

Hemp and Cannabis: What Is What and Why It Matters

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Overview

Over the last few years, intoxicating hemp products, like delta-8 tetrahydrocannabinol (THC) and delta-10 THC have exploded on the market due to the legalization of hemp as an agricultural product. This presentation will:

- Explore the differences between hemp and cannabis.
- Explore how cannabis and hemp products are regulated differently.
- Review state and federal attempts to regulate hemp and hemp-derived products.

References with hyperlinks are included at the end of the presentation; specific citations may be found in the slideshow notes, which will be made available after the training.



Cannabis and Hemp: What Is What?



2018 Farm Bill

- In 2018, the Farm Bill de-scheduled hemp and hemp-derived products, removing them from the purview of the Controlled Substances Act. This made hemp a legal agricultural product federally.
- The intent of the bill was to legalize hemp as an industrial product for things such as clothing and fuel, and to legalize non-intoxicating cannabinoids, such as cannabidiol (CBD).
- However, hemp retailers have taken advantage of the federal definition of hemp, to make intoxicating hemp products, such as delta-8 THC and delta-10 THC, that they claim are legal.



Federal Definition of Hemp

Hemp: "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivates, 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."

> 50 grams x 0.3% = 150 mg of delta-9 THC. Legal and unregulated.



<u>Source: Wikimedia – A snickers bar with the</u> <u>wrapper still intact</u>



Definitions of Cannabis

- Federal definition
 - "All parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, preparation of such plant, its seeds or resin ... "marihuana does not include - hemp."
- <u>Maryland definition</u>
 - Cannabis means "the plant Cannabis sativa L. and any part of the plant, including all derivative, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration greater than 0.3% on a dry weight basis... 'Cannabis' does not include hemp..."

LEGAL FICTION!

The Result

Hemp = delta-9 concentration of not more than **0.3% on a dry** weight basis

Subject to a patchwork of laws and regulations, no consistent safety, manufacturing, or packaging or labeling standards

Cannabis = delta-9 concentration of greater than **0.3% on a dry weight basis**

In states where cannabis use is legal, subject to the regulated cannabis market



Why This Matters: Intoxicating Hemp-Derived Products



Intoxicating Hemp-Derived Products

- Legal Delta-9 THC products: Federally legal hemp products can contain more than the delta-9 THC limits set in state law (i.e., 100 mgs/serving in Maryland) if their delta-9 THC concentration is 0.3% on a dry-weight basis.
 - Think again of the snickers bar that weighs 50 grams a product like that can have 150 mg of delta-9 THC and still legally be a hemp product.
- Legal THC Isomer products: Delta-8 THC, delta-10 THC products can be derived from hemp.
 - Delta-8 THC and delta-10 THC are naturally occurring in the cannabis plant but at incredibly low levels.
 - To attain the level found in most delta-8 THC and delta-10 THC products, they are chemically derived from CBD or delta-9 THC. The manufacturing process uses strong chemicals, and there are no standards for how these products must be prepared and subsequently purified.



Why Does This Matter?

- Due to the high levels of delta-8 THC, delta-9 THC, and delta-10 THC in products on the market, these products can be just as intoxicating or more intoxicating than regulated cannabis products.
- These products can look very similar to regulated cannabis products (e.g. product packaging, product look), which makes enforcement of these products hard.
- The health effects of these products are similar to cannabis products, including effects to attention and memory, and potential effects to cardiovascular health.
 - They also pose unique health risks due to how they are manufactured, including potential exposure to heavy metals and solvents.

Legal Provisions Applicable to Cannabis Products

Even though intoxicating hemp products look similar to cannabis products, they are two legally different products.

- Advertising
 - Cannot advertise directly or appeal to youth.
- Point of sale
 - Must be sold at a licensed dispensary.
- Packaging and labeling
 - Cannot be packaged in a way that appeals to youth.
 - Cannot resemble a product that is made for youth.
- <u>Testing</u>
 - Must meet safety standards for manufacturing, including lab testing.





Federal and State Efforts to Regulate Intoxicating Hemp-Derived Products



Federal Efforts - Food and Drug Administration Authority

- The 2018 Farm Bill retained Food and Drug Administration (FDA) authority over hemp and hemp-derived products.
- Since 2018, the FDA has not issued regulations for hemp and hemp-derived products.
- Hemp products are regulated by the Food and Drug Cosmetic Act (FDCA)
 - Food Adulteration (may render it injurious to health).
 - Food Additive must petition FDA for approval. Safe for intended use.
 - Dietary Supplement Structure function claims, well-being claims.
 - Drug Diagnosis, cure, mitigation, treatment, or prevention of disease claims.



Statement from FDA Commissioner Scott Gottlieb (2018)

- A statement from former FDA commissioner Scott Gottlieb clarified that the FDA will treat products containing cannabis or cannabis-derived compounds just as any other FDA-regulated products
 - They're subject to the same rules requirements as other FDA-regulated products containing any other substance
 - This includes rules and requirements around food additives, dietary supplements, and drug claims.
- Under the FDCA, its unlawful to introduce drug ingredients like these into the food supply or to market as dietary supplements.



FDA Consumer Update (Dec. 2021)

In 2021, the FDA released a consumer update regarding delta-8 THC products and made key warnings about the product.

- Delta-8 THC products have not been evaluated or approved by the FDA.
- The FDA has received adverse event reports (e.g. hallucinations, vomiting, tremors, anxiety, dizziness, confusion and loss of consciousness) involving delta-8 THC products.
- Delta-8 THC has psychoactive and intoxicating effects.
- Delta-8 THC products often involve use of potentially harmful chemicals to create the concentrations of delta-8 THC claimed.
- Delta-8 THC products should be kept out of the reach of children and pets.
- Delta-8 THC products may be marketed in ways that put the public health at risk.



FDA Warning Letters (2022)

The FDA issued warning letters to five companies for selling delta-8 THC products in violation of the FDCA.

- Unapproved new drug: based on diagnosis, cure, mitigation, treatment, or prevention of disease claims.
 - The delta-8 THC products in question claimed to offer relief and support for autoimmune diseases by suppressing the body's immune response.
- Misbranded drugs inadequate directions for safe use.
- Adulterated food
 - No food additive regulation authorizes the use of delta-8 THC.
 - Use of unauthorized food additive has adulterated the food products.

FDA, Federal Trade Commission Warning Letters (July 2024)

- Warning letters to companies selling food products containing delta-8 THC that mimic chips, candies and snacks from popular national brands in violation of the FDCA.
- Serves as part of the FDA and Federal Trade Commission (FTC) joint effort to take action against companies selling illegal copycat food products containing delta-8 THC.
- Public health officials are concerned about youth access to these products
 - Can be more intoxicating than legal cannabis products
 - Impurities in the product harmful or have unpredictable effects on consumers
 - The manufacturing process can introduce heavy metals and solvents into the products.

Maryland

In 2023, the <u>Cannabis Reform Act</u> defined "tetrahydrocannabinol" to mean:

- "Any tetrahydrocannabinol, including delta-8 tetrahydrocannabinol, delta-9 tetrahydrocannabinol, and delta-10 tetrahydrocannabinol, regardless of how derived;
- Any other cannabinoid, except cannabidiol that the administration determines to cause intoxication; and
- Any other chemically similar compound, substance, derivative, or isomer of tetrahydrocannabinol, as identified by the administration."



Cannabis Reform Act

- Limited the sale of certain THC products to licensed dispensaries only. Licensed, non-dispensary businesses (e.g., gas stations, smoke shops, tobacco vendors) may sell low-potency THC products, including those that contain up to:
 - 0.5 mgs of THC per serving OR
 - 2.5 milligrams of THC per package
 - Remember the snickers bar: the snickers bar containing 150 mg of delta-9 THC would be illegal to sell under this rule.
- Products over this potency limit can only be sold at licensed cannabis dispensaries and must comply with the manufacturing, laboratory testing, and packaging and labelling standards for regulated cannabis products

Maryland Hemp Coalition, Inc. v. Wes Moore et. al

- In 2023, The Hemp industry sued the state to stop enforcement of the licensing provisions of the Cannabis Reform Act, claiming it prevented them from either continuing to sell their product or obtaining a license to do so.
- <u>The court agreed and has temporarily stopped the State</u> from enforcing the potency and licensing rules against any person who was already lawfully in the business of selling hemp-derived products prior to July 1, 2023.
- The state can still take enforcement action against retailers who started selling these products after July 1, 2023. These products are still being sold throughout the state.
- The main enforcement agency is the Alcohol, Tobacco, and Cannabis Commission.



SB 214/HB 12 (2025)

- Passed in 2025, SB 214/HB 12 gives the ATCC greater enforcement power over THC products sold outside of licensed dispensaries.
- Authorizes the ATCC to issue citations for selling delta-8 THC and delta-10 THC to individuals under 21 years of age.
- Except for a licensed dispensary, a person may not sell or distribute a THC product that:
 - Is above 0.5 mg THC per serving or 2.5 mg THC per package
 - Is advertised as containing more than 0.5 mg THC per serving or 2.5 mg of THC per package
 - Violates packaging or labeling requirements for cannabis products
- The ATCC can seize, destroy, or confiscate THC products that violate these rules or that are offered or displayed for sale in a place that is not appropriately licensed to sell THC products.

Points of Contact – Hemp Concerns

- Tips and information about unlicensed sales of THC products can be sent to: ATCC Tips (<u>atcc.tips@maryland.gov</u>).
- Policy and law questions can be sent to: Thomas Akras, Director of the Legal and Legislative Division of the ATCC (<u>thomas.akras1@maryland.gov</u>), and Jeffrey Hann, Associate Director of the Legal and Legislative Division of the ATCC (<u>jeffrey.hann@maryland.gov</u>).
- Cannabis specific inquiry inbox: <u>atcclegalquestions.unlicensedmarket@maryland.gov</u>.



Questions?

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Citations

- 7 U.S.C. § 1639(o).
- Md Crim. Code § 5-101.
- 21 U.S.C. § 802(16).
- See 5 Things to Know about Delta-8 Tetrahyrdocannabinol Delta-8 THC, The Food and Drug Administration, <u>https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc</u> (last visited Aug. 20, 2024).
- Md. Code, Alc. Bev. § 36-903
- Md. Alc. Bev. Code § 36-1101
- Md. Code Regs. § 14.17.18.02
- Md. Code Regs. § 14.17.13.04



Citations

- Hemp Production and the 2018 Farm Bill, The Food and Drug Administration, <u>https://www.fda.gov/news-events/congressional-testimony/hemp-production-and-2018-farm-bill-07252019</u> (last visited Aug. 20, 2024).
- Scott Gotlieb, Statement from FDA Commissioner Scott Gotlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds, The Food and Drug Administration, <u>https://www.fda.gov/news-events/press-announcements/statement-fda-commissionerscott-gottlieb-md-signing-agriculture-improvement-act-and-agencys</u> (last visited Aug. 20, 2024).
- FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products, The Food and Administration, <u>https://www.fda.gov/news-events/press-announcements/fdaissues-warning-letters-companies-illegally-selling-cbd-and-delta-8-thc-products</u> (last visited Aug. 20, 2024).

Citations

- FDA, FTC Continue Joint Effort to Protect Consumers Against Companies Illegally Selling Copycat Delta-8 THC Food Products, The Food and Drug Administration, <u>https://www.fda.gov/news-events/press-announcements/fda-ftc-continue-joint-effort-protect-consumers-against-companies-illegally-selling-copycat-delta-8</u> (last visited Aug. 20, 2024).
- H.B. 556, 2023 Leg., 445 Sess. (Md. 2023) (available at <u>https://mgaleg.maryland.gov/mgawebsite/Legislation/Details/hb0556?ys=2023RS</u>).
- Brenda Wintrode, Judge pauses Maryland ban on THC-containing hemp products, The Baltimore Banner, <u>https://www.thebaltimorebanner.com/politics-power/state-government/hemp-cbd-lawsuit-C6IAWIC2PNEB7LXKWZAR7AIFNQ/</u> (Oct. 13, 2023).