National Trends and State Updates on Regulating Intoxicating Hemp-Derived Products

Gillian L. Schauer, PhD, MPH
Executive Director
Cannabis Regulators Association

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Disclosures and Disclaimers

I do not have anything to disclose.

This presentation is my own and does not necessarily represent an official position of CANNRA or of any of the state agencies with whom I work.

Cannabinoids being manufactured from hemp continue to expand

- Delta-8 THC
- Delta-10 THC
- THC-O-Acetate
- Hexahydrocannabinol (HHC)
- THC-P
- THC-H
- THCjd



Introducing THCh and THCjd The Strongest Cannabinoids

by Sponsor • 05/14/2022 12:00 am - Updated 05/13/2022 12:03 pm

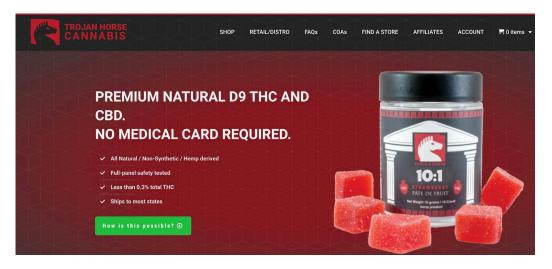


WILLAMETTE WEEK

THC-O Is A New Cannabinoid That May Lead to Powerful Psychedelic Highs

Despite causing borderline psychedelic highs, THC-O is derived from federally legal hemp.

What are we seeing on the market?





Gummies – Tropical Blast – 5:1 – 15 count – 15mg D9 THC \$19.99







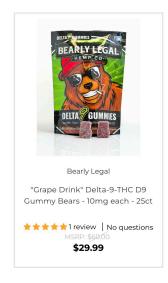




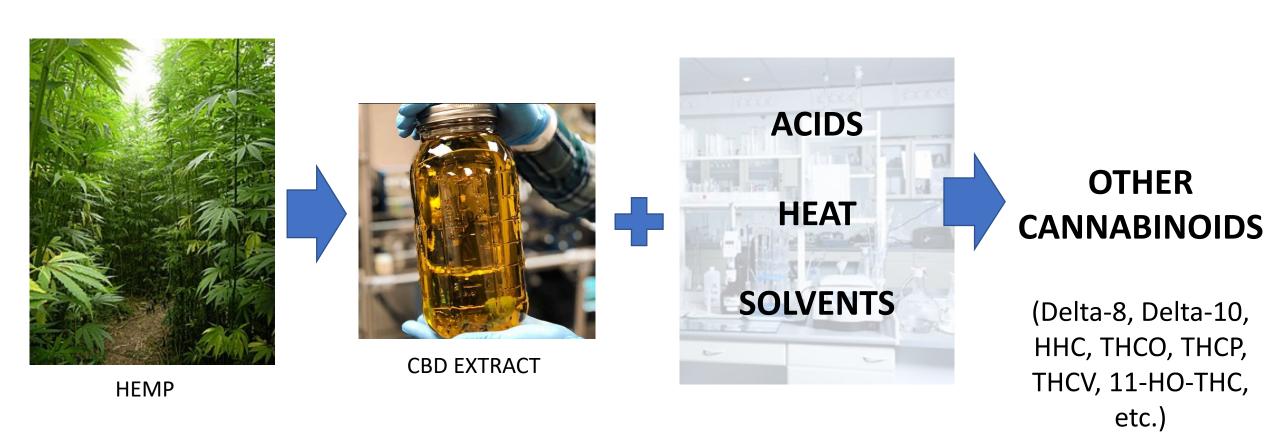








Quick review of chemically derived cannabinoid process....



New data underscores risks of adulterants, byproducts, and metals



pubs.acs.org/crt

Rapid Report

Novel Δ^8 -Tetrahydrocannabinol Vaporizers Contain Unlabeled Adulterants, Unintended Byproducts of Chemical Synthesis, and Heavy Metals

Iiries Meehan-Atrash and Irfan Rahman*



Cite This: Chem. Res. Toxicol. 2022, 35, 73-76



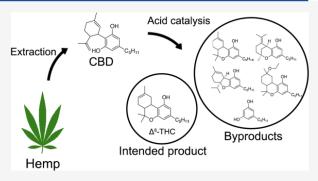
ACCESS I

III Metrics & More

Article Recommendations

s Supporting Information

ABSTRACT: Cannabis e-cigarettes containing Δ^8 -tetrahydrocannabinol (Δ^8 -THC) produced synthetically from hemp-derived cannabidiol (CBD) have recently risen in popularity as a legal means of cannabis consumption, but questions surrounding purity and unlabeled additives have created doubts of their safety. Herein, NMR, GC-MS, and ICP-MS were used to analyze major components of 27 products from 10 brands, and it was determined none of these had accurate Δ^8 -THC labeling, 11 had unlabeled cutting agents, and all contained reaction side-products including olivetol, $\Delta^{4(8)}$ -isotetrahydrocannabinol, 9-ethoxyhexahydrocannabinol, Δ^9 -tetrahydrocannabinol (Δ^9 -THC), heavy metals, and a novel previously undescribed cannabinoid, iso-tetrahydrocannabifuran.



Vaping Cannabinoid Acetates Leads to Ketene Formation

Kaelas R. Munger,^a Robert P. Jensen^b and Robert M. Strongin*^a

^a Department of Chemistry, Portland State University, Portland, OR 97207

^b FloraWorks Holdings, Inc., Milwaukie, OR 97222

Address any correspondence to Dr. Robert M. Strongin at the Department of Chemistry, Portland State University, Portland, Oregon, 97207-0751; strongin@pdx.edu

ABSTRACT

 Δ^8 -THC acetate is a relatively new psychoactive cannabis product that is available online and in vape shops across the US since it is currently unregulated. Because it contains a similar substructure to vitamin E acetate, which has been shown to form the poison gas ketene during vaping, we investigated potential ketene formation from Δ^8 -THC acetate, as well as other cannabinoids acetates, CBN acetate and CBD acetate, under vaping conditions. Ketene was consistently observed in vaped condensates from all three acetates as well as from a commercial delta-8 THC acetate product purchased online.

Adverse events continue

Spotsylvania woman charged with murder after 4-year-old son ate 'large amount' of THC gummies A doctor told investigators that if medical intervention had happened

faster, the death could have been prevented.



Delta 8 THC sellers warn customers to check products before buying

By Maggie Green and Diane Wilson via 16



Friday, September 16, 2022

FAIRFAX COUNTY

Several Students Sickened After Taking Delta-8 THC Edibles at

Fairfax County Fire and Rescue sent several ambulances to Liberty Middle School in Clifton after seven

By Carissa DiMargo • Published October 27, 2022 • Updated on October 27, 2022 at





Updated adverse event data

- National Poison Center Data between Jan 1, 2021 and Feb 28, 2022:
 - 2,362 exposure cases
 - 41% involved pediatric patients less than 18 years of age
 - 40% involved unintentional exposure to Delta-8 (and 82% of these unintentional exposures impacted pediatric patients)
 - 70% of cases required health care facility evaluation, 8% of those resulted in admission to critical care (45% of patients requiring evaluation were pediatric patients)
 - One pediatric case was coded with a medical outcome of death

Source: U.S. FDA "5 Things to Know about Delta-8 Tetrahydrocannabinol". Available from: https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc

Action from FDA continues to be limited



FDA warns companies for illegally selling food and beverage products that contain #CBD. These CBD products in forms that are appealing to children, such as lollipops, gummies, and cookies, are especially concerning. fda.gov/food/cfsan-con...









Two major issues states are facing in regulation:

 Chemically derived impairing cannabinoids (Delta-8, Delta-10, HHC, THCO, etc.)

2) Impairing amounts of Delta-9 THC in products that meet the legal definition of "hemp" per the 2018 farm bill.



Considerations in Establishing Cannabinoid Limits for Hemp Products

Rationale for Rulemaking

What does 0.3% look like?		
	Hemp Potency Limit	Adult-Use Marijuana Limit ²
20 g pack of gummies:	60 mg Δ ⁹ -THC	50 mg Δ ⁹ -THC
85 g bar of chocolate:	255 mg Δ^9 -THC	50 mg Δ ⁹ -THC
12 oz beverage:	>1,000 mg Δ^9 -THC	50 mg Δ ⁹ -THC

Examples of how states are dealing with these issues:

- Oregon HB 3000 (2021) → Gave broad regulatory authority to OLCC to regulate impairing hemp-derived cannabinoids, set THC limit per serving in hemp (2mg/serving, 20mg/package).
 Recent task force to review regulations made to date.
- Michigan HB 4517 (2021) → Gave CRA authority to set a limit of THC in products, requires licensing from CRA for sales of Delta-8 and other forms of THC.
- **Nevada SB 49 (2021)** → Broadly defines THC (D8,9,10, THCO) and requires a license and approval from NV CCB to make or sell Delta-8.
- Colorado SB22-205 (2022) → Created a taskforce to make recommendations to regulate intoxicating hemp and THC products. Report with recommendations due to legislature Jan 1.
- Virginia HB 30 (2022) Task force to analyze industrial hemp extracts and other substances containing THC intended for human consumption. Draft report was delivered on Nov. 8th.
- Minnesota HB 3595 (2022) → Legalized consumable hemp-derived products up to 5mg THC/serving, 50 mg/package with no purchase limits, and no required licensing.

Challenges in regulation of hemp

- Highly technical subject that can be difficult for non-scientists
 - Disagreement on how to define "impairing" or "intoxicating"
 - Disagreement on how to define "synthetic"
 - What to do about non-natural synthetics (like THCO, THCP, HHC)?
 - What to do about full spectrum products with high levels of THC?
 - What to do about biosynthetically derived cannabis?
- Different agencies regulating hemp and cannabis
- New molecules coming out regularly; lacking data and safety profiles

CANNRA Resources for education



CANNABINOID HEMP: AN OVERVIEW

WHAT IS HEMP?

"Hemp" refers to certain types of cannabis and cannabis-derived products. Both "marijuana" (referred to here as cannabis) and "hemp" refer to the same plant: Cannabis sativa. Federally, the difference between cannabis and hemp is the amount of delta-9-tetrahydrocannabinol (THC) they contain by weight. Delta-9-THC is the primary substance (but not the only substance) associated with the "high" that people feel after consuming marijuana. Generally:

- . Lower-THC cannabis is "hemp": Up to 0.3% delta-9-THC by weight
- . Higher-THC cannabis is "marijuana": More than 0.3% delta-9-THC by weight

7 USC § 16390 (1) HEM

The term "hemp" means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

CAN PEOPLE GET HIGH ON HEMP?

Yes. One of the common misconceptions about hemp is that all hemp products are non-intoxicating because they contain low concentrations of delta-9 THC. In reality, there are currently a wide range of intoxicating hemp products being sold in the United States. These intoxicating hemp products generally fall into two categories:

- "Edibles" with large doses of delta-9-THC: "Low THC" is relative depending on the type of product. Under federal
 law, all hemp products are limited to no more than 0.3% delta-9-THC by weight. In dried plant material, this is a
 very small amount of THC compared with cannabis. But in foods and beverages, which weigh more than dried
 plant matter, 0.3% can be a lot of THC. The National Institute on Drug Abuse (NIDA) has established a "standard
 dose" of THC as 5 mg. With that dose in mind, at 0.3% THC by weight.
 - o Approximately one teaspoon of liquid (5.7 g) contains more than three doses of THC (17 mg)
 - A "snack size" pack of fruit snacks (20 g) contains 12 doses of THC (60 mg)
 - A typical chocolate bar (50 g) contains 30 doses of THC (150 mg)

This is widely known in certain parts of the hemp industry, and these types of hemp edibles with large doses of THC are available for purchase in most states and online. Some of these products even contain more THC than states allow in their state-legal adult use cannabis programs.

Semi-synthetic hemp-derived cannabinoids: Substances that are extracted from hemp can be converted into
intoxicating compounds or cannabinoids using basic chemistry. Because hemp is defined only in terms of delta-9THC, federally, there is no limit on the amount of other potentially intoxicating cannabinoids that can be present in
hemp products. These intoxicating hemp derivatives are commonly sold in vape cartridges and edible products.
Common intoxicating hemp derivatives include: Delta-8-THC, THCO, HHC, and HHCO. These cannabinoids have not been widely studied for safety in human consumption and some of them are new compounds not found in nature.

WHAT ABOUT NON-INTOXICATING HEMP PRODUCTS?

There are plenty of non-intoxicating hemp products too:

- Grain: Hemp seeds can be processed into ingredients for foods, cosmetics, or industrial uses. Foods commonly
 derived from hemp seeds include hemp hearts, hemp milk, hemp protein, and hemp seed oil. These food products
 are intended for human consumption, and generally contain nondetectable amounts of THC.
- Fiber: Hemp stalks can be processed into fiber for a wide variety of uses. Hemp fiber is used to make paper, textiles, clothing, plastic, and building materials like hempcrete.
- Cannabinoids: Many American hemp farmers grow hemp as a source of cannabinoids like Cannabidiol (CBD). CBD
 alone is a non-intoxicating cannabinoid that is used in a wide variety of consumer products.



AN OVERVIEW OF REGULATORY CHALLENGES FOR CANNABINOID HEMP

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

LACK OF ENFORCEMENT OF FDA REGULATIONS

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

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

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

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

PRODUCTS WITH INTOXICATING AMOUNTS OF DELTA-9-THC

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

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

SEMI-SYNTHETIC DERIVATIVES

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