 246 S.E.2d 489 (Ga. Ct. App. 1978). However, this legislative scheme cannot fairly be read to legalize delta-8 THC or any other isomer of THC in itself. And although the Hemp Farming Act was passed later in time and is more specific than section 44-53-190, we believe these statutes do not conflict in the way that the industry posits. Instead, the Hemp Farming Act simply creates a specific exception to accomplish a particular purpose, as contemplated in section 44-53-190(D).

Conclusion:

In conclusion, we believe a court would hold that the Hemp Farming Act does not provide an exception for, and does not legalize, delta-8 THC or any other isomer of THC in itself. Section 44-53-190(D)(18) (2018) categorizes all isomers of THC as Schedule I controlled substances “unless specifically excepted.” The only exceptions found in the Hemp Farming Act involve “a delta-9 THC concentration of not more than 0.3 percent on a dry weight basis.” S.C. Code Ann. § 46-55-10 (Supp. 2020); *see also* 7 U.S.C. § 5940. Our Office has observed in the past that “the Hemp Farming Act of 2019 was not drafted with the greatest of clarity and needs legislative or judicial clarification.” However, we believe that any good-faith reading of the plain language of the Act in conjunction with section 44-53-190 supports our conclusion here. *See Op. S.C. Att’y Gen.*, 2019 WL 3243864 (July 10, 2019). This reading also is consistent with the prior opinion of this Office which reflects our view that the General Assembly intended the Hemp Farming Act to create an exception that is narrow. *Op. S.C. Att’y Gen.*, 2019 WL 3243864 (July 10, 2019)

Lawful hemp as contemplated by the Hemp Farming Act may contain trace amounts of THC isomers, such as delta-8. *See Aycock v. State*, 246 S.E.2d 489 (Ga. Ct. App. 1978). This opinion should not be read so as to speak to those trace amounts. We express no opinion on what any upper limit of THC isomer concentrations in lawful hemp might be, beyond the statutorily-

Chief Mark A. Keel
South Carolina Law Enforcement Division
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October 4, 2021

expressed limit placed on delta-9 THC. *See* S.C. Code Ann. § 46-55-10 (Supp. 2020). We understand that your question is focused on delta-8 and other THC isomers in themselves, not these trace amounts. This opinion should be read in the context of, and consistent with, the other prior opinions of this Office which address the Hemp Farming Act.

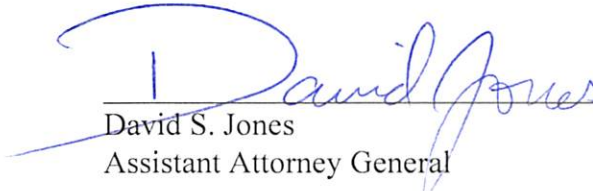
The industry has advanced several arguments in favor of construing the Hemp Farming Act as legalizing delta-8 and other isomers of THC. These are arguments that a serious stakeholder can make in good faith, as a result of some of the gaps in the Hemp Farming Act. They highlight the persisting need for legislative clarification, which prior opinions of this Office have identified. *Op. S.C. Att'y Gen.*, 2019 WL 3243864 (July 10, 2019).

However, we believe that the application of the law here is relatively straightforward. The basic purpose of the Hemp Farming Act is to create a legal framework for the licensed, regulated production of industrial hemp as defined, and it must be construed consistent with that purpose. The plain text of the Hemp Farming Act and section 44-53-190(D) each operate in tandem to create a narrow exception for lawful hemp as defined, while preserving the existing prohibition on other isomers of THC.

In summary, our Office agrees with SLED's essential analysis that the Hemp Farming Act did not legalize THC except as defined in lawful hemp. If the General Assembly intended to undertake legalization of THC on the scale that the industry posits, they would have done so expressly and unambiguously. Instead, the legislative scheme of the Hemp Farming Act was much narrower: to create a legal framework for the licensed, regulated production of industrial hemp as defined. It cannot fairly be read to accomplish sweeping THC legalization or a similar sea change from previous policy.

We reiterate that any determination as to whether there has been a violation of the Hemp Farming Act or other criminal laws is a factual question which this Office cannot answer in an opinion. *Op. S.C. Att'y Gen.*, 2019 WL 3243864 (July 10, 2019). We defer to law enforcement and the local prosecutor's office to make such determinations on a case-by-case basis. *Id.*

Sincerely,


David S. Jones
Assistant Attorney General

Chief Mark A. Keel
South Carolina Law Enforcement Division
Page 8
October 4, 2021

REVIEWED AND APPROVED BY:

A handwritten signature in blue ink, appearing to read "Robert D. Cook", is written over a horizontal line.

Robert D. Cook
Solicitor General

Texas

Department of State Health and Human Services



TEXAS
Health and Human
Services

Texas Department of State
Health Services

Consumable Hemp Products - Frequently Asked Questions

Which one is required: A DSHS Consumable Hemp Product License or DSHS Hemp Retail Registration?

A Consumable Hemp Product License is required to make any change to a consumable hemp product or its packaging and to sell it wholesale or retail. Any change can be repackaging hemp flower from bulk into smaller packages, relabeling a bottle of CBD oil, adding your own label to a package of CBD gummies, or adding CBD oil to cupcakes.

If consumable hemp products (CHPs) are only going to be sold in retail and no changes will be made to the CHPs or its packaging, an applicant will need to complete the Texas Department of State Health Services (DSHS) Hemp Retail Registration.

If an applicant has one or multiple locations that do both activities, they will need to obtain the Consumable Hemp Product License. If a CHP is made at one location then sold at another, the applicant needs to obtain a Consumable Hemp Product License and complete the DSHS Hemp Retail Registration for the retail location.

What is DSHS required to do because of House Bill (HB) 1325?

HB 1325 requires DSHS to:

- Establish a manufacturing licensure program for CHPs.
- Create a registration process for retailers selling CHPs containing cannabidiol (CBD).
- Work with the Texas Department of Public Safety on random testing for CHPs containing CBD sold at retail.

What is DSHS' role?

DSHS has oversight of food, drug, cosmetics and medical device manufacturers, distributors and retailers, including those that may use or market hemp or CBD as an ingredient in those products. Local jurisdictions can also regulate retail sales of food, drugs, cosmetics and medical devices, but cannot prohibit the sale of CHPs.

DSHS does not regulate a person's private possession or private use of any food, drug, cosmetic product or dietary supplement. Neither does DSHS administer the [Texas Compassionate Use Act](#).

Can CHPs be manufactured in Texas?

Yes. In accordance with HB 1325, Texas Health and Safety Code (HSC) Chapter 443, and HSC Chapter 431, Texas firms can manufacture CHPs such as food, drugs, cosmetics and devices containing "hemp or one or more hemp-derived cannabinoids, including cannabidiol." The products must be properly tested, packaged and labeled per HSC 443 and 25 Texas Administrative Code 300. The firms must obtain the DSHS Consumable Hemp Product License before operation.

Products that contain hemp ingredients on the U.S. Food and Drug Administration's Generally Recognized as Safe (GRAS) list — hulled hemp seeds, hemp seed protein, and hemp seed oil — are not considered CHPs in Texas. Manufacturers of such products must obtain the [DSHS Food Manufacturer License](#).

Can consumable hemp products in Texas contain Delta-8 tetrahydrocannabinol (THC)?

No. Texas Health and Safety Code Chapter 443 (HSC 443), established by [House Bill 1325](#) (86th Legislature), allows Consumable Hemp Products in Texas that do not exceed 0.3% Delta-9 tetrahydrocannabinol (THC). All other forms of THC, including Delta-8 in any concentration and Delta-9 exceeding 0.3%, are considered Schedule I controlled substances. A list of Schedule I controlled substances can be found at the following link: [Schedule I Controlled Substances](#).

Complaints regarding controlled substances should be referred to law enforcement. DSHS has no regulatory authority over controlled substances.

What are the requirements to sell CHPs in retail?

To sell CHPs in Texas, retailers must complete the DSHS Hemp Retail Registration. Retailers must ensure the product is safe for consumption by being free of heavy metals, pesticides, harmful microorganisms, and residual solvents. Additionally, CHPs sold must not contain more than 0.3 percent of Delta-9 tetrahydrocannabinol (THC). Products that are being manufactured or handled in a manner that creates a health hazard for people who may use them can be detained.

During routine inspection or complaint investigations, DSHS, within its statutory authority, can detain products, including dietary supplements, that are labeled as or contain hemp, including CBD, and that make unproven health claims such as preventing, diagnosing, treating or curing a health or medical condition.

- Note: HB 1325 contains limitations regarding retail sales of out-of-state CHPs. The out-of-state CHPs must be processed or manufactured in compliance with one of the following:
- That state or jurisdiction's plan approved by the United States Department of Agriculture (USDA).
- In absence of a state-submitted plan, a plan established by the USDA.
- The laws of that state or jurisdiction if the products are tested in compliance with, or similar to, those set out in Section 443.151 of HB 1325.

Where can GIS coordinates and the legal description of a property be found for the DSHS Consumable Hemp Product License process?

If the property is leased, the legal description may be in the lease agreement. If the property is owned, it may be in the deed.

Some people have found this information on their county property appraisal website.

DSHS will accept a screenshot or a clear photo of the legal description of the property for the DSHS Consumable Hemp Product License process. Another option is to write the information in a Word document with the information and website where the information was found.

These are some examples of the **legal description of property**:

- Lots 6, 7, and the South ½ of Lot 3, West 60 feet of South ½ of Lot 4, West 60 feet of Lot 5 and Lot 8, Block 20, OLD SURVEY, Leesville, Vernon Parish, Louisiana.
- Lot 1, Block 1, Minneapolis Addition, Hennepin County, Minnesota.
The GIS coordinates may be found where the legal description of the property is listed. There are apps that can find this information, including Google Maps. To get the GIS coordinates in Google Maps, type in the address and right click the red coordinate marker on the map to reveal the information.

This is an example of **GIS coordinates**:

- 1100 W. 49th St., Austin, TX 78756 — 30.320473, -97.734052.

What should a consumer know?

CBD is currently available as an FDA-approved prescription drug. DSHS does not regulate a person's private possession or private use of any food, drug, cosmetic product, or medical device, and HB 1325 will not change those parameters. Questions regarding medicinal use of CHPs (including CBD) should be directed to a physician.

What is the process for a retailer to open additional locations selling CHPs?

The retailer will need to contact DSHS by calling 512-834-6626 or email the [Hemp Licensing and Registration Program](#). They will need to provide the following:

- The registration or license number.
- The business name of the new location(s).
- The full address of the new location(s).

What is the process for a retailer to close locations selling CHPs?

The retailer will need to contact DSHS by emailing the [Hemp Licensing and Registration program](#) and providing:

- The registration or license number.
- The full address of the location(s).
- A brief statement that the location is closing and the date of closing.

Where can inquiries, comments and questions be sent about CHPs and farming hemp?

To learn more about CHPs, email the [DSHS Hemp Program](#).

To learn more about the license for CHPs or retail registrations, email the [Hemp Licensing and Registration program](#).

To learn about farming hemp, visit the [Texas Department of Agriculture's Hemp Regulations webpage](#) or email the [TDA Hemp Program](#).

Last updated October 15, 2021

Vermont

Agency of Agriculture, Food and Markets



STATE OF VERMONT

Agency of Agriculture, Food and Markets

SEARCH

CONTACT

[HEMP PROGRAM \(/NEWS\)](#)

IS THE MANUFACTURE OF DELTA-8-THC OR ITS USE IN HEMP PRODUCTS PERMITTED UNDER THE VERMONT HEMP PROGRAM?

23 APRIL 2021



Is the Manufacture of Delta-8-THC or its Use in Hemp Products Permitted under the Vermont Hemp Program?

The short answer is “No”.

Delta-8-THC is a psychoactive compound (similar to delta-9-THC) that occurs naturally in only very small amounts in hemp. The natural concentration of delta-8-THC is so low that it is unlikely to have any effects on the consumer. However, delta-8-THC can be synthetically made from hemp. As a primary example, cannabidiol (CBD) can be isolated and manufactured or synthesized into delta-8-THC. Some producers use this chemical process to convert CBD into delta-8-THC and delta-8-THC products. Manufacturing delta-8-THC from CBD has become a way to create a psychoactive substance under the guise of being derived from legally produced hemp, which by definition does

not have high concentrations of psychoactive cannabinoids.

The Vermont Hemp Rules were adopted in May 2020 and ban the “use of synthetic cannabinoids in the production of any hemp product or hemp-infused product.” Vermont Hemp Rules § 6.3. So, while naturally occurring delta-8-THC is not barred from hemp or hemp products, Vermont producers cannot manufacture the delta-8-THC cannabinoid from hemp.

Because the Vermont Hemp Rules expressly prohibit the use of synthetic cannabinoids in hemp products and/or hemp-infused product, Vermont Hemp Program registrants that manufacture and/or label products containing delta-8-THC are violating State law and risk enforcement by the Vermont Agency of Agriculture, Food and Markets. In addition, delta-8-THC manufactured from hemp may be a controlled substance under federal and/or State law. As a result, anyone who uses, possesses, or distributes delta-8-THC may face federal and/or State criminal sanctions.

While delta-8-THC cannot be manufactured from hemp, the Vermont Hemp Rules allow producers to create distillates and isolates of hemp’s naturally occurring cannabinoids to create hemp products. In this process, please note that primary botanical extraction is only permitted by solvent-free mechanical, CO2, ethanol, or lipid methods unless the Secretary approves an alternative extraction method. See Vermont Hemp Rules § 6.2. When using solvent based extraction methods, the product must be in compliance with Vermont Hemp Rules Section 8, and analytical contaminant results must demonstrate that the final product does not exceed Cannabis Quality Control Program action limits.

You can find the Vermont Hemp Rules here, https://agriculture.vermont.gov/sites/agriculture/files/documents/PHARM/hemp/Vermont_Hemp_Rules_effective_05_21_20.pdf (https://agriculture.vermont.gov/sites/agriculture/files/documents/PHARM/hemp/Vermont_Hemp_Rules_effective_05_21_20.pdf).

Cannabis Quality Control Program action limits here, https://agriculture.vermont.gov/sites/agriculture/files/documents/PHARM/hemp/FINAL_cannabis_testing_tables_10-16-20.pdf (https://agriculture.vermont.gov/sites/agriculture/files/documents/PHARM/hemp/FINAL_cannabis_testing_tables_10-16-20.pdf).

Hemp is an important and burgeoning agricultural product. To maintain recent industry gains, it is important that Hemp Program registrants manufacture hemp products that do not violate the Vermont Hemp Rule and federal law, and that consumers understand what they are buying. Toward that end, synthetic delta-8-THC—and other synthetic cannabinoids—are not allowed in hemp products.

For more information, please contact Stephanie Smith, stephanie.smith@vermont.gov (<mailto:stephanie.smith@vermont.gov>) or 802-661-8051.

TAGS:

[Hemp Program \(/tags/hemp-program/\)](/tags/hemp-program/)

Contact Information

Agency of Agriculture, Food & Markets

116 State Street
Montpelier, Vt 05620-2901
802.828.2430



Program Contacts

- Media Inquiries 802.622.4662
- Licensing & Registration 802.828.2436
- Business Development 802.828.1619
- Feed, Seed, Fertilizer & Lime 802.828.5050
- Working Lands 802.622.4477
- Public Health & Resource Management 802.828.2431

- Laboratory 802.585.6073
- Animal Health 802.828.2421
- Dairy 802.828.2433
- Consumer Protection / Weights & Measures 802.828.2433

- Produce Program **802.461.5128**
- Meat Inspection **802.828.2426**

- Water Quality **802.828.2431**
 - Grants **802.622.4098**
 - Enforcement **802.828.2431**
 - Reports **802.272.0323**
 - BMP's **802.828.3474**
- Act 250 **802.828.2431**
- Pesticide **802.828.2431**

Washington

Liquor and Cannabis Board



Clarifying Statement Regarding LCB Rulemaking Authority re THC Isomers other than Delta-9

Washington State Liquor and Cannabis Board sent this bulletin at 05/03/2021 02:09 PM PDT

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May 3, 2021

Clarifying Statement Regarding LCB Rulemaking Authority re THC Isomers other than Delta-9

Issue

Delta-8 THC is a psychoactive compound naturally occurring in very low levels in cannabis. With the recent federal legalization of hemp, delta-8 and other THC compounds other than state regulated delta-9, can be chemically derived from CBD that was originally generated from hemp.

Delta-8 derived from hemp has emerged for sale nationwide, including small amounts within the regulated Washington State supply chain, as well as in unregulated convenience stores and commercial internet websites. It is an emerging issue nationwide with concerns surrounding it that include: youth access, health effects resulting from the extraction process, and the impact of a product that is generally unregulated competing with a tightly regulated state cannabis marketplace.

Research

In recent months, the LCB has been researching delta-8 through multiple channels. Discussions are ongoing with state public health officials, cannabis industry representatives and other state regulators through the national trade organization the Cannabis Regulators Association (CANNRA). Most states are currently fact finding and

communicating with Washington and other states. Some have moved quickly to prohibit delta-8 through rule or legislation.

Reason for Policy Statement

On April 28, 2021, LCB issued [Policy Statement Number PS-21-01](#) regarding: *The regulation of tetrahydrocannabinols (THC), other than Delta-9*; and the conversion of CBD, hemp, or both to delta- 8 THC, delta-9 THC, or any other cannabis compound that is not currently identified or defined in the Revised Code of Washington (RCW), the Washington Administrative Code (WAC), or both. The LCB's policy statement is in response to multiple stakeholder requests and national concerns for clarification.

Through PS-21-01, the LCB is notifying the public and stakeholders that the agency will be addressing the issue. State law encourages agencies to advise the public of its current opinions, approaches, and likely courses of action by means of interpretive or policy statements. Current interpretive and policy statements are advisory only. To better inform the public, agencies are encouraged to also convert long-standing interpretive and policy statements into rules.

LCB Intent

The LCB's intent is to open public discussion around this issue. While the Board has broad rulemaking authority to act quickly when the public health, safety or welfare is at risk, the Board's intention is to approach the issue conservatively and transparently, collecting input and actively collaborating with stakeholders. Until the LCB has reached a conclusion through the public rulemaking process whether to adopt rules to create enforceable requirements regarding products that contain delta-8, this policy statement is advisory. The LCB will continue to enforce existing rules pertaining to packaging and labeling reviews to ensure there is not an excess of 10 mg of any type of THC in edible products.

The policy statement represents the Board's continued effort to make the public and stakeholders aware of our intentions and invite participation. The Board will soon approve a CR 101 to make the process public and begin standard rulemaking. As always, interested parties may [sign up for email notifications](#) or check the LCB website at lcb.wa.gov for updates.

###

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NOTICE OF ADOPTION OF A POLICY STATEMENT

Title of Interpretive Statement: Tetrahydrocannabinol (THC) compounds other than delta-9 and the conversion of CBD, hemp, or both to delta-8 THC, delta-9 THC, or any other cannabis compound that is not currently identified or defined in the Revised Code of Washington (RCW), the Washington Administrative Code (WAC), or both. Policy Statement Number PS-21-01.

Issuing Entity: Washington State Liquor and Cannabis Board.

Subject Matter: This policy statement offers the Washington State Liquor and Cannabis Board's position on the regulation of tetrahydrocannabinols (THC), other than delta-9; and the conversion of CBD, hemp, or both to delta-8 THC, delta-9 THC, or any other cannabis compound that is not currently identified or defined in the Revised Code of Washington (RCW), the Washington Administrative Code (WAC), or both. This policy statement also relates to cannabis packaging and label approval requests that are considered on a case-by-case basis, consistent with WAC 314-55-105.

Effective Date: April 28, 2021.

Contact Person: Katherine Hoffman, Policy and Rules Manager, 360-664-1622.

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: April 28, 2021

TIME: 1:32 PM

WSR 21-10-045



Policy Statement

Title: Tetrahydrocannabinol (THC) compounds other than delta-9 and the conversion of CBD, hemp, or both to delta- 8 THC, delta-9 THC, or any other cannabis compound that is not currently identified or defined in the Revised Code of Washington (RCW), the Washington Administrative Code (WAC), or both.

Number: PS21-01

References: [RCW 69.50.101](#)
[RCW 69.50.201](#)
[RCW 69.50.204](#)
[RCW 69.50.325](#)
[RCW 69.50.326](#)
[RCW 69.50.401](#)
[RCW 69.50.455](#)
[RCW 19.86.020](#)
[WAC 314-55-095](#)
[WAC 314-55-105](#)
[WAC 314-55-109](#)

Contact: Katherine Hoffman, Policy and Rules Manager, WSLCB

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Email: katherine.hoffman@lcb.wa.gov

Effective Date: April 28, 2021

Approved By: Justin Nordhorn, Policy and External Affairs Director, WSLCB

[RCW 34.05.230 – Interpretive and policy statements](#)

- (1) An agency is encouraged to advise the public of its current opinions, approaches, and likely courses of action by means of interpretive or policy statements. Current interpretive and policy statements are advisory only. To better inform the public, an agency is encouraged to convert long-standing interpretive and policy statements into rules.

Introduction

This policy statement is offered in response to multiple stakeholder requests and national concern for clarification regarding:

- The regulation of tetrahydrocannabinols (THC), other than delta-9; and
- The conversion of CBD, hemp, or both to delta- 8 THC, delta-9 THC, or any other marijuana compound that is not currently identified or defined in the Revised Code of Washington (RCW), the Washington Administrative Code (WAC), or both.

This policy statement also relates to marijuana packaging and label approval requests that are considered on a case-by-case basis, consistent with WAC 314-55-105.

BACKGROUND

The Washington State Liquor and Cannabis Board (LCB) has become aware of products entering the regulated market with labeling noting the presence of cannabinoids other than delta-9 THC and CBD additives. These products include, but are not limited to marijuana infused edibles and marijuana concentrates.

The LCB is also aware of products with labeling noting the presence of THC compounds other than delta-9 THC in markets it does not regulate.

LCB reviews and pre-approves marijuana infused labeling for edible products that will be sold in licensed retail marijuana stores. LCB does not review or approve labeling for marijuana concentrates, usable marijuana, marijuana mix, or marijuana topical products that will be sold in licensed retail marijuana stores. LCB does not have statutory or regulatory authority for products containing cannabis compounds other than delta-9 THC sold outside the licensed marijuana system regulated by the WSLCB.

LCB has learned that CBD isolate from hemp or other sources is being genetically or chemically altered to result in potentially intoxicating, psychoactive compounds not derived from marijuana as defined in RCW 69.50.101(y), or synthetic equivalents of substances contained in the cannabis plant. LCB has learned that these compounds have appeared in the marijuana system regulated by the WSLCB. The agency has also learned that such compounds other than delta-9 THC have also appeared in the licensed marijuana system regulated by the WSLCB.

Washington State statute and the rules that implement those statutes provide a framework describing the types of activities that cannabis licensees may engage in. Initiative 502 (I-502) provided the backdrop to establish exceptions to illegal marijuana sales by affording allowances for licensees to produce, process, and sell marijuana products at retail within Washington State. The only products that can be sold in licensed marijuana retail stores are marijuana concentrates, usable marijuana, and marijuana infused products, and paraphernalia, consistent with RCW **69.50.325(3)(a)**.

AUTHORITY AND ANALYSIS

RCW **69.50.204** identifies Schedule I controlled substances. Specifically, RCW 69.50.204(c)(30)(i) defines Schedule I tetrahydrocannabinols (THC), as follows:

Tetrahydrocannabinols meaning tetrahydrocannabinols naturally contained in a plant of the genera Cannabis, as well as synthetic equivalents of the substances contained in the plant, or in the resinous extractives of the genera Cannabis, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:

(A) 1 - cis - or trans tetrahydrocannabinol, and their optical isomers, excluding tetrahydrocannabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the United States Food and Drug Administration; (**Note: this refers to Delta 9-THC**)

(B) 6 - cis - or trans tetrahydrocannabinol, and their optical isomers; (**Note: this refers to Delta 8 THC**).

RCW **69.50.455** describes synthetic cannabinoids in relation to unfair or deceptive practice under RCW **19.86.020** as follows:

(1) It is an unfair or deceptive practice under RCW 19.86.020 for any person or entity to distribute, dispense, manufacture, display for sale, offer for sale, attempt to sell, or sell to a purchaser any product that contains any amount of any *synthetic cannabinoid*. The legislature finds that practices covered by this section are matters vitally affecting the public interest for the purpose of applying the consumer protection act, chapter 19.86 RCW. Violations of this section are not reasonable in relation to the development and preservation of business.

(2) "Synthetic cannabinoid" includes any chemical compound identified in RCW 69.50.204(c)(30) or by the pharmacy quality assurance commission under RCW 69.50.201.

Marijuana is defined in **RCW 69.50.101(y)** as all parts of the plant cannabis with a THC concentration of greater than 0.3 percent THC on a dry weight basis; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. The term does not include: (1) The mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination. This is similar to the Federal definition of marijuana (see 21 U.S.C. § 802(16)), and hemp, as described in RCW 15.140.020(5) is expressly excluded from this definition.

RCW 69.50.101(z) provides that "marijuana concentrates" means products consisting wholly or in part of the resin extracted from any part of the plant *Cannabis* having a THC concentration of greater than ten percent. This language is also reflected in WAC **314-55-105(1)(d)**.

RCW 69.50.101(uu) provides that "THC concentration" means the percent of delta-9 tetrahydrocannabinol content per dry weight of any part of the plant *Cannabis*, or per volume or weight of marijuana product, or the combined percent of delta-9 tetrahydrocannabinol and tetrahydrocannabinolic acid in any part of the plant *Cannabis* regardless of moisture content.

Thus, for tetrahydrocannabinols that are naturally occurring constituents of the cannabis plant, any material that contains greater than 0.3% delta-9 THC by dry weight is a Schedule I controlled substance, by virtue of its containing tetrahydrocannabinol, but may be possessed in limited quantities by persons over 21, and produced, processed, and sold in the licensed marijuana system regulated by the WSLCB.

Further, delta-8 THC, as defined in RCW 69.50.204(c)(30)(i)(B), whether naturally occurring or synthetically derived, remains a Schedule 1 controlled substance.

RCW 69.50.360 describes certain acts that are not considered criminal or civil offenses. Specifically, subsection (3) provides that delivery, distribution, and sale, on the premises of a licensed retail outlet, of any combination of the following amounts of marijuana concentrates, useable marijuana, or marijuana-infused product to any person twenty-one years of age or older do not constitute criminal or civil offenses under Washington law:

- (a) One ounce of useable marijuana;
- (b) Sixteen ounces of marijuana-infused product in solid form;

- (c) Seventy-two ounces of marijuana-infused product in liquid form; or
- (d) Seven grams of marijuana concentrate.

RCW 69.50.4013(3)(a) provides that the possession, by a person twenty-one years of age or older, of useable marijuana, marijuana concentrates, or marijuana-infused products in amounts that do not exceed those set forth in RCW [69.50.360\(3\)](#) is not a violation of this section, this chapter, or any other provision of Washington state law.

Finally, **RCW 69.50.326** provides that marijuana producers and processors may use a CBD product as an additive *only* for the purpose of enhancing the cannabidiol concentration of any product authorized for production, processing or sale under chapter 69.50 RCW, provided that the CBD product has a THC level of 0.3 or less on a dry weight basis. The agency interprets this to mean that CBD, regardless of origin, may *not* enter the I-502 system by any means other than as an additive to a product that is approved for sale within the system, meaning any marijuana product with a THC concentration of greater than 0.3 percent THC on a dry weight basis. This language is also reflected in **WAC 314-55-109**.

Policy Statement:

LCB is concerned that derivatives, extracts, cannabinoids, isomers, and CBD isolate from hemp or other sources that is genetically or chemically altered to result in potentially intoxicating or psychoactive compounds, or synthetic equivalents of substances contained in the cannabis plant, is being used or is being added to products, including marijuana infused edibles and marijuana concentrates that are entering the licensed marijuana system regulated by the LCB. The agency is also concerned about the health implications related to compounds other than delta-9 THC and CBD added to such products.

Delta-8 cultivated in licensed LCB facilities that is derived from marijuana and not otherwise synthesized may be added to marijuana products produced and processed in the licensed marijuana system. Delta-8 THC created by a process of genetic or chemical alteration of licensed marijuana may not be added to marijuana products produced and processed in the licensed marijuana system. However, derivatives, extracts, cannabinoids, isomers, and CBD isolate from hemp or other sources that is genetically or chemically altered into compounds would be considered synthetic equivalents of the substances contained in the plant under RCW 69.50.204, and may not be produced or processed in licensed LCB facilities, nor may they be sold in licensed marijuana retail stores consistent with RCW 69.50.325, RCW 69.50.401 and RCW 69.50.455. Statute prohibits the distribution, dispensing, manufacture, display for sale, offer for sale, attempt to sell, or sale to a purchaser any product that contains any amount of any synthetically derived delta-8 or delta-9 THC. Statute also provides that marijuana retailers may sell marijuana concentrates, usable marijuana paraphernalia or marijuana infused-products, within statutory limits.

Further, the process of genetic or chemical alteration of hemp or other sources to potentially intoxicating, psychoactive compounds may generate additional chemicals that are not naturally occurring in marijuana. Currently, there are no mandatory testing standards for these compounds, and no potency or concentration limits have been established in statute or regulation concerning these compounds in Washington State. The impact of those different chemicals on health are unknown and could be harmful.

LCB understands that some accredited/certified testing laboratories are able to test for the presence of delta-8 THC, but testing for THC isomers is evolving and not standardized. For example, Delta-8 THC as a stand-alone product is not currently being tested for contaminants, but only for cannabinoid testing. Thus, it is unclear whether delta-8 or CBD isolate from hemp or other sources that is genetically or chemically altered into compounds are safe for consumer use.

The role of LCB is to promote public safety and trust through fair administration and enforcement of applicable laws. To encourage and promote best practices, and until the agency has both authority *and* verifiable information on which to base its decision making regarding delta-8 THC, as well as derivatives, extracts, cannabinoids, isomers, or CBD isolate from hemp or other sources that are genetically or chemically altered into compounds other than delta-9 THC, regardless of the form of THC, total THC amount cannot exceed that allowed per serving as specified in WAC 314-55-095.

Since all compounds of THC are recognized as Schedule I substances under RCW 69.50.204(c)(30)(i), the ten milligram active THC limit per serving applies to all products identified within WAC 314-55-095. Delta-8 cultivated within LCB licensed facilities may be added to marijuana products produced and processed in the licensed marijuana system. Health implications related to compounds other than delta-9 THC and CBD added to marijuana products produced and processed in LCB licensed facilities and sold in the licensed marijuana system are unknown and could be harmful. For these reasons, delta-8 THC, as well as derivatives, extracts, cannabinoids, isomers, and CBD isolate from hemp or other sources that are genetically or chemically altered into compounds may not be produced or processed in LCB licensed facilities, and may not be sold in licensed marijuana retail stores.

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Executive Summary

The Unregulated Distribution And Sale Of Consumer Products Marketed As Delta-8 THC

Executive Summary

There is a rapidly expanding crisis in the United States involving a psychoactive form of THC which is derived from unregulated industrial hemp, referred to as Delta-8 tetrahydrocannabinol or Delta-8 THC. Delta-8 THC is an “isomer” (chemical analog) of Delta-9 THC, the molecule better known as the source of marijuana’s high, which reportedly has 75% of potency of Delta-9 THC. Over the past year or so, sales of this drug have spread across the country through such outlets as tobacco stores, newsstands, and local pharmacies, as well as internet sales. While efforts to legalize and to regulate the sale of cannabis and cannabinoids derived from cannabis should encompass Delta-8 THC, the fact that it is being sold outside of the regulated marketplace with no oversight or testing and is readily available to children is alarming, and it presents a public health risk of potentially wider impact than the vape crisis.

This Delta-8 THC crisis has been spawned by a supposed loophole in the federal 2018 Farm Act, which legalized the cultivation and sale of “industrial hemp,” a form of cannabis that contains negligible quantities of psychoactive chemicals, as well as products naturally derived from industrial hemp. Despite such arguments by supporters of unregulated Delta-8 THC distribution, there is no such “loophole:” the 2018 Farm Act does not legalize the production of psychoactive drugs simply because the base material has been extracted from industrial hemp, and the DEA’s current rulemaking clearly confirms this position. Moreover, Delta-8 THC is being marketed and sold in violation of consumer protections provided by the Food and Drug Act and FDA rules, as well as in violation of state laws—and a growing list of states have acted to specifically address the Delta-8 THC issue.

To highlight the dangers of the unregulated sale of Delta-8 THC and similar products, the USCC has commissioned testing of Delta-8 THC products procured from various states and as well as examination of the labelling and marketing of these products. These tests reveal that not only do Delta-8 THC products commonly have vastly varying amounts of Delta-8 THC, they but they also can contain amounts of Delta-9 THC in clearly illegal quantities, as well as pesticides and heavy metals. The packaging of such products is often misleading or outright false as to the ingredients of the product and its legal status, and often includes unsubstantiated claims about medical or other benefits. The results of this survey are summarized in this paper.

The members of the US Cannabis Council support the safe and regulated sale of cannabis products. The unregulated sale of untested cannabis products hurts, can cause catastrophic public harm to, and will hinder further reform toward a safe, well-regulated, federally legal cannabis industry. While further action should be taken by federal authorities and states to confirm that the unregulated sale of Delta-8 THC has not been sanctioned, state and federal authorities have several paths currently available to enforce the law and to address this crisis.

The USCC supports prompt action from regulators, law enforcement, and the cannabis community to stem the Delta-8 THC crisis including the following:

1. Action by state Attorneys General to apply Consumer Protection Act and/or the States' Unfair and Deceptive Act and Practices law to stop the sale and distribution of Delta-8 products, as was done to clamp down on the unregulated sale of "alcopops"
2. The issue of cease-and-desist letters from state law enforcement to all unregulated producers of Delta-8
3. Rulemaking under state regulation to ensure that Delta-8 THC is produced and marketed only through state-licensed cannabis programs
4. Further action by the Federal Drug Enforcement Agency to clarify that the Farm Act 2018 does not legalize the sale of unregulated Delta-8 THC

1. Introduction

In December 2018, the United States Congress passed the Agriculture Improvement Act, more commonly known as the 2018 Farm Bill. This law removed hemp -- defined as cannabis with concentrations of Delta-9 tetrahydrocannabinol (Delta-9 THC) below .3% -- from the definition of marijuana in the Controlled Substances Act (CSA). Inasmuch as the Farm Bill exempted only Delta-9 THC, some have taken this to mean that other extracts from industrial hemp were effectively legalized, including delta-8 tetrahydrocannabinol (Delta-8 THC), a lesser-known psychoactive cannabinoid. This novel legal interpretation has driven an explosion of Delta-8 THC production and intra- and inter-state commerce across the country over the past two years.

In August 2020, the DEA promulgated an Interim Final Rule (2020 IFR) which confirmed that hemp-derived THC products were not legalized by the 2018 Farm Bill. Some industry players are claiming that the final rule does not confirm the illegal status of Delta-8 THC because it fails to mention this substance by name and are challenging the rule. Some players have even stated support for the production and marketing of Delta-8 THC products. More established industry groups including the US Hemp Roundtable, however, have rejected the argument that unregulated Delta-8 THC has been legalized and believe that the availability of Delta-8 THC products could undermine efforts to bring other hemp products to market. The crisis has been furthered by the reluctance of some state regulators to weigh in on the interpretation of the federal Farm Act 2018 or, absent further federal guidance or specific state regulation, to act against the unregulated Delta-8 THC market.

At present, products purporting to contain Delta-8 THC are being marketed across the country through unregulated retail outlets and the internet. These products are not subject to ingredient testing to detect

and prevent dangerous contaminants such as lead, heavy metals, certain pesticides, etc. Moreover, notwithstanding the claims from these manufacturers and distributors that these hemp-derived products do not contain more than the federal limit of .3% Delta-9 THC, independent testing (described below) has found the opposite. Indeed, recent independent testing of these Delta-8 products sold in Florida has found substantial amounts of Delta-9 THC as well as heavy metals. Moreover, these products are being sold to children.

As a general matter, there is no evidence that Delta-8 THC is inherently dangerous or problematic, but like any medication or intoxicant, particularly one with psychoactive properties, it should be carefully regulated to ensure that it is (a) sold to adults or those authorized by law to purchase, and (b) safe for consumers and patients to use through testing, labeling, and the other regulatory requirements that are part of effective state cannabis programs.

What is Delta-8 THC?

When people refer to THC, they are typically talking about Delta-9 THC, the primary form of THC found in cannabis. Delta-9 THC is possibly the most potent psychotropic cannabinoid and produces its intoxicating effects by interacting with the CB1 receptor in the human body. However, other isomers of THC do exist. Isomers are variations of molecules with identical chemical formulas but a distinct arrangement of atoms. Delta-8 THC is one such isomer of Delta-9 THC.

A commonly accepted scientific definition of Delta-8 THC comes from the National Cancer Institute:

An analogue of tetrahydrocannabinol (THC) with antiemetic, anxiolytic, appetite-stimulating, analgesic, and neuroprotective properties. Delta-8-tetrahydrocannabinol (delta-8-THC) binds to the cannabinoid G-protein coupled receptor CB1, located in the central nervous system; CB1 receptor activation inhibits adenylyl cyclase, increases mitogen-activated protein kinase activities, modulates several potassium channel conductances and inhibits N- and P/Q-type Ca²⁺ channels. This agent exhibits a lower psychotropic potency than delta-9-tetrahydrocannabinol (delta-9-THC), the primary form of THC found in cannabis.

Delta-8 differs in structure from Delta-9 THC in the placement of a double bond between carbon atoms 8 and 9 rather than carbon atoms 9 and 10. Due to its altered structure, Delta-8 THC has a lower affinity for the CB1 receptor, and therefore has a lower psychotropic potency than Delta-9 THC. Relative to the psychotropic potency of Delta-9 THC, Delta-8 THC has been estimated to be about 75% or perhaps two-thirds as potent. Delta-8 THC has been described as “marijuana light” or “pain relief with less psychoactivity.” Although Delta-8 THC does exist naturally in the cannabis plant, it is only present at very low levels. The cost-effective manufacturing process of Delta-8 THC involves the isomerization of CBD via exposure to an acidic environment. Delta-8 THC can also be manufactured from Delta-9 THC.

2. Current Commercialization of Delta-8 Products: Product Safety and Legality Issues

Delta-8 THC products have become widely available across the U.S. since businesses began selling Delta-8 THC products in 2019. Consumer sales expanded rapidly in 2020 and continue to grow in 2021, leading

one industry expert to state that it is the “fastest growing segment” of products derived from hemp. One prominent Delta-8 THC retailer saw sales increase exponentially every month over the past year. Delta-8 THC is now available for purchase at gas stations, drug paraphernalia shops, and convenience stores. Anecdotally, Delta-8 THC product sales have been especially strong in states without medical or adult-use cannabis laws.

Recent media stories now include reports of Delta-8 products falling into the hands of minors with dangerous results. For example, in April, authorities raided a southeastern Wisconsin (Waukesha County) CBD store after two children overdosed from a product their parent said was from the store. Investigators reportedly stated that they tested some products at the store that were found to contain 20 percent THC.¹ Other states have similarly raised concerns about the accessibility of Delta-8 THC products to minors through unregulated distribution points and consequently have issued warnings through poison control centers. See, e.g., West Virginia.²

3. Delta-8 THC Product Testing

In connection with preparing this paper on Delta-8 THC products, 16 samples of non-cannabis based, over-the-counter products featuring Delta-8 THC were procured in April 2021 for chemical testing. All samples were legally obtained from various non-regulated retail stores or online retail vendors from across the U.S. including from California, Florida, Nevada, Texas, Michigan, Massachusetts, North Carolina, and Indiana. The samples were analyzed for a suite of chemicals including cannabinoid profiles, heavy metals, residual solvents, and exploratory analysis for unknown compounds. The purpose of the analyses was to determine whether the samples, which were advertised as containing no more than the federal legal limit of Delta-9 THC (.3%), actually complied with that limit and, in addition, whether the samples were generally safe from a consumer safety perspective.

Methods

All samples were processed by ProVerde Laboratories, an independent testing facility in Milford, MA, for cannabinoid profiles by solvent dilution and UPLC-UV analysis, residual solvents by full evaporative technique (FET) GC/MS headspace analysis, and elemental analysis by microwave digestion and ICP-MS analysis. In addition, a portion of each sample was subjected to analysis by solvent dilution and GC/MS liquid injection analysis for exploratory analysis and unknown identification.

Results

All investigated samples contained a mixture of THC isomers with Delta-8 THC featured as the primary cannabinoid per the product’s label claim. Notably, however, all samples also contained illicit Delta-9 THC at levels substantially higher than the USDA 0.3% upper limit, with the exception of a single sample of a tincture where the total cannabinoid concentration was substantially diluted to 10 mg/mL. The mean Delta-9 THC value was about 3.4%, with a range of about 1.3% - 5.3%. None of the tested samples were 2018 Farm Bill compliant. **The mean Delta-9 THC concentration of the sample set was more than 10 times greater than the USDA limit of 0.3%. Accordingly, all samples are non-compliant (illegal) products.**

All investigated samples contained a mixture of various other elements including:

- Heavy Metals: Lead was detected in four of the 16 samples investigated, though the detected levels in the four samples was below the USP limit for inhalation.
- Other Metals: Seven of 16 samples failed USP limits for inhalation on copper (Cu), chromium (Cr) or nickel (Ni).
- 7-10 compounds in each of the samples analyzed were of unknown identification and thus unknown toxicological significance.

Residual Solvents Analysis

Dichloromethane and methanol were found once in different samples of the set of 16. Hexane was found in three of the 16 samples. All detected levels were below US limits for inhalation. Acetone was detected in every sample. Ethanol was detected in 13, ethyl acetate in seven, Heptane once, isopropanol in nine of the 16 samples; all detected levels were below US limits for inhalation.

Unknown Ingredients

The testing also identified ingredients in most of the samples that have some similarities to known cannabinoids but are not found in the current NIST mass spectral library. These compounds appear to be either isomers of known cannabinoids or new, unknown compounds with no toxicological characterization available, which is concerning.

4. The Federal Legal Status of Delta-8 THC

Attached is a memorandum of law prepared by the law firm of Cadwalader, Wickersham & Taft (the “Cadwalader Memo”). The Cadwalader memo analyzes the state of federal law as it applies to Delta-8 THC. As summarized below, the Cadwalader memo concludes that there are several reasons why claims that Delta-8 THC is federally legal as a result of the 2018 Farm Bill or otherwise are incorrect.

i) The 2018 Farm Bill: Implications for the Legal Status of Delta-8 THC

Many commentators and marketers suggest that Delta-8 THC is legal on the federal level under the 2018 Farm Bill, which defined “hemp” as “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.” 7 U.S.C. § 1639o. The 2018 Farm Bill also revised the CSA definitions of “marihuana” to exclude the new definition of hemp and the definition of “tetrahydrocannabinols” to exclude “tetrahydrocannabinols in hemp.” Because Delta-8 naturally occurs in small quantities in cannabis,³ advocates of Delta-8 THC argue that these changes could be interpreted as exempting Delta-8 from control under the CSA.

However, the Drug Enforcement Administration (“DEA”), in August 2020, issued an “interim final rule” (IFR) to codify in the DEA regulations the CSA amendments made by the 2018 Farm Bill (Aug. 21, 2020). The DEA recognized the revised definition of “marihuana” and clarified that to qualify for the “hemp” exception

to the definition of marihuana, “a cannabis-derived product must itself contain 0.3% or less Δ 9-THC on a dry weight basis.” But the DEA also clarified that the “definition of hemp does not automatically exempt any product derived from a hemp plant, regardless of the Δ 9-THC content of the derivative” and that “a cannabis derivative, extract, or product that exceeds the 0.3% Δ 9-THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less Δ 9-THC on a dry weight basis.”

ii) Synthetically Derived THC

The DEA also noted in the IFR that the 2018 Farm Bill “does not impact the legal status of synthetically derived tetrahydrocannabinols because the statutory definition of ‘hemp’ is limited to materials that are derived from the plant *Cannabis sativa* L. For synthetically derived tetrahydrocannabinols, the concentration of Δ 9-THC is not a determining factor in whether the material is a controlled substance. All synthetically derived tetrahydrocannabinols remain schedule I controlled substances.” Neither DEA regulations nor the CSA define “synthetically derived.” However, the level of naturally occurring Delta-8 THC found in hemp is negligible and Delta-8 THC products are all produced from hemp extracts by conversion through chemical reaction of naturally occurring cannabinoids into Delta-8 THC. As of April 2021, the DEA published Controlled Substance by DEA Drug Code Number 7370 lists “Delta-8 THC” among “other names” for tetrahydrocannabinols.⁴

iii) The Federal Analog Act

Even if CBD-derived Delta-8 is not viewed as “synthetically derived,” Delta-8 would likely still be at high risk of being treated as a “controlled substance analogue” by the DEA. The Federal Analogue Act, 21 U.S.C. § 813, treats a controlled substance analogue, if intended for human consumption, to be treated for the purposes of federal law as a controlled substance in Schedule I of the Controlled Substances Act. A “controlled substance analogue” is any substance that has: (1) a substantially similar chemical structure to a schedule I or II controlled substance; and (2) a substantially similar stimulant, depressant, or hallucinogenic effect on the central nervous system. As to the first prong, the chemical structure of Delta-8 and Delta-9 are virtually identical.

With regard to the second prong, experts estimate the effect of Delta-8 to be approximately 75% of the potency of Delta-9, which may easily meet the second requirement that the analogue have a “substantially similar” effect on the central nervous system. Given the near-universal agreement that the 2018 Farm Bill was not meant to legalize intoxicants, it would be consistent with the law for the DEA to view enforcement under the Federal Analogue Statute as consistent with the Farm Bill’s intent.

iv. Delta-8 and the FDCA

The 2018 Farm Bill also made clear that nothing in it would affect or modify the FDA’s authority under the Federal Food Drug and Cosmetic Act (“FDCA”). After the 2018 Farm Bill’s passage, the FDA Commissioner publicly stated that “it’s unlawful under the FDCA to introduce food containing added CBD or [Delta-9] THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived.” It is the FDA’s position that it is “illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements.” The FDA has also

stated that Delta-9 THC and CBD products cannot be sold as dietary supplements or food additives under the FDCA.

While the FDA has not issued a statement specific to Delta-8, there is no basis to believe the FDA will treat it differently from CBD and THC. Any substance intentionally added to food is a food additive, and therefore subject to pre-market review and approval by the FDA, unless the substance is generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use. Other than certain hemp seed products, no cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA. Therefore, sales of Delta-8 remain prohibited by the FDA as a food additive or dietary supplement. As for Delta-8 vaping products, there is no reason to believe the FDA will treat them differently from CBD vaping products—if sold as a tobacco product then they may not be sold without FDA pre-market authorization. If sold as a drug, then vaping products cannot be marketed without an FDA-approved drug application. As a result, Delta-8 products in their present market form as vaping products and consumables are illegal under the FD&C Act. Notably, to date the FDA has not aggressively pursued state licensed marijuana sellers under the FDCA, but whether the FDA would take that same approach to unlicensed sellers of Delta-8 is unclear.

5. Approaches to Delta-8 THC at the State Level

In many states, a plain reading of the hemp program laws indicate that the sale of Delta-8 THC would not be permitted because in defining hemp, the states have not distinguished between THC Delta-9 and its derivatives and isomer. Beyond that, broadly speaking, states fall into three categories: states that prohibit Delta-8 THC by rule or guidance (as described above, or in regulatory guidance), states (two) that permit regulated Delta-8 THC by rule or guidance, and states that have not specifically addressed the issue. Notably, many states that explicitly ban Delta-8 THC products (as opposed to relying on the apparent exclusion in the definition of hemp) rely upon a state agency's determination that Delta-8 THC is a synthetic form of THC and thus prohibited under the CSA and related DEA guidance, including the IFR.

A good example of this is North Carolina where the Department of Agriculture website states “Currently, DEA takes the position that synthetically derived THC is illegal as a controlled substance. Since Delta-8 THC appears at negligible and non detectable concentrations in hemp, Delta-8 THC is normally derived from chemical conversion from CBD into Delta-8 THC. Therefore, it appears from DEA's August 21, 2020 Interim Final Rule, titled “Implementation of the Agriculture Improvement Act of 2018,” that it will treat Delta-8 THC derived from chemical conversion or other synthetic methods as illegal.”

The attached chart highlights a sampling of 13 states' positions on Delta-8 THC and includes an analysis of applicable state laws as well as related guidance provided in connection with our review of this issue. The state categorizations are representative of the results of a 50-state regulatory agency survey conducted by an independent law firm for this report.

Turning to a state that permits Delta-8 THC, the Florida Department of Agriculture and Consumer Service (FDCAS) issued a statement on the topic of Delta-8 THC, which suggests that Delta-9 THC content remains the standard for determining whether a product qualifies as a hemp product. The statement reads: “Any

hemp or hemp extract products offered for sale or sold in Florida must comply with all labeling rules and have a certificate of analysis that shows a total THC ($\text{THCA} \times .8777 + \text{THC Delta 9} = \text{total THC}$) content of 0.3% or less. Any hemp or hemp extract product that does not comply with all statutes and rules is subject to enforcement and possible destruction by the Florida Department of Agriculture and Consumer Services.” According to FDCAS, this guidance means as long as the total THC as defined above is below 0.3%, the product sold may contain and be marketed as Delta-8 THC. Notably, manufacturers in Florida represent one of the principal sources of Delta-8 THC products sold in other states and via the internet.

Nevada is an example of a state that has adopted an approach to treat Delta-8 THC like Delta-9 THC so that these products may only be sold through the state’s regulated cannabis framework. The Nevada Revised Statutes, in a section updated on July 1, 2020, provide that the definition of “THC” specifically includes Delta-8 THC. Referencing this definition in the law, the Nevada Cannabis Compliance Board (CCB), which oversees the state’s regulated cannabis market, recently offered the following in a newsletter: “Products exceeding 0.3% THC, including Delta-8 and Delta-9 THC, would be considered cannabis. As such, a license from the CCB would be required to make it or sell it.”

As this topic gains more national attention, it is possible that more states will begin to take a reasonable and responsible approach of regulating Delta-8 THC similarly to Nevada by permitting the manufacturing and sale of Delta-8 THC products only through state-licensed cannabis businesses. States without state-licensed cannabis businesses may choose to specifically ban Delta-8 THC products at the state level, which is within their authority. Until a state takes a position publicly, consumers and businesses are left guessing as to the legal status of these products.

In addition to agency guidance, several states have pending bills or newly enacted laws addressing Delta-8 THC. Other recent state legislative and regulatory activities concerning Delta-8 THC as of this writing include:

- **Hawaii HB 422** was introduced into the Hawaii House on January 25, 2021. The bill adds Delta-8 THC to the list of controlled substances.
- **Illinois HB 0147** has passed the Illinois House and is currently in the Senate. The bill directs the Illinois Department of Agriculture to establish testing, packaging, and labeling requirements for all non-marijuana cannabinoid products. This would extend to Delta-8 products.
- **Louisiana HB 640** was introduced in the Louisiana House on April 2, 2021 and is scheduled for a floor debate on May 10, 2021. The bill makes several minor changes to the state’s hemp production program and defines “Total THC Concentration” to include Delta-8, Delta-10, Delta-6a(10a), Delta-6a(7), Delta-7, and Delta-9 THC.
- **Michigan HB 4517** was introduced to the house on March 16, 2021 and includes language that amends the definition of THC to include “a tetrahydrocannabinol, regardless of whether it is artificially or naturally derived” and “a tetrahydrocannabinol that is a structural, optical, or geometric isomer of a tetrahydrocannabinol . . .” The bill also gives the marijuana regulatory agency the power to exclude specific tetrahydrocannabinols from the definition of THC if it determines that the tetrahydrocannabinol does not have the potential for abuse based on several specific factors.
- **North Dakota HB 1213** is awaiting the Governor’s signature. The bill amends the definition of THC to include Delta-9 and Delta-8 THC. The bill also amends the THC possession laws so that possession of an amount less than 2 grams is an infraction and possession of more than 2 grams is a misdemeanor.

- **North Dakota HB 1045** was signed by the Governor on April 26, 2021. The law allows the Commissioner of Agriculture to set the allowable THC concentration in hemp and defines THC to include Delta-9, Delta-8, Delta-10, and Delta-7 THC. The bill also prohibits North Dakota hemp licensees from selling hemp or hemp products that were “created using the isomerization of cannabinoids to create isomers of tetrahydrocannabinol, including Delta - 8, Delta - 9, and Delta – 10 tetrahydrocannabinol.”
- **Oklahoma HB 1961** was introduced in the Oklahoma House on February 1, 2021. The bill would bring delta-8 under the purview of the state’s regulated marijuana program by defining marijuana to include Delta-8 and Delta-10 tetrahydrocannabinol with a concentration in excess of .3% on a dry weight basis.
- **Oregon HB 3000** was introduced in the Oregon House on January 21, 2021 and a public hearing was held on April 20, 2021. The bill gives regulatory authority over “artificially derived cannabinoids” to the Oregon Liquor Control Commission. The bill also defined THC to include “all tetrahydrocannabinols that are artificially or naturally derived, including but not limited to Delta-8 tetrahydrocannabinol and Delta-9 tetrahydrocannabinol.”
- **Texas HB 2593** was amended in the Senate to add the following language to the definition of a controlled substance: “Controlled substance” means a substance, including a drug, an adulterant, and a dilutant, listed in Schedules I through V or Penalty Group 1, 1-A, 2, 2-A, 2-B, 3, or 4. The term includes the aggregate weight of any mixture, solution, or other substance containing a controlled substance. The term does not include hemp, as defined by Section 121.001, Agriculture Code, or the tetrahydrocannabinols in hemp, except that the term includes a consumable hemp product, as defined by Section 443.001, if the sum of all tetrahydrocannabinol concentrations in the product is more than 0.3 percent on a dry weight basis. The addition of this language would make any product that contains > 0.3% of any form or combination of forms of THC (including Delta-8) a controlled substance. The bill was amended in the senate and now must go back to the House for concurrence.
- On May 14, 2021 the **Colorado Marijuana Enforcement Division** notified marijuana business owners that modified or synthetic versions of THC derived from industrial hemp could not be sold in Colorado stores.

Regardless of what individual state legislatures have determined in terms of the legality of Delta-8 THC, each state Attorney General has the power to ban Delta-8 THC from the shelves of stores in each of the 50 states, plus the District of Columbia. Indeed, state Attorneys General have utilized their powers in the past to prohibit products such as “alcopops,” “Four Loko,” and other inappropriate products marketed toward young people.⁵ Specifically, state Attorneys General have two extremely powerful tools in their arsenal — the individual state Consumer Protection Act and the Unfair and Deceptive Acts and Practices (UDAP) law. Taken together, these two laws provide the wide-ranging power for a state Attorney General to remove Delta-8 because it is potentially harmful to users, including underaged people, as well as the lack of transparency and disclosure of the packaging concerning the contents of Delta-8 and the potential consequences of its use. Thus, while some may argue about the legality of Delta-8, the state Attorneys General may exert their inherent powers authorized by the Consumer Protection Acts and UDAP to unilaterally eliminate Delta-8 from the marketplace.

6. Statements Made by Relevant Organizations

For the most part, hemp and marijuana industry trade organizations have expressed concern with the current situation in which a substantial unregulated and uncontrolled Delta-8 THC market has been allowed

to proliferate. Indeed, at least one hemp industry group, the US Hemp Roundtable (USHR), has issued a statement opposing the marketing and selling of intoxicating products as hemp, fearing that it jeopardizes the future of non-intoxicating hemp products such as CBD. The USHR press release states, “The U.S. Hemp Roundtable, the hemp industry’s national business advocacy organization, is opposed to marketing products, under the guise of the hemp name, for any intoxicating value or euphoric effect -- an irresponsible practice highlighted in recent news reports.” While the group’s press release does not directly reference Delta-8 THC, it does point to articles from Rolling Stone and The New York Times on the topic of Delta-8 THC.

Other actors in the space are skeptical about whether the Delta-8 THC is pragmatic for the cannabis industry. Morgan Phaxia, a co-founder of the cannabis investment fund Poseidon Asset Management, offered a statement that typifies this mindset, saying that the sale of Delta-8 THC is “playing a game around uncertainty, which we don’t need to do anymore.”⁶

Conclusion

As discussed above, there is no evidence that Delta-8 THC is an inherently dangerous or problematic substance; rather, it is an analog of Delta-9 THC which is increasingly accepted by a number of states for use by individuals suffering from a range of state identified medical conditions and as a recreational intoxicant for use by adults. That said, like any substance falling into these categories, distribution and sales of **Delta-8 THC should be carefully regulated and controlled so that consumers can be confident the products’ contents are known and safe as well as predictable in their effects.** The unregulated distribution of Delta-8 THC products is inconsistent with these principles and poses significant risks to adults and minors. Moreover, the continued proliferation of unregulated and unsafe Delta-8 THC products has the potential for confusing patients and consumers leading to a loss of confidence in the nascent cannabis industry. Only by including Delta-8 THC products in the existing Delta-9 THC regulatory scheme can we ensure that THC products continue to be distributed and used in a safe and appropriate manner.

A CALL TO ACTION

The Health Risks of Delta-8 THC and What's Needed Now

The sale of Delta-8 THC, the psychoactive cannabinoid synthesized from hemp, is making news across the United States, particularly in states where cannabis remains illegal. Sales of Delta-8 products have exploded at gas stations and convenience stores across the country, creating easy access for underage consumers as the market is flooded with information claiming that the compound offers a “legal” high.

This represents a major consumer safety issue, posing dangers greater than the “vape crisis” of 2019.

We as a regulated, tested, verified, and taxed industry are voicing our concern.

Indeed, most of the regulated cannabis industry agree that any product containing any psychoactive cannabinoids, such as Delta-8 THC, must be regulated, tested and controlled in the same manner as inhalable or consumed cannabis products in the regulated cannabis market. Unregulated, untested products should not be offered by unlicensed producers to consumers in stores, online, or anywhere.

The spread of Delta-8 THC is being driven by spurious legal arguments that the Farm Act 2018 legalized the sale of psychoactive cannabinoids merely because they are derived from chemicals extracted from hemp. The Drug Enforcement Agency’s August 2020 Interim Final Rule has clarified that the Farm Bill 2018 did not legalize “synthetic” compounds merely because the raw materials are extracted from hemp. Nevertheless, proponents of an unregulated Delta-8 THC market point to lack of specific references to Delta-8 THC in guidance from federal and many state regulators to insist that despite the law and existing guidance, a “loophole” or “grey areas” still exist. As a result, Delta-8 THC is currently being sold across the country with no safeguards in place. The product is easily purchased by minors. There are no requirements for testing of potency, pesticides, or adulterants. Childproof packaging is not required, and neither are warning or informational labels of any type.

Regulating Delta-8 THC is critical to avoid similar issues the industry saw with the vape crisis in 2019—when products from the unregulated market caused major health issues for consumers and damaged public trust for the entire industry. We are at risk for a similar crisis if regulators and state lawmakers - and concerned consumers - do not act:

- The process to convert CBD to Delta-8 THC may require the use of chemicals not safe for consumption.
- Many of the processors converting the compound in the unregulated market are not qualified chemists working with the appropriate lab equipment, and the potential for residual chemicals or contamination is real.
- Where Delta-8 THC producers make testing claims, there are no standards for such testing, leading to misleading claims. Furthermore, the labs claiming to verify product safety are not accredited and may not produce accurate results.

To date, over 12 states have adopted specific measures to ban Delta-8 sales, while other states such as New York, Illinois, Oregon, and California are adopting regulatory frameworks that allow for Delta-8 THC or any THC only if it is tested, verified, and sold through the regulated marketplace. Just this week, it was announced that hemp-derived Delta-8 and Delta-10 THC are now banned in Colorado dispensaries, a significant development given the state's leading position in cannabis legislative issues.

Most recently, The Michigan [Poison Center at Wayne University](#) issued a warning notice about Delta-8 after “two cases of severe adverse reactions were reported in children who {...} developed sedation, slowed breathing, low blood pressure and slowed heart rate, requiring admission to the intensive care unit.” According to the [University of Virginia Health](#) Poison Center, “Delta-8-THC ingestions reported to poison control centers have been associated with a variety of clinical symptoms, including drowsiness, bradycardia, and hypotension sometimes requiring vasopressors. Other patients report feeling confused and anxious, with tachycardia and generalized numbness.”

Leading cannabis industry organizations (the [USCC](#) and [US Hemp Roundtable](#)) have made their position clear:

Delta-8 is federally illegal (FDA and DEA) and is a safety risk due to it being a psychoactive product that is not being regulated and tested. We are extremely concerned that another vape crisis is coming if the agencies and state lawmakers do nothing. Any psychoactive product from hemp or cannabis should be tested, verified safe and only sold through the regulated marketplace.

If you are interested, we can share independently verified test results recently conducted on Delta-8 samples. Also, please note that representatives from the [USCC](#) and [US Hemp Roundtable](#) are available to discuss the dangers of having unregulated, untested, unverified Delta-8 THC in the public marketplace.

We look forward to connecting on this important issue soon.

Delta-8 THC Independent Test Results

Background

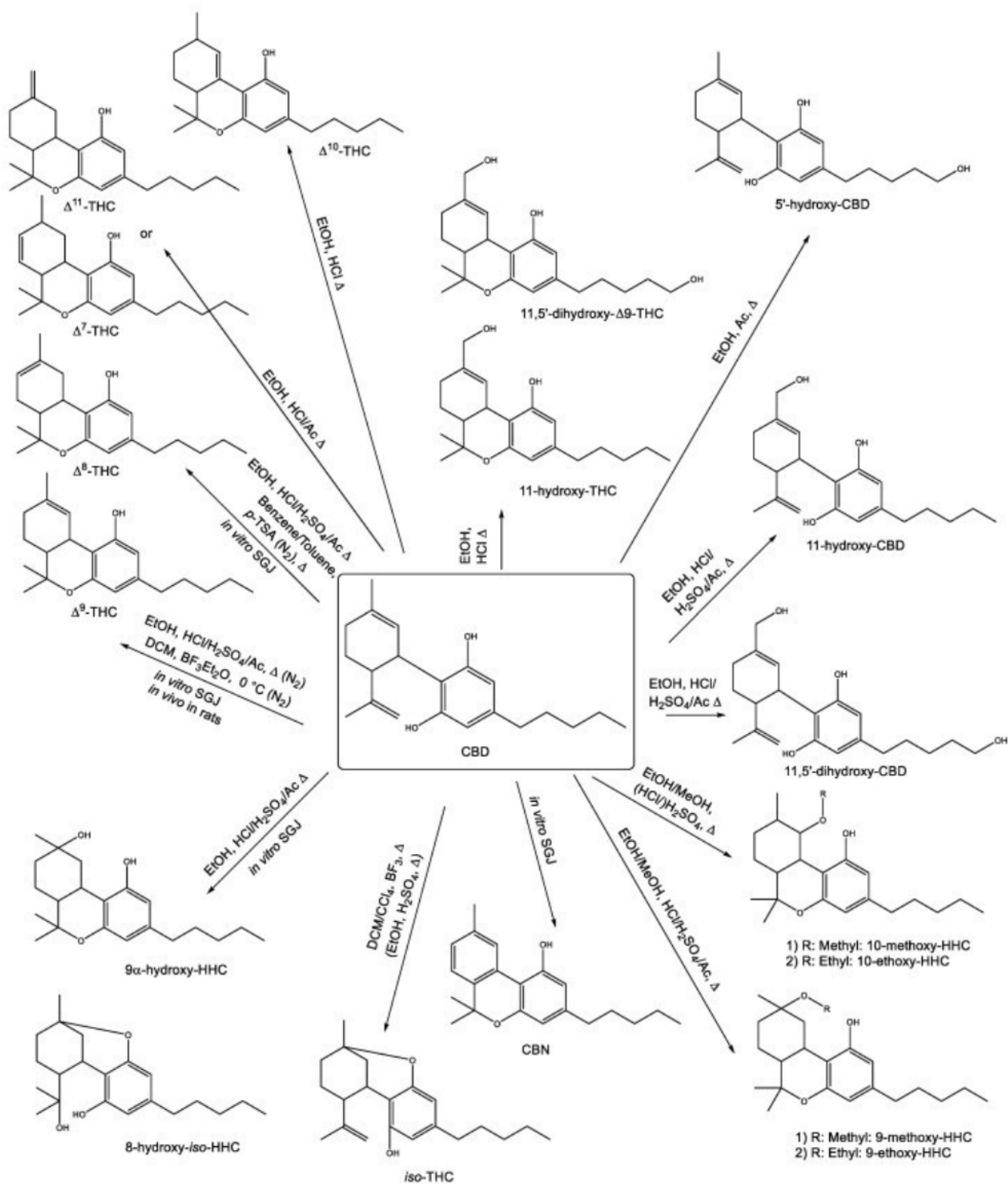
The legal hemp industry has been coexisting with the regulated cannabis industry for a number of years on a state-by-state basis. However, the passing of the 2018 Farm Bill by the USDA accelerated the entry of new hemp cultivators, processors, manufacturers, and retailers eager to profit off the newly deregulated cannabidiol (CBD) market. CBD based materials began appearing everywhere from grocers to pharmacies such as CVS, to gas stations, typically with substantial price tags for the CBD based materials. Unfortunately, the 2018 Farm Bill did not require or specify a safety testing protocol. The only requirement was that all materials must be regulated delta-9-tetrahydrocannabinol (D9-THC) compliant. The D9-THC compliance level was set at less than 0.3% by weight, which was already in use by many states' agricultural bureaus.

While no safety testing was required by the 2018 Farm Bill, many responsible CBD based businesses would electively perform safety testing consistent with the regulated cannabis industry, often utilizing the same laboratories and testing suites. Unfortunately, many businesses could either not afford the cost of testing, or simply did not care about the perceived safety of their products and there was (and still is) no mechanism to control the bad players in the legal hemp market.

To compound the problem, the surplus of available hemp and CBD rapidly rose due to the large influx of new contributors post the 2018 Farm Bill. The glut of available raw materials compounded by limited demand for CBD based products began to erode the market price of hemp biomass and associated CBD oils and isolate to the point where many CBD businesses could not continue. The solution to these business problems was to convert their devalued CBD into a higher value product by isomerization chemistry processes.

Research papers discussing the conversion of CBD into THC molecules were published many decades ago^(1,2) and these processes were revived by modern CBD manufacturers. Isomerization reactions typically involve organic solvents, acids, catalyst elements or salts, heat, and time. The THC molecule has 30 structural isomers, one of them is predominantly produced natively by the cannabis plant, the (6aR,10aR)-delta-9-THC isomer. The isomerization reaction is non-specific and results in the creation of mixtures of synthetic THC isomers with D8-THC often the dominant product. Other cannabinoid isomers, and many other unintended reaction byproducts (Figure 1) that are typically cannabinoid-like molecules, but with various functional group substitutions that render them unknown are also present. Without additional purification or cleanup, these reaction products almost always contain D9-THC at levels greater than the 0.3% limit in addition to the newly formed unknown compounds which have an uncharacterized safety profile and may be of high risk for consumer use.

Figure 1 – Overview of various chemical conversions of cannabidiol (CBD) to different conversion products and the respective conditions, which are reported in the literature.⁽³⁾



Scope

Sixteen samples of non-cannabis based, over-the-counter products featuring D8-THC were sourced in April of 2021. The samples originated in many different states within the U.S. including California, Florida, Nevada, Texas, Michigan, Massachusetts, North Carolina, and Indiana. The samples were analyzed for a suite of chemicals including cannabinoid profiles, elemental analysis including heavy metals, residual solvents, and exploratory analysis for unknown compounds. The purpose of the analyses was to evaluate the legality of the samples from a D9-THC perspective, and well as to evaluate general consumer safety of the products.

Methods

All samples were processed by ProVerde Laboratories in Milford, MA for cannabinoid profiles by solvent dilution and UPLC-UV analysis, residual solvents by full evaporative technique (FET) GC/MS headspace analysis, and elemental analysis by microwave digestion and ICP-MS analysis.

All samples were legally obtained from various non-regulated retail stores or online retail vendors.

This narrative describes the results and compares the samples.

Results

Cannabinoid Content

All investigated samples contained a mixture of THC isomers with D8-THC featured as the primary cannabinoid per the product's label claim. All investigated samples also contained regulated D9-THC at levels substantially higher than the USDA 0.3% upper limit with the exception of a single sample of tincture where the total cannabinoid concentration was substantially diluted to 10 mg/mL. The mean D9-THC value was about 3.4%, with a range of about 1.3% - 5.3%. None of the tested samples were 2018 Farm Bill compliant. The mean D9 concentration of the sample set was more than 10 times greater than the USDA limit of 0.3% and all samples are non-compliant (illegal) products.

Elemental Analysis

All investigated samples contained a mixture of various elements as trace composition.

Heavy Metals: No mercury (Hg), arsenic (As), or cadmium (Cd) were detected in any sample. Lead (Pb) was detected in four of the 16 samples investigated, but the detected levels in the four samples was below the USP limit for inhalation.

Other Metals: Of the remaining elemental panel, seven of 16 samples failed USP limits for inhalation on copper (Cu), chromium (Cr) or nickel (Ni).

The presence of elevated levels of copper, chromium and nickel are likely due to reaction catalysts and poor cleanup or purification and creates substantial additional risk to consumers.

Residual Solvents Analysis

All investigated samples also contained a mixture of chemical solvents. USP classifies chemical solvents into three categories; 1. Solvents to be avoided, 2. Solvents to be limited, and 3. Solvents with low toxic potential.

Class 1: No benzene was found in any samples.

Class 2: No acetonitrile or cyclohexane was detected in any samples. Dichloromethane, and methanol were found once in different samples of the set of 16. Hexane was found in three of the 16 samples. All detected levels were below US limits for inhalation.

Class 3: Dimethyl sulfoxide and pentane were not detected in any samples. Acetone was detected in every sample. Ethanol was detected in 13, ethyl acetate in 7, Heptane once, isopropanol in 9 of the 16 samples. All detected levels were below US limits for inhalation.

Butane, isobutane, and propane were also measured, but were not detected in any samples.

Vitamin E Acetate Analysis

VCE acetate (VEA) was a constituent of concern in 2019 due to a series of VEA laden vape carts that induced respiratory problems. VEA was not detected in any of the samples and does not appear to be a diluent or additive of concern.

Exploratory Analysis

Exploratory analysis showed a commonality of about 10 or 11 analytical peaks that appear to be forming as secondary reaction products. Cannabicitran (CBT), exo-THC, and CBN appear as small peaks in nearly every D8 cart sample investigated. Further, there are about seven peaks that reoccur in most of the samples that have mass spectra similar to known cannabinoids but can not be definitively identified with a current NIST mass spectral library. These compounds appear to be isomers of known cannabinoids or may have minor functional group or double bond positional adjustments rendering them as new, unknown compounds with no toxicological characterization available.

One sample in particular, the High Life - Gorilla Glue cart showed a substantially different unknown profile than most of the other samples. Several unknown cannabinoid-like compounds were present; however, the mass spectral fragmentation showed that the compound mass was not 314 atomic mass units (AMU) like all other standard cannabinoids but had been increased to 360 AMU. The difference of 46 AMU and considering the fragmentation rule of N+1 (47) suggests that these peaks may be CH₂SH substituted cannabinoids. The mass spectral comparison is presented in Figure 3.

If the reaction were performed using a sulfur catalyst and a particular acid selection, these types of molecules could be formed. Interestingly, this sample had one of the highest sulfur values of the group with over 4,000 ppm of sulfur detected.

The unknown compounds create substantial risk for consumer safety.

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Table 1. Cannabinoid Concentration Results

Lab Sample #	TestDate	Brand	Product	State	Matrix	D9-THC	CBD	CBDV	CBG	CBC	CBN	D8-THC	EXO-THC
94183	5/6/2021	High Life	Gorilla Glue	MA	Vape Oil	4.4341	0	0	0	0	0.1355	76.1838	1.6967
94184	5/6/2021	3CHI	Caribbean Dream	IN	Vape Oil	3.7638	0	0	0	0	0	93.6328	2.7088
94185	5/6/2021	Organic CBD Nugs	Grape Ape	TX	Vape Oil	5.0307	0	0	0	0	0.1482	84.9216	1.4947
94186	5/6/2021	EightySix	Blue Dream	CA	Vape Oil	3.93	0	0	0	0	0.4571	66.3305	3.8952
94187	5/6/2021	ChillPlus	Pineapple Express	FL	Vape Oil	1.2958	0.7709	0	0	0	0	92.6559	1.216
94188	5/6/2021	The Hemp Doctor	Sour Diesel	NC	Vape Oil	4.8749	0	0	0	0	0.1148	92.1463	1.8425
94189	5/6/2021	Treetop Hemp Co	Skywalker OG	CA	Vape Oil	2.8742	0	0	0	0	0	80.0427	1.337
94190	5/6/2021	MoonWkr	Strawberry Gelato	NV	Vape Oil	2.4569	0	0	0	0	0.0682	92.2344	1.3653
94191	5/11/2021	VIIA	Lemon Diesel	CA	Vape Oil	1.4188	4.3451	0.16	0.1916	1.0283	0.7054	86.2685	1.312
94192	5/11/2021	Delta Effex	Grand Daddy Purp	CA	Vape Oil	1.8864	0.0317	0	0	0	0	91.1463	1.1818
94300	5/9/2021	Miracle Leaf Delta8	THC	FL	Tincture	0.13	0	0	0	0	0.1336	6.5171	0.2592
94301	5/11/2021	Urb Delta8	DAB5 Banana Runtz	FL	Vape Oil	4.8209	0	0	0	0	0.342	89.7287	3.141
94302	5/11/2021	Moon Men	Delta8 Shatter	FL	Vape Oil	3.3589	0	0	0	0	0	95.9689	1.7562
94303	5/11/2021	Privada RUNTZ	RUNTZ Delta8 DAB DART	??	Vape Oil	2.1138	0	0	0	0	0	92.7028	1.4847
94304	5/11/2021	MED Roots	DELTA EIGHT Strawberry Cough	MI	Vape Oil	3.3307	0	0	0	0	0.1541	83.7729	1.4845
94305	5/11/2021	Palm Treez	Delta8 Disidos	FL	Vape Oil	5.2925	0	0	0	0	0	90.6909	2.81

Red - Exceeds USDA Limit of 0.3% by wt. for D9-THC

Results reported in Wt. %

Cannabinoids with no detections in any samples were not presented

Table 2. Elemental Concentration Results

Lab Sample #	Test Date	Brand	Product	State	Matrix	Al	As	Ca	Cl	Co	Cu	Fe	Hg	K	Mg	Mn	Mo	Ni	P	Pb	S	Se	Zn	Zr
94183	4/10/2021	High Life	Gorilla Glue	MA	Vape Oil	0.182	0	0.011	0	0.004	0.055	4.085	0	3.479	0	0	0.593	8.201	0	4.384	0	0.063	0.007	
94184	4/10/2021	3CHI	Caribbean Dream	IN	Vape Oil	0.226	0	7.849	0	0	0.054	0.883	0	2.896	0	0	0.14	8.966	0	2.884	0	0.141	0.017	
94185	4/10/2021	Organic CBD Nugs	Grape Ape	TX	Vape Oil	0.226	0	5.819	0	0	0.073	1.725	0	3.092	0	0	1.409	5.042	0	3.263	0	5.334	0.006	
94186	4/10/2021	EightySix	Blue Dream	CA	Vape Oil	1.53.77	0	6.011	0	0.009	0.058	5.704	0	2.292	0	0	0.465	3.331	0	7.067	0	0	0.434	
94187	4/10/2021	ChillPlus	Pineapple Express	FL	Vape Oil	2.018	0	6.74	0	0	2.221	2.841	0	2.488	0	2.688	0	1.153	4.095	0.903	3.373	0	2.145	0.006
94188	4/10/2021	The Hemp Doctor	Sour Diesel	NC	Vape Oil	0.216	0	7.052	0	0.118	45.911	3.717	0	2.426	0	0.072	0	8.411	1.84	0.324	3.84	0.01	515.78	0.006
94189	4/10/2021	Treetop Hemp Co	Skywalker OG	CA	Vape Oil	0	0	6.139	0	0.072	3.187	2.18	0	2.574	0	0	0	0.695	2.946	0.076	4.126	0	3.196	0.01
94190	5/6/2021	MoonWkr	Strawberry Gelato	NV	Vape Oil	0.438	0	1.019	0	1.419	0	5.044	0	0	0.677	0.124	210.729	0.884	0	1.345	0	0.29	0.022	
94191	5/6/2021	VIIA	Lemon Diesel	CA	Vape Oil	0.17	0	0	0	0	0.175	0	0.805	0.103	0	157.248	0	3.25	0	1.802	0	0	0.007	
94192	5/7/2021	Delta Effex	Grand Daddy Purp	CA	Vape Oil	0.359	0	2.511	0	1.055	0.031	10.079	0	17.362	2.753	0.244	803.803	0.366	0	0	0	0.717	0.345	0.02
94300	5/7/2021	Miracle Leaf Delta8	THC	FL	Tincture	0.279	0	3.056	0	0	0.319	0.316	0	7.021	1.08	0	27.075	0	1.629	0	0	0.002	0.15	0.007
94301	5/7/2021	Urb Delta8	DAB5 Banana Runtz	FL	Vape Oil	0.34	0	3.191	0	0.207	0.549	0.957	0	8.745	2.313	0	15.262	0	2.178	0	0	0.838	0.134	0.007
94302	5/7/2021	Moon Men	Delta8 Shatter	FL	Vape Oil	0.547	0	9.663	0	0	0.071	6.418	0	6.488	1.26	0	10.662	0	3.472	0	0	0	0.345	0.096
94303	5/7/2021	Privada RUNTZ	RUNTZ Delta8 DAB DART	??	Vape Oil	0.735	0	9.457	0	0	0.086	0.629	0	6.502	1.581	0	12.517	0	4.547	0	0	0	0.085	0.007
94304	5/7/2021	MED Roots	DELTA EIGHT Strawberry Cough	MI	Vape Oil	0.661	0	3.467	0	0	0.055	0.406	0	3.481	1.127	0	21.036	0	5.366	0	0	0.510	0.143	0.021
94305	5/7/2021	Palm Treez	Delta8 Disidos	FL	Vape Oil	0.447	0	3.2	0	0	0.268	1.435	0	10.034	2.383	0	5.873	0.363	1.991	0	0	0	0.339	0.009

Red - Exceeds USP Limit

Results reported in ppm

Table 3. Chemical Solvent Results

Lab Sample #	TestDate	Brand	Product	State	Matrix	Acetone	Acetonitrile	Benzene	Butane	Cyclohexane	Dichloro-methane	Dimethyl Sulfoxide	Ethanol	Ethyl Acetate	Heptane	Hexane	Isobutane	Isopropanol	Methanol	Pentane	Propane	
94183	5/10/2021	High Life	Gorilla Glue	MA	Vape Oil	10.89	0	0	0	0	0	0	4.65	0	0	0	0	0	0	0	0	
94184	5/10/2021	3CHI	Caribbean Dream	IN	Vape Oil	24.12	0	0	0	0	0	0	64.56	162.23	0	0	0	0	0	0	0	
94185	5/10/2021	Organic CBD Nugs	Grape Ape	TX	Vape Oil	13.58	0	0	0	0	0	0	60.09	1511.76	0	0	0	50.42	0	0	0	
94186	5/10/2021	EightySix	Blue Dream	CA	Vape Oil	13.92	0	0	0	0	0	0	111.83	250.64	0	0	0	3.03	0	0	0	
94187	5/10/2021	ChillPlus	Pineapple Express	FL	Vape Oil	1.64	0	0	0	0	0	0	1.3	108.45	0	0	0	1.84	0	0	0	
94188	5/10/2021	The Hemp Doctor	Sour Diesel	NC	Vape Oil	8.05	0	0	0	0	0	0	0	0	0	0	0	3.85	0	0	0	
94189	5/10/2021	Treetop Hemp Co	Skywalker OG	CA	Vape Oil	3.62	0	0	0	0	0	0	6.85	0	0	0	0	27.53	0	0	0	
94190	5/10/2021	MoonWkr	Strawberry Gelato	NV	Vape Oil	31.4	0	0	0	0	0	0	5.55	259.45	0	0.97	0	261.52	0	0	0	
94191	5/10/2021	VIIA	Lemon Diesel	CA	Vape Oil	22.84	0	0	0	0	2.22	0	9.56	0	0	1.35	0	1.83	0	0	0	
94192	5/10/2021	Delta Effex	Grand Daddy Purp	CA	Vape Oil	2.57	0	0	0	0	0	0	59.22	0	0	0	0	0	16.02	0	0	
94300	5/10/2021	Miracle Leaf Delta8	THC	FL	Vape Oil	1.37	0	0	0	0	0	0	1.13	0	0	0	0	0	0	0	0	
94301	5/10/2021	Urb Delta8	DAB5 Banana Runtz	FL	Vape Oil	3.12	0	0	0	0	0	0	1.62	0	11.02	0	0	0	0	0	0	
94302	5/10/2021	Moon Men	Delta8 Shatter	FL	Vape Oil	2.48	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
94303	5/10/2021	Privada RUNTZ	RUNTZ Delta8 DAB DART	??	Vape Oil	3.65	0	0	0	0	0	0	53.04	0	0	1.64	0	0	0	0	0	
94304	5/10/2021	MED Roots	DELTA EIGHT Strawberry Cough	MI	Vape Oil	40.26	0	0	0	0	0	0	326.32	128.33	0	0	0	123.84	0	0	0	
94305	5/10/2021	Palm Treez	Delta8 Disidos	FL	Vape Oil	10.91	0	0	0	0	0	0	1.76	8.18	0	0	0	0.38	0	0	0	
						USP Limit	5000	410	2	-	3880	600	5000	5000	5000	290	-	5000	3000	5000	-	
Results reported in ppm																						
All Results were under USP limits (USP 467 - Residual Solvents)																						

Figure 2. Exploratory Analysis and Detail of Unknowns

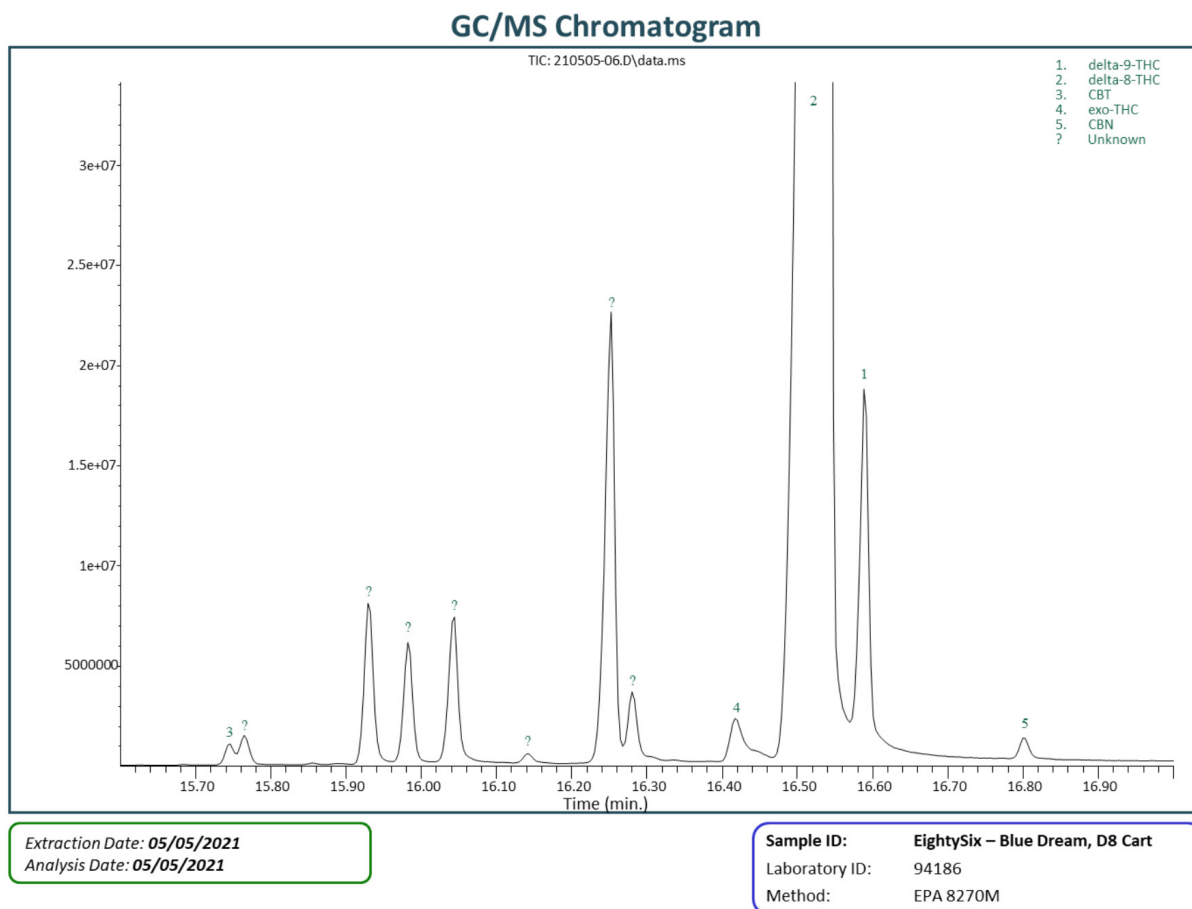
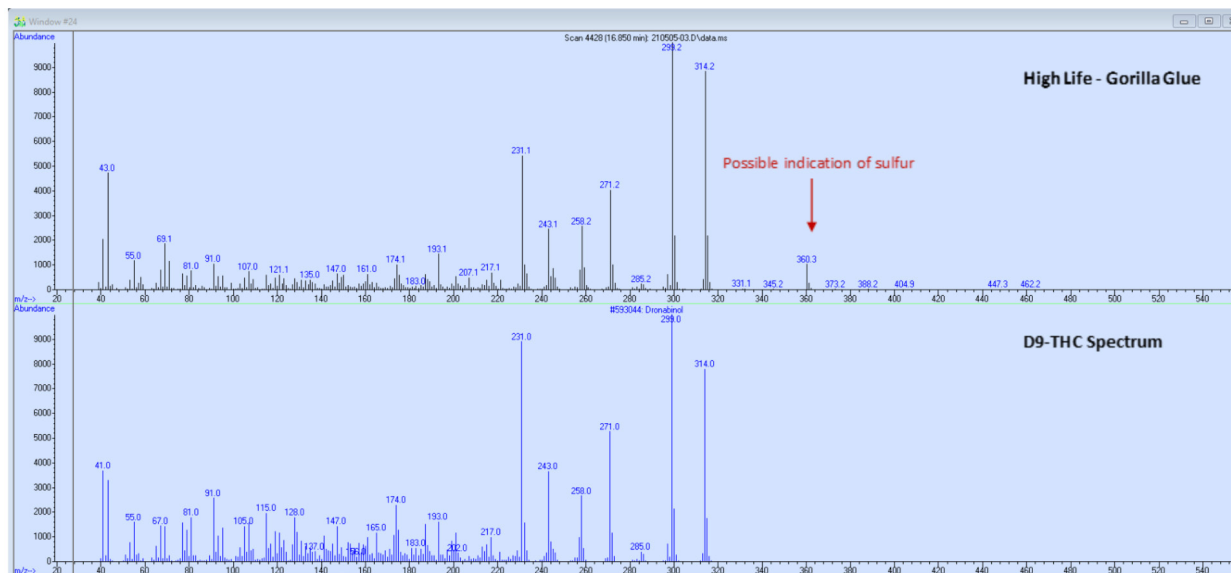


Figure 3. High Life - Gorilla Glue – Mass Spectral Comparison to D9-THC (as Dronabinol)



Federal Memorandum

C A D W A L A D E R

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Memorandum

To: US Cannabis Council
From: Cadwalader, Wickersham & Taft LLP
Date: May 13, 2021
Re: Federal Risks of Delta-8

Delta-8-Tetrahydrocannabinol (“Delta-8”) is the newest cannabinoid to hit the United States market after Congress legalized the production of hemp in 2018. Unlike CBD, which is non-psychoactive, Delta-8 is being marketed as a “legal” high with less potent, but similar effects to Delta-9-Tetrahydrocannabinol, the primary psychoactive in marijuana. Because Delta-8 is so new, much confusion exists around its legal status at the federal level, though most informed commentators believe that it will ultimately fall under the regulatory framework of the Controlled Substances Act (“CSA”).

Many commentators and marketers suggest that Delta-8 is legal on the federal level under the 2018 Farm Bill,¹ which defined “hemp” as “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.” 7 U.S.C. § 1639o. The 2018 Farm Bill also revised the CSA definitions of “marihuana” to exclude the new definition of hemp and the definition of “tetrahydrocannabinols” to exclude “tetrahydrocannabinols in hemp.” H.R.2 § 12619. Because Delta-8 naturally occurs in small quantities in cannabis,² they argue that these changes could be interpreted as exempting Delta-8 from control under the CSA.

However, the Drug Enforcement Administration (“DEA”), in August 2020, issued an “interim final rule” to codify, in the DEA regulations, the CSA amendments made by the 2018

¹ The “2018 Farm Bill” refers to the Agricultural Improvements Act of 2018.

² See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3736954/>

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Farm Bill.³ 85 Fed. Reg. 51639 (Aug. 21, 2020). The DEA recognized the revised definition of “marihuana” and clarified that to qualify for the “hemp” exception to the definition of marihuana, “a cannabis-derived product must itself contain 0.3% or less Δ^9 -THC on a dry weight basis.” *Id.* at 51641. But the DEA also clarified that “definition of hemp does not automatically exempt any product derived from a hemp plant, regardless of the Δ^9 -THC content of the derivative” and that “a cannabis derivative, extract, or product that exceeds the 0.3% Δ^9 -THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less Δ^9 -THC on a dry weight basis.” *Id.* The DEA further recognized that the effect of the 2018 Farm Bill was to “limit[] the control of tetrahydrocannabinols.” *Id.* Accordingly, tetrahydrocannabinols are deemed not controlled if they are “naturally occurring constituents of the plant material,” and “contain 0.3% or less of Δ^9 -THC by dry weight” “unless specifically controlled elsewhere under the CSA.” *Id.* The DEA also noted that the 2018 Farm Bill “does not impact the status of synthetically derived tetrahydrocannabinols (for Controlled Substance Code Number 7370) because the statutory definition of ‘hemp’ is limited to materials that are derived from the plant *Cannabis sativa* L. For synthetically derived tetrahydrocannabinols, the concentration of Δ^9 -THC is not a determining factor in whether the material is a controlled substance. All synthetically derived tetrahydrocannabinols remain schedule I controlled substances.” Neither DEA regulations nor the CSA define “synthetically derived.” As of April 2021, the DEA-published Controlled Substance by DEA Drug Code Number 7370 lists “Delta-8 THC” among “other names” for tetrahydrocannabinols.⁴

Therefore, Delta-8 is at high risk of being treated as a Schedule I controlled substance by the DEA under the 2020 Interim Final Rule. Delta-8 is not commercially produced by direct extraction from hemp because the quantities of naturally occurring Delta-8 are so small. Instead, it is lab-made by converting hemp-extracted CBD to Delta-8 through a chemical process.⁵ The conversion from CBD to Delta-8 also often creates Delta-9 at a concentration about the 0.3% threshold, although apparently some producers are working to minimize Delta-9 conversion.⁶ Delta-8 can also be chemically converted from Delta-9 by an even simpler process than CBD-conversion.⁷ While none of these methods of conversion necessarily meet a strict scientific

³ https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0821.htm

⁴ https://www.deadiversion.usdoj.gov/schedules/orangebook/d_cs_drugcode.pdf. Some commentators have stated that the DEA uses the same code number for Delta-8 and “marihuana,” (see, e.g., <https://www.hklaw.com/en/insights/publications/2020/10/hemp-industry-brings-case-against-dea-to-clarify-deas-hemp-rule>), but the most recent update to the drug codes assigns “marihuana” drug code number 7360 and “tetrahydrocannabinols” like Delta-8 drug code number 7370.

⁵ <https://www.cannabistech.com/articles/how-delta-8-is-made-in-the-lab/>

⁶ See, e.g., <https://acslabcannabis.com/blog/extraction/the-ultimate-guide-to-delta-8-thc-synthesis-methods-safety-and-purity/>

⁷ <https://extractionmagazine.com/2021/02/19/converting-cbd-to-delta-8-thc/>

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definition of “synthesis,” they do involve chemical manipulation of CBD (and Delta-9) to produce Delta-8 (and Delta-9). Moreover, it will likely be difficult for authorities to determine whether Delta-8 was derived from CBD or converted from Delta-9. For those reasons, it remains very likely that the DEA will view CBD-derived Delta-8 as a “synthetically derived” tetrahydrocannabinol under Schedule I.

Even if CBD-derived Delta-8 is not viewed as “synthetically derived,” Delta-8 would likely still be at high risk of being treated as a “controlled substance analogue” by the DEA. The Federal Analogue Act, 21 U.S.C. § 813, treats a controlled substance analogue, if intended for human consumption, to be treated for the purposes of federal law as a controlled substance in Schedule I of the Controlled Substances Act. A “controlled substance analogue” is any substance that has: (1) a substantially similar chemical structure to a schedule I or II controlled substance; and, (2) a substantially similar stimulant, depressant, or hallucinogenic effect on the central nervous system. 21 U.S.C. § 802(32). As to the first prong, the chemical structure of Delta-8 and Delta-9 are virtually identical—the only structural difference between them is the location of a carbon double-bond in the molecule. In Delta-9, the double-bond exists between the 9th and 10th carbon atom, whereas in Delta-8 the double-bond exists between the 8th and 9th carbon atom. This minor structural difference gives Delta-8 increased chemical stability, and thus shelf life, and reduces the efficiency at which Delta-8 binds to the CB1 receptor in the brain—which is why the “high” created by Delta-8 is thought to be less potent than the effect created by Delta-9. Nevertheless, experts estimate the effect of Delta-8 to be approximately 75% of the potency of Delta-9, which may easily meet the second requirement that the analogue have a “substantially similar” effect on the central nervous system. Given the near-universal agreement that the 2018 Farm Bill was not meant to legalize intoxicants, the DEA may very well view enforcement under the Federal Analogue Statute as consistent with the Farm Bill’s intent.

Ultimately, the ambiguity around the DEA’s interpretation of the 2018 Farm Bill Amendments and the language in the Farm Bill defining “hemp” as both the plant and its “derivatives” may arguably provide defenses were the DEA to seek an enforcement action against a Delta-8 producer or retailer. Nevertheless, the risk that Delta-8 will be treated as a Schedule I drug remains high until tested in the courts or clarified by the DEA or Congress.

Delta-8 also remains subject to FDA oversight. The 2018 Farm Bill also made clear that nothing in it would affect or modify the FDA’s authority under the Federal Food Drug and Cosmetic Act (“FD&C Act”). 7 U.S.C. § 1639r(c). After the 2018 Farm Bill’s passage, the FDA Commissioner publicly stated that “it’s unlawful under the FD&C Act to introduce food containing added CBD or [Delta-9] THC into interstate commerce, or to market CBD or THC

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products as, or in, dietary supplements, regardless of whether the substances are hemp-derived.”⁸ It is the FDA’s position that it is “illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements.” The FDA has also stated that Delta-9 THC and CBD products cannot be sold as dietary supplements or food additives under the FD&C Act.⁹

While the FDA has not issued a statement specific to Delta-8, it is likely that it will be treated similarly to CBD and THC. Any substance intentionally added to food is a food additive, and therefore subject to pre-market review and approval by the FDA, unless the substance is generally recognized as safe (GRAS) by qualified experts under the conditions of its intended use. 21 U.S.C. §§ 321(s) and 348. Other than certain hemp seed products, no cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA.¹⁰ Therefore, sales of Delta-8 remain prohibited by the FDA as a food additive or dietary supplement. As for Delta-8 vaping products, the FDA will likely treat them similarly to CBD vaping products—if sold as a tobacco product then they may not be sold without FDA pre-market authorization. If sold as a drug, then vaping products cannot be marketed without an FDA-approved drug application.¹¹ As a result, Delta-8 products in their present market form as vaping products and consumables are illegal under the FD&C Act. To date, the FDA has not aggressively pursued state-licensed marijuana sellers under the FD&C Act, but whether the FDA would take that same approach to unlicensed sellers of Delta-8 is unclear.

In conclusion, retailers and producers of Delta-8 are at serious risk of federal enforcement for selling illegal products. A high risk exists that Delta-8 will ultimately be deemed as a Schedule I controlled substance by the DEA due to ambiguities in the DEA’s interpretation of amendments to the CSA by the 2018 Farm Bill. In addition, the FDA has not approved the use of Delta-8 as a drug, dietary supplement, or food additive, so the current Delta-8 products on the market—edibles and vaping products—are being sold illegally under the FD&C Act.

⁸ <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-signing-agriculture-improvement-act-and-agencys#:~:text=Press%20Announcements-.Statement%20from%20FDA%20Commissioner%20Scott%20Gottlieb%2C%20M.D.%2C%20on%20signing%20of,cannabis%20and%20cannabis%2Dderived%20compounds&text=Scott%20Gottlieb%20M.D.,2018%20was%20signed%20into%20law>

⁹ <https://www.fda.gov/media/131878/download>

¹⁰ FAQ No. 10 <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>

¹¹ See, e.g., Report to the U.S. House Subcommittee on Appropriations and the U.S. Senate Committee on Appropriations Cannabidiol (CDB) at 12 (March 2020) <https://nysba.org/app/uploads/2020/03/FDA-CBD-Report-to-Congress-March-2020.pdf>

Related Media Coverage of Delta-8 THC

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Amendment potentially harmful to hemp industry removed by Senate	Alabama Political Reporter	Brandon Moseley	https://www.alreporter.com/2021/04/27/amendment-potentially-harmful-to-the-hemp-industry-removed-by-senate/	4/27/21
Delta-8 THC Jumps Thru Legal Loopholes	Cannabis Tech	KARHLYE FLETCHER	https://www.cannabistech.com/articles/delta-8-thc-jumps-thru-legal-loopholes/	11/16/20
An unregulated, weed-like drug dubbed 'CBD on crack' has spiked in popularity. Now the legal pot industry is calling for a crackdown.	Chicago Sun Times	Tom Schuba	https://chicago.suntimes.com/cannabis/2021/4/12/22378819/delta-8-thc-wake-bakery-canna-cafe-marijuanacannabis-botanic-alternatives-dispensary-cbd	4/13/21
Delta-8 THC Offers A Legal High, But Here's Why The Booming Business May Soon Go Up In Smoke	Forbes	Will Yakowicz	https://www.forbes.com/sites/willyakowicz/2021/03/12/delta-8-thc-offers-a-legal-high-but-heres-why-the-booming-business-may-soon-go-up-in-smoke/?sh=58aa0a5d5b3d	3/12/21
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Delta-8 THC Is the Next Big Thing in Weed, and We Tried It	GQ	Chris Cohen	https://www.gq.com/story/delta-8-thc-is-the-next-bighthing-in-weed	4/20/21
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More states banning delta-8 THC as regulators clarify its legality under federal law	Hemp Industry Daily	Laura Drotleff	https://hempindustrydaily.com/more-states-banning-delta-8-thc-as-regulators-clarify-its-legality-under-federal-law/	5/4/21
What's Up With the Sudden Delta-8 THC Craze?	Inside Hook	Logan Mahan	https://www.insidehook.com/article/health-and-fitness/what-is-delta-8-thc	5/5/21
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Omaha police: 3-year-old hospitalized after getting into mom's Delta 8 THC gummies	KETV Omaha	N/A	https://www.ketv.com/article/omaha-police-3-year-old-hospitalized-after-getting-into-thc-gummies/36365122#	5/7/21
Explainer: How Oregon lawmakers plan to address Delta-8 THC	KOIN Portland	Kelcie Grega	https://www.koin.com/news/oregon/explainer-how-oregon-lawmakers-plan-to-address-delta-8-thc/	5/2/21

Title	Publication	Editor	Link	Date
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Delta-8 Craze Puts Pot Attorneys On The Spot	Law360.com	N/A	https://www.law360.com/articles/1377167/delta-8-craze-puts-pot-attorneys-on-the-spot	4/29/21
How long will delta-8 remain legal?	Leafly	Bruce Kennedy	https://www.leafly.com/news/politics/how-long-will-delta-8-remain-legal	4/27/21
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United States: Delta-8: A New Low In Highs	Mondaq.com	Andrew Kline and Michael Bleicher	https://www.mondaq.com/unitedstates/cannabishemp/1065892/delta-8-a-new-low-in-highs	5/7/21
Delta 8: The Sudden Buyer Craze and Hazy Legal Status for a Hemp Product	Newsweek	John Jackson	https://www.newsweek.com/delta-thc-hemp-1583417	4/19/21
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This Drug Gets You High, and Is Legal (Maybe) Across the Country	NY Times	Matt Richtel	https://www.nytimes.com/2021/02/27/health/marijuana-hemp-delta-8-thc.html	2/27/21
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