







WHAT'S THE DEAL WITH DELTA-8 THC?

Frequently Asked Questions



Cannabis is a species of plant containing hundreds of different chemical compounds known as cannabinoids.¹

The two most prevalent cannabinoids are cannabidiol (CBD), a non-psychoactive compound, and Delta-9 tetrahydrocannabinol (THC), the compound responsible for the psychoactive effects experienced when using marijuana.² Delta-8 THC, on the other hand, is a compound not naturally occurring in significant amounts in the cannabis plant. Instead, concentrated amounts are manufactured through a chemical extraction process from hemp-derived CBD.³ Often marketed as "weed lite" or "diet weed," Delta-8 THC is estimated to be 50 to 75 percent as psychoactive as Delta-9 THC, and is frequently sold and marketed as an intoxicating product.⁴

Delta-8 THC is widely available in a variety of products, such as gummies, tinctures, candies, vape pens, oils, combustible products, and beverages, and is often found online and in convenience stores, gas stations, tobacco



Photo: Association for Nonsmokers — MN (ANSR)

product shops, CBD shops, and other retail establishments. The growing popularity of Delta-8 products has raised concerns regarding legal sale and manufacture and health and safety risks, particularly to youth, and spurred a rare health warning by the CDC in September 2021.⁵ This fact sheet addresses a few frequently asked questions about Delta-8 THC products, including regulatory options. (Please note that Delta-8 THC is just one of many similar compounds extracted from the cannabis plant that are marketed and sold as intoxicating alternatives to Delta-9 THC.)



Q. What's the back story on Delta-8?

A: Delta-8 quickly rose to prominence after the passage of the 2018 Farm Bill. The 2018 Farm Bill authorizes the cultivation, processing, and sale of hemp and hemp-derived products containing no more than 0.3 percent Delta-9 THC.⁶ The ensuing boom in U.S. hemp cultivation resulted in a surplus of CBD, a non-psychoactive cannabinoid that can be inexpensively derived from hemp.⁷ In turn, Delta-8 THC extracted from hemp-derived CBD became a popular product over the last several years, even though its legal manufacture and sale is arguably in a regulatory "gray area."8

Under federal law, Delta-9 THC remains illegal and is categorized as a Schedule 1 controlled substance — i.e., a drug with high potential for abuse with no currently accepted medical use in treatment in the U.S.⁹ Hemp-derived Delta-8 THC, however, is *not specifically* categorized as a Schedule 1 drug.¹⁰ The DEA has clarified that "All synthetically derived tetrahydrocannabinols remain schedule I controlled substances" but did not clarify whether "synthetically derived" means synthesis and extraction of Delta-8 THC from CBD.¹¹

As a result, producers in the cannabis industry have quickly developed psychoactive cannabis products from CBD-derived Delta-8 THC, arguing that they are not synthetically derived since they are derived from legal hemp. Regardless of how these products are derived, the U.S. Food & Drug Administration has *not* evaluated or approved them for safe use in any context.¹² In fact, the FDA has issued warning letters to several manufacturers and sellers of Delta-8 products for violations of the Federal Food, Drug, and Cosmetic Act, including marketing unapproved new drugs, misbranding, and adding Delta-8 THC to food products.¹³

Q. What's the difference between Delta-8, Delta-9, and Delta-10?

A: Although both Delta-8 and Delta-10 are THC compounds, their psychoactive properties naturally occur only in trace quantities in the legal hemp plant.¹⁴ *Delta-8 and Delta-10 THC* are not only less psychotropically potent than Delta-THC, but they have different pharmacological profiles and chemical structures than Delta-9.¹⁵

Little research has been done on Delta-10, and while some studies indicate that it may have psychoactive effects, they appear less potent than Delta-8 and far less potent than Delta-9 THC. In contrast, *Delta-9* THC is the compound most responsible for the psychotropic effects of cannabis and is commonly associated with adult use or recreational cannabis, which is currently legal and regulated in eighteen U.S. States. This compound can be highly potent, lead to intense intoxication, and be accompanied by side effects such as fogginess, exhaustion, paranoia, anxiety, and other effects. In the compound while some studies indicate that it may have psychoactive effects of the psychotropic effects of cannabis and far less potent than Delta-9 THC. In contrast, Delta-9 THC is the compound most responsible for the psychotropic effects of cannabis and is commonly associated with adult use or recreational cannabis, which is currently legal and regulated in eighteen U.S. States. This compound can be highly potent, lead to intense intoxication, and be accompanied by side effects such as fogginess, exhaustion, paranoia, anxiety, and other effects. In the compound can be highly potent.





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Although Delta-8, Delta-9, Delta-10, and many other isomers¹⁸ all occur naturally in cannabis, they can also be extracted from hemp-derived CBD through a chemical process using solvents.¹⁹ This process yields a solution that may contain Delta-8 THC, Delta-9 THC, Delta-10 and other byproducts, but can be further processed to remove Delta-9 THC, leaving Delta-8, Delta-10, or other isomers.²⁰

Q, How prevalent are Delta-8 products in the marketplace?

A: Often marketed as a less-potent alternative to marijuana, Delta-8 THC is one of the fastest growing product segments in the cannabis market. Delta-8 THC is sold in inhalable, smokeable, ingestible, and sublingual products including edibles, capsules, oils, tinctures, vapes, pre-rolled joints, cigarettes, and raw flowers.²¹ Delta-8 THC products are increasingly sold in marijuana, CBD, and hemp marketplaces, as well as tobacco product shops. Most states and territories permit full or restricted hemp marketplaces that sell hemp and hemp-derived CBD products.²² Also, products sold as concentrated delta-8 THC are widely available online.²³

Until recently, most states have not specifically regulated the sale, manufacture, and distribution of Delta-8 THC, and similar intoxicating or impairing products have quickly saturated these markets by taking advantage of gaps in state regulations and their enforcement, or a lack of understanding about the products. Delta-8 products have been most popular in states without regulated adult-use cannabis markets, but they are still a popular choice for consumers seeking a milder experience than the high provided by Delta-9 THC.²⁴

Q. What are the health impacts of Delta-8?

A: While there may be therapeutic uses for Delta-8 THC,²⁵ Delta-8 can pose potential health risks. Both the Centers for Disease Control and Prevention and the U.S. Food & Drug Administration



(FDA) have issued warnings of serious adverse events related to Delta-8 THC use.²⁶ Between December 2020 and February 2022, the FDA received 104 reports of adverse events, most of which occurred after individuals ingested foods containing Delta-8 THC.²⁷ Symptoms included hallucinations, vomiting, tremors, anxiety, dizziness, confusion, and loss of consciousness.²⁸ In addition, between January 2021 and February 2022, U.S. poison control centers received 2,363 reports of negative exposures to Delta-8 THC products.²⁹ Many of these cases concerned unintentional ingestion of Delta-8 THC products and a disturbing 82 percent involved children.³⁰

Inconsistent labeling practices and impure processing pose additional risks to public health. Frequently, Delta-8 products have brightly-colored packaging, flavoring, and candy-like appearances that appeal to younger audiences.³¹ Many times, these products are also not required to have child-proof packaging, which can increase the risk of pediatric consumption.³² In addition, product labels may be inaccurate, incomplete, or misleading, which increases the risk of inadvertent intoxication.³³ Moreover, depending on how the product was manufactured, it can contain byproducts or additional quantities of Delta-9 THC — chemicals that can produce unintended health consequences for consumers. One testing laboratory, for instance, found that Delta-8 products frequently contain up to 30 unidentified substances.³⁴ Overall, the available research on Delta-8 THC is sparse, and more studies are needed to determine this compound's broader impact on human health.

Q. Are Delta-8 products federally regulated?

A: Delta-8 THC producers and sellers operate in a legal gray area under federal law. Some argue that hemp-derived Delta-8 THC can be regulated as a Schedule I controlled substance because: (1) analog controlled substances may be regulated under the Controlled Substance Analogue Enforcement Act if they are "substantially similar" to a listed substance, and (2) the chemical extraction process used in manufacturing Delta-8 THC qualifies it to be a synthetic substance, which is regulated as a Schedule I controlled substance under a DEA Interim Final Rule.³⁵

Others argue that Delta-8 THC is a legal hemp product because it is extracted from hemp containing no more than 0.3 percent Delta-9 THC.³⁶ This position appears to be supported by the DEA, which has stated that the only cannabinoid regulated as a controlled substance is Delta-9 THC. In May 2022, the 9th Circuit Court of Appeals issued a ruling in a trademark infringement case that Delta-8 THC is not a Schedule 1 substance under federal law.³⁷ However, this ruling does not address the existing regulatory authority over food and drugs that the FDA holds through the Food, Drug, and Cosmetic Act and other federal regulations that may apply.

Recent legislation suggests that the federal government may soon take up the issue of the regulatory status of Delta-8 THC.³⁸ However, until the federal government clarifies its position,



Delta-8 THC is a compound not naturally occurring in significant amounts in the cannabis plant.



the regulation of Delta-8 THC is within the purview of the states. It is important to note that regardless of whether Delta-8 THC is regulated as a Schedule 1 substance, the requirements for sale, marketing, and distribution of drugs and food under the Food, Drug, and Cosmetic Act apply and restrictions of food additives under U.S. Department of Agriculture regulations also apply.

Q. What are some ways in which states might regulate Delta-8 THC and similar intoxicating products?

A: States are adopting a range of restrictions and bans on Delta-8 THC products.³⁹ Below are a few possible regulatory approaches:

- Prohibit manufacture and sale of products with THC isomers on both hemp and regulated marijuana markets. This is the approach taken by North Dakota, which redefined hemp and THC and outlawed the sale of hemp-derived THC products, effectively banning Delta-8 and Delta-10 products.⁴⁰ This approach, however, might create problems by pushing some consumers to the illicit market.⁴¹
- Regulate THC isomers within the context of the hemp regulatory framework. This approach could incorporate specific measures including enhanced testing requirements, establishing packaging and labeling requirements, and standardized serving sizes.⁴² Limiting transactions to a single market would allow for uniform product regulation in the interest of promoting consumer health and safety.⁴³ However, this approach may not fully address the regulations necessary for a psychoactive, intoxicating product and may become a backdoor to legalization of intoxicating cannabis products without full consideration of regulations necessary to protect public health. Please note that some hemp and cannabis product trade associations have stated that they believe



these intoxicating derivatives should be regulated as adult-use cannabis or with greater regulation than non-intoxicating hemp products.⁴⁴

- Prohibit manufacture and sale of products with THC isomers on the hemp market, but allow products in regulated adult-use or recreational cannabis markets. This is the approach taken by Michigan, which considers THC isomers to be marijuana and places Delta-8 products under the authority of marijuana regulators. Such an approach may be a viable option for states that already have established adult-use marijuana markets. These markets are highly regulated and include requirements—such as minimum age laws and vendor licenses—that add an extra layer of consumer protection.
- Allow products with THC isomers on both markets. This is the practice in most states. However, this approach can undermine the regulated market as the stakes to enter the adult-use market are high and producers are unlikely to internalize added costs to participate in the adult-use market if barriers to enter the hemp market are lowered.
- Key take-aways from commercial tobacco regulation may also be instructive for state and local regulation:
 - Ensure that smoke-free laws and policies apply to the use of Delta-8 and similar substances as both combustible products and as electronic smoking devices (e-cigarettes or "vapes") to protect others from exposure to secondhand smoke.
 - Ensure that the minimum legal sales age of 21 and other youth access restrictions are addressed, including restrictions on products that are marketed or appealing to children.
 - Urge the FDA to use its existing regulatory authority over food additives, food products, and drugs to protect the health and safety of consumers.

Contact Us

Please contact the Public Health Law Center at <u>publichealthlawcenter@mitchellhamline.edu</u> with any questions about the information included in this publication.

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Endnotes

- 1 Practical Law Commercial Transactions, Hemp and the 2018 Farm Bill: Overview § 1 (2022), Westlaw W-019-2195.
- 2 Id.
- 3 U.S. Food & Drug Admin., 5 Things to Know about Delta-8 Tetrahydrocannabinol Delta-8 THC (2021), https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc.
- 4 Ctrs. for Disease Control & Prevention, *Increases in Availability of Cannabis Products Containing Delta-8 THC and Reported Cases of Adverse Events* (2021), https://emergency.cdc.gov/han/2021/han00451.asp.
- 5 Ctrs. for Disease Control & Prevention Health Alert Network, *Increases in Availability of Cannabis products Containing Delta-8 THC and Reported Cases of Adverse Events* (2021). https://emergency.cdc.gov/han/2021/han00451.asp.
- 6 Agricultural Improvement Act of 2018, Pub. L. No. 115-334, § 10113, 132 Stat. 4490 (2018).
- 7 Britt E. Erickson, Delta-8-THC Craze Concerns Chemists, Chemical & Engineering News, August 30, 2021, at 24, 25.
- 8 Melvin D. Livingston et al., *Popularity of Delta-8 THC on the Internet Across US States, 2021*, 112 Am. J. Pub. Health 296-99 (2022), https://doi.org/10.2105/AJPH.2021.306586.
- 9 U.S.C. Title 21 § 801, et seq. (1970), http://www.law.cornell.edu/uscode/text/21/chapter-13.
- 10 See, e.g., Chris Roberts, Legal Marijuana, in All 50 States No Legalization Required? How Hemp Companies Are Hacking Federal Drug Laws, Forbes (Aug. 31, 2021), https://www.forbes.com/sites/chrisroberts/2021/08/31/legal-thc-in-all-50-states-no-marijuana-legalization-required-this-texas-company-says-its-hacked-federal-drug-laws/?sh=282080db8fa6.
- 11 DEA Clarification in Federal Register Vol. 85 No. 163 (Aug. 21, 2020), https://www.govinfo.gov/content/pkg/FR-2020-08-21/pdf/2020-17356.pdf.
- 12 U.S Food & Drug Admin., supra note 3.
- 13 U.S. Food & Drug Admin., FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products (May 4, 2022), https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-companies-illegally-sell-ing-cbd-and-delta-8-thc-products.
- 14 Id.
- 15 Eric C. Leas, The Hemp Loophole: A Need to Clarify the Legality of Delta-8-THC and Other Hemp-Derived Tetrahydrocannabinol Compounds, 111 Ам. J. Pub. Health 1927, 1927 (2021), https://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2021.306499.
- 16 Andriana Ruscitto, Latest Cannabinoid in the Spotlight: Delta-10 THC, Cannabis Business Times (June 10, 2021), https://www.cannabisbusinesstimes.com/article/delta-10-tetrahydrocannabinol-thc-infinitecal-acs-laboratory/ (citing Torbörn U.C. Järbe et al., Separation of the Discriminative Stimulus Effects of Stereoisomers of Δ^2 and Δ^3 -Tetrahydrocannabinols in Pigeons, 156 European J. of Pharmacology 361 (1988)).
- 17 See Leas, supra note 15.
- 18 An isomer is one of two or more compounds composed of the same chemical elements in the same proportions but differing structurally. THE FREE DICTIONARY, https://www.thefreedictionary.com/isomer.
- 19 Id.
- 20 Erickson, supra note 7, at 25.
- 21 Brightfield Group, What's the Fate of Delta-8?: Consumer, Product, and Regulatory Trends (2021), https://global-uploads.web-flow.com/596691afde3c5856d866ae50/60ccb681f666fc369e9cacb6_Q221_US%20CBD_Delta-8_Report_FINAL.pdf.
- 22 See, e.g., Hemp City, https://hempcity.com; see also Sales of Hemp-Based Products in the United States in 2018 and 2022, by Product Category, Statistica (2022), https://www.statista.com/statistics/980325/hemp-based-products-sales-us/.



- 23 See Delta-8 THC: The Latest Cannabinoid, ToxTalks (2021), https://med.virginia.edu/toxicology/wp-content/uploads/sites/268/2021/03/Mar21-Delta8THC.pdf; see, e.g., Nothing But Hemp, https://www.nothingbuthemp.net/on-line-store/Delta-8-Full-Category-c79920012.
- 24 Omar Sacirbey, *Is Delta-8 THC a Threat to the Marijuana Industry*, MJ BIZ DAILY (March 11, 2022), https://mjbizdaily.com/ is-delta-8-thc-a-threat-to-the-marijuana-industry; see also Melvin D. Livingston et al., supra note 8.
- 25 See Leas, supra note 15.
- 26 See Ctrs. for Disease Ctrl. & Prevention, supra note 4; Food & Drug Admin., supra note 3.
- 27 See Food & Drug Admin., supra note 3.
- 28 Id
- 29 See Ctrs. for Disease Ctrl. & Prevention, supra note 4.
- 30 10
- 31 Kelly Johnson-Arbor & Susan Smolinske, *The Current State of Delta-8 THC*, Am. J. EMERGENCY MEDICINE (2021), doi: 10.1016/j.ajem.2021.06.066.
- 32 Id.
- 33 Id.
- 34 Erickson, supra note 7, at 26.
- 35 Practical Law Commercial Transactions, supra note 1.
- 36 Id.
- 37 AK Futures LLC v. Boyd St. Distro, LLC, 35 F.4th 682 (9th Cir. 2022).
- 38 H.R. Rep. No. 117-82; S. Rept. 117-34; see also Consolidated Appropriations Act, 2022, Pub. Law No. 117-103, 139 Stat. 49 (2022) (For instance, Committee reports for the Agricultural Appropriations Bill that was incorporated in the Consolidated Appropriations Act, 2022, direct the USDA, HHS, and DEA to study the scientific basis for the current 0.3% Delta-9 THC threshold and recommend alternatives if necessary).
- 39 See, e.g., Hemp Benchmarks, *Delta-8 THC: State-by-State Updates* (2022), https://www.hempbenchmarks.com/hemp-market-insider/delta-8-thc-state-updates.
- 40 N.D. H.B. 1045 (2022), https://legiscan.com/ND/text/1045/id/2362117.
- 41 ICR CSU-Pueblo, September 2021 Cannabis Research Webinar Dr. Gillian Schauer, YouTube (Sept. 13, 2021), https://www.youtube.com/watch?v=spwvu_Uyiiw&t=61s.
- 42 Id.
- 43 Id.
- 44 See U.S. Hemp Roundtable, hempsupporter.com.
- 45 Mich. H.B. 4517 (2021), http://www.legislature.mi.gov/(S(hbanyq4v4eqewx51v034jztz))/mileg.aspx?page=GetObject&objectname=2021-HB-4517.
- 46 ld.
- 47 See Leas, supra note 15, at 1928.