# TOWARD NORMALIZED CANNABINOID REGULATION

## The Regulation of Hemp-Synthesized Intoxicants

AMERICAN TRADE ASSOCIATION FOR CANNABIS AND HEMP
ATACH

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# ACKNOWLEDGEMENTS

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Sincerely,

Michael Bronstein
Co-Founder and President
American Trade Association for Cannabis & Hemp

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# Executive Summary

This report discusses the rising popularity of Hemp-Synthesized Intoxicants (HSI's) and the challenges they create due to a lack of a consistent and normalized regulatory framework for the production, testing, and sale of intoxicating and non intoxicating products. The American Trade Association for Cannabis & Hemp ("ATACH") recommends solutions for lawmakers and regulators at both the federal and state levels. These solutions account for the organization's guiding view that adult-use cannabis must be legalized and that regulators and businesses should establish a pathway to improve consumer safety and facilitate functional growth of the regulated cannabis industry in the United States in the interim.

The foundational principle of cannabis regulation is that intoxicating products should be regulated when available for consumers.[1] However, when Congress drew the line in the definition of hemp at 0.3% tetrahydrocannabinol (THC) by dry weight in the previous Farm Bills, it did so imprecisely and aimed primarily at the cultivation stage, rather than anticipating the broad range of finished consumer products. Now, intoxicating hemp products have emerged outside the purview of regulation. The result is that when contrasted with federal law related to marijuana, delta-9 THC and other intoxicating cannabinoids are both legal and illegal at the same time, based entirely on how the various intoxicating molecules are produced. However, non-intoxicating cannabinoid products such as CBD are legal although not approved by the FDA, and no federal regulatory pathway otherwise exists.

The situation urgently needs a regulatory framework.

We highlight four areas of concern regarding the proliferation of hemp-synthesized intoxicating products: lack of age limits, residual chemicals, consumer labels, and testing, which are all features of the regulated state-legal cannabis markets. We suggest that lawmakers should adopt a regulatory framework that encourages participation in the regulated market for producers, establishes critical best practices, testing standards, and labeling requirements, and educates consumers on the risks of unregulated products.

The report calls on Congress to adopt an amended definition of hemp to better account for the wide range of products in the marketplace today, from textiles to intoxicants, and closes the federal so-called "loophole" that exists by regulating finished product. We also encourage federal testing standards, labeling requirements, and assistance for states that need equipment, training, and staff in state labs for intoxicating cannabinoids, in particular. And, we note that the regulatory focus should be at processing, production, and retail point of sales, rather than at the farm and in the field.

We also make recommendations that must immediately be implemented for consumer protection and public health and safety. For example, states should immediately set age limits for hemp-synthesized intoxicants where they do not currently apply. Where available, states should use existing marijuana programs, which are already designed to regulate the intoxicant delta-9 THC from the cannabis sativa L plant, of which hemp is a variety. Such programs should establish manufacturing standards unique to a laboratory environment, standardize product packaging and labeling requirements, and create mechanisms for enforcement of public health and safety standards based on potential dangers posed by the unregulated HSI market. If no program currently exists, states should adopt a singular regulatory program for intoxicating cannabis products, inclusive of both marijuana and hemp finished products. States must avoid creating a separate regulatory structure outside of state-legal cannabis programs, or risk regulatory and consumer confusion of cannabis intoxicants.

This issue is not going away, it gets more complicated as time goes on, and must be addressed head on now. Hemp-synthesized intoxicating products are popular, widespread, easy to make, and produce an intoxicating effect desired by consumers of marijuana products. We believe the best approach is to regulate production through a consistent and normalized regulatory scheme as the country continues moving toward the federal legalization of cannabis.

# Terminology

This report uses specific terms that may not be familiar to all readers, and these terms are sometimes used inconsistently in cited resources. We follow the standard set by the Congressional Research Service guide on hemp and related terms.[2] Here are the key terms used:

**Analog** - Used in this paper, it is a molecule designed to imitate THC and bind to the nervous system similarly but made from different materials and not found in nature. THCp is a delta-9 THC analog.

**Cannabis** - Refers to the plant Cannabis sativa L., which includes both legal categories of "hemp" and "marijuana" varieties. In some cited resources, "cannabis" is used interchangeably with "marijuana."[3]

**Delta-9 Equivalency (DNE)** - Compares the potency of various HSI's to delta-9 THC, marijuana's primary intoxicating ingredient, and is used as a reference point. DNE is related to Total Intoxicating Cannabinoid Content (TICC), a proposed ASTM International definition, which helps consumers predict a product's potency compared to marijuana's active ingredient.

**Hemp** - The term “hemp” means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.[4] Under various state law contexts, the definition can be less precise. In resources cited in this paper, products made from hemp — including even extracts from hemp or products such as food that are made using that extract, can themselves be referred to simply as “hemp” or “industrial hemp” under state law.[5]

**Hemp-Synthesized Intoxicant (HSI)** - An intoxicating cannabinoid which is synthesized from a non-intoxicating constituent found in hemp varieties of the Cannabis sativa L. plant. They are not naturally-created products, but are typically created through a semi-synthetic conversion process

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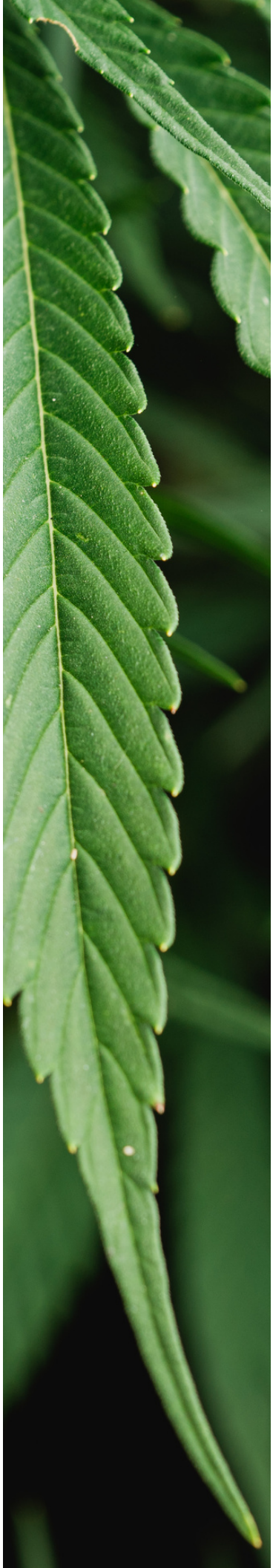
that takes non-intoxicating cannabidiol ("CBD") and converts it into one or more intoxicating cannabinoids using heavy metals, volatile solvents or other chemical processes. Common HSI's include delta-9, delta-8, delta-10, THCp, THCO, HHC, and THCV.[6] See Appendix B for more HSI's.

**Isomer** - Refers to a molecule structurally similar to delta-9 THC , and made of the same building blocks but with different atom connectivity. Common isomers are delta-8 THC and delta-10 THC.

**Marijuana (or marihuana)** - Refers to the same plant as the hemp plant, but one that contains an amount of delta-9 THC that is greater than 0.3% of the weight of the plant material when dry,[7] measured within 30 days before harvest. Used here, it refers to the "recreational" or intoxicating form of the plant. "Medical marijuana" refers to the same form of the plant (high in delta-9 THC), but which is consumed for medical purposes or consistent with a state medical marijuana program. "Marijuana" can refer to the plant, or to the dried flowers and leaves that consumers consume.[8]

**Phytocannabinoid** - A diverse group of naturally occurring cannabinoids found in Cannabis sativa L. or other sources. Within the plant, many are present in trace amounts but which can be reproduced in larger quantities in a lab using other cannabis constituents, like CBD.

**Total Intoxicating Cannabinoid Concentration (TICC)** - The combined concentration of natural, chemically converted, and artificially derived cannabinoids, measured in delta-9 THC Equivalency (DNE) units. This includes intoxicating substances like delta-9 THC, delta-8 THC, delta-10 THC, and their optical isomers. TICC indicates the total amount of intoxicating cannabinoids in a product, providing a potency standard regardless of the source or types of cannabinoids present.[9]



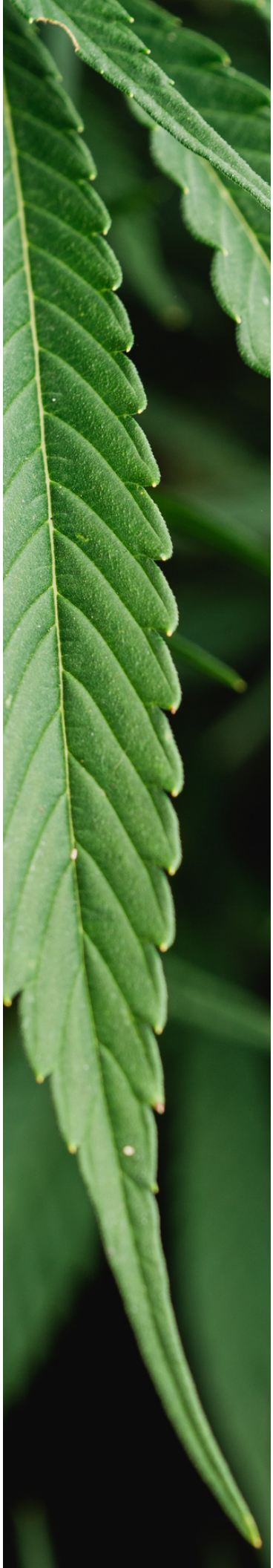
# Background

## The Creation of Industrial Hemp

The 2014 and 2018 Agriculture Improvement Acts (often referred to collectively as the “Farm Bill”) began the process of regulating hemp in the United States as an agricultural crop. In the 2014 Farm Bill, Congress initiated a pilot program for "industrial hemp," allowing for hemp cultivation for research purposes, restricted to either institutions of higher education or state departments of agriculture. This legislation allowed these entities to produce hemp crops and perform USDA-sponsored research on marketable uses of hemp.[10]

In 2018, hemp became a federally regulated crop eligible for various benefits, including crop insurance and disaster relief. The definition of industrial hemp was updated to include derivatives, extracts, and cannabinoids, with a delta-9 THC concentration of not more than 0.3%.[11] Most importantly, industrial hemp was removed from the definition of marijuana in the Controlled Substances Act (“CSA”) and from Drug Enforcement Agency (“DEA”) oversight. The USDA became the main regulator of industrial hemp in coordination with state departments of agriculture, while the DEA retained control over marijuana and non-hemp-derived substances. The FDA had authority over hemp products intended for human consumption. The USDA published its legal opinion on May 28, 2019 that hemp or a derivative that contains not more than 0.3% delta-9 THC on a dry weight basis is no longer a controlled substance under the Controlled Substances Act.[12]

Although the FDA retained its authority over hemp-derived products intended for human consumption, the agency took only limited steps towards developing a regulatory model for these products, including data-gathering initiatives and consumer warnings. The agency also maintained that since the 2014 Farm Bill, use of CBD or THC in products intended for human consumption are illegal as either a dietary supplement or a food ingredient because they have not been approved. Nonetheless, enforcement was limited and hemp producers have operated under state laws without significant enforcement or oversight by the FDA. However today, the FDA maintains that it lacks the necessary tools to regulate cannabinoids effectively and has urged Congress to provide more guidance.[13] The 2023 Farm Bill may be an opportunity for Congress to address these issues.



Other agencies, such as the FTC and EPA also possess authority over certain aspects of hemp-derived products, including fraud, deceptive advertising, and pesticide use.

While the Farm Bill delegated authority to FDA, the agency clearly fell short, and the 2014 and 2018 Farm Bills only established limitations related to the cultivation of the hemp plant and not the processing and sale of its derivative forms. Critically absent from the Farm Bill is a framework, short of FDA's involvement, for how finished products intended for human consumption should be regulated.

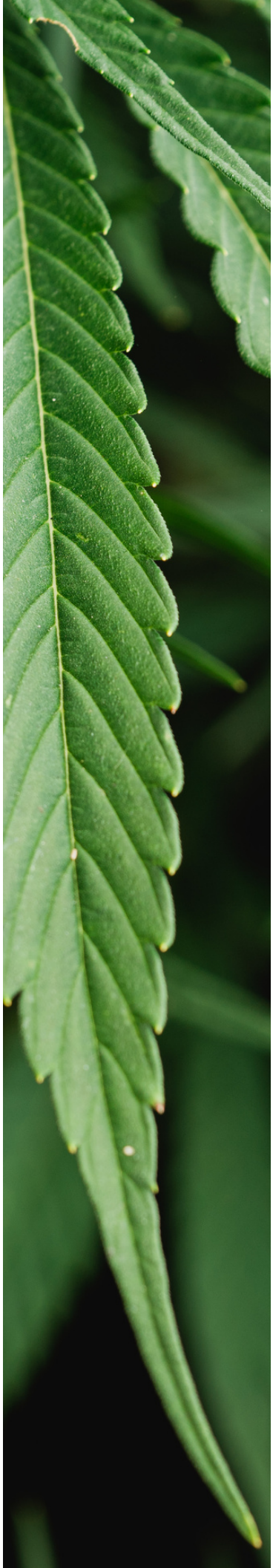
Relying on this regulatory gap, the HSI industry emerged shortly after passage of the 2018 Farm Bill, armed with an incomplete definition of hemp that based its legality on only a percentage of delta-9 THC content or the original plant and lacking fundamental finished product safety regulations. Today's HSI marketplace is rife with intoxicating products which some argue technically fall within the 2018 Farm Bill's definition of hemp[14] but are much more intoxicating than products even in state-sanctioned marijuana programs.

**The 2023 Farm Bill must address this regulatory gap and deploy a "fit for purpose" framework that contemplates the cultivation, processing, and sale of hemp products and derivatives, which take many forms.**

## The AK Futures Case

The 2018 Farm Bill raised questions about the legal status of industrial hemp-synthesized intoxicating cannabinoids. The initial response from the courts and the DEA[15] seemed to validate the notion that intoxicating cannabinoids that are synthesized from CBD are simply not controlled substances within the Controlled Substances Act.

In *AK Futures LLC v. Boyd Street Distro, LLC*,[16] the 9th Circuit examined the legality of delta-8 THC vaping products produced by AK Futures. Boyd Street argued that AK Futures couldn't have a valid trademark on a product containing a controlled substance. However, the Ninth Circuit Court found that delta-8 THC in AK Future's products fit the definition of "hemp" and was not a controlled substance.[17] The court's opinion, however, relied on its finding that the delta-8 THC at the center of the case was naturally-occurring, when in fact it was synthesized into existence. Nonetheless, that rationale was not challenged further in that proceeding.



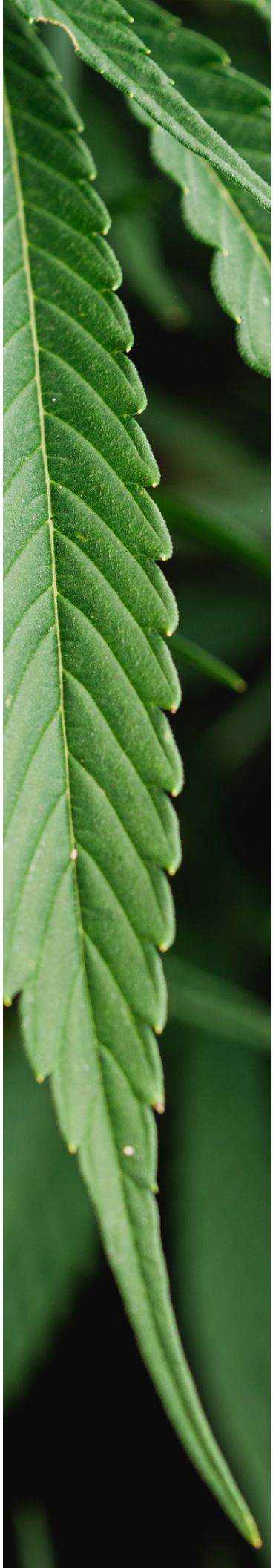
There are further limitations. While the court analyzed the legal claim under the 2018 Farm bill and the Controlled Substances Act, it did not provide an analysis or discuss the Federal Food, Drug, and Cosmetics Act (FFDCA) or the Federal Analogue Act, which may also apply. Finally, it is also worth mentioning that the ruling by the 9th Circuit is only binding on federal courts in Alaska, Arizona, California, Hawaii, Idaho, Montana, Nevada, Oregon, and Washington. State courts and federal courts in other circuits may not necessarily follow the determination.

## DEA's Response

Initially, many thought the DEA would target HSI's like delta-8, because the delta-8 THC in consumer products is not naturally occurring in the hemp plant, but rather is the result of a synthetic process using constituents of hemp, and therefore a Schedule I controlled substance.[18] Others suggested the Analogue Act allowed for prosecution of artificially created intoxicating cannabinoids. However, in the fall of 2021, the DEA seemed to indicate a different position through letters to Alabama regulators and more recently to a North Carolina attorney.

In response to Alabama's Board of Pharmacy, the DEA clarified that while synthetic cannabinoids were controlled substances, Congress exempted "tetrahydrocannabinols in hemp," including all derivatives and extracts.[19] To the DEA, this meant that intoxicating cannabinoids naturally occurring in hemp were not controlled substances under the Controlled Substances Act.

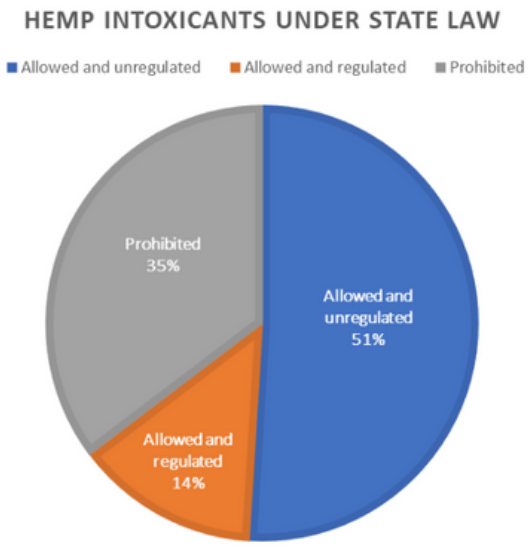
A recent DEA letter discussed the status of delta-8 THCO and delta-9 THCO,[20] which are analogs of THC and not phytocannabinoids. The letter indicated that while it might be legal to synthesize cannabinoids in a lab environment, the resulting intoxicating cannabinoid must be one that is found naturally in the cannabis plant—a phytocannabinoid. Synthetically produced intoxicants that contain molecules that do not have analogs in the plant remain controlled substances.

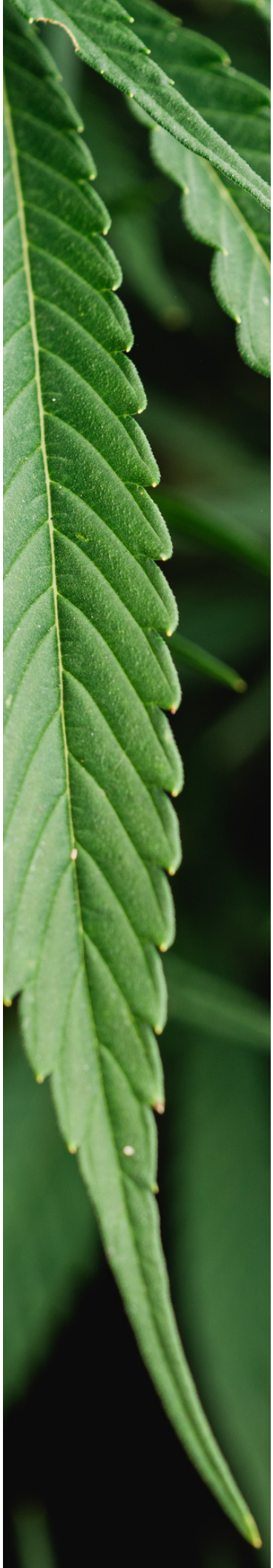


At the time of this publication, the DEA seems to be taking a different approach, based on recent public statements.[21] In these statements, the DEA outlined what many to believe to be its current position, which is that using a chemical step to convert the CBD molecule into THC is a synthetic process, and that any product that contains any amount of synthetic THC is a controlled substance under Schedule I of the Controlled Substances Act, unless it is specifically exempted.[22] Rather than looking at the origins of the material used (i.e. CBD from hemp) and the end result (ie. a molecule that could at least theoretically appear naturally in a hemp plant), the DEA now appears to be looking at the processes used to produce it. Based on that analysis, HSI's are Schedule I controlled substances.

## Impact on States

The impact on states since the passage of the 2018 Farm Bill was broad, and their responses varied. Many states moved quickly to change their hemp laws along with those related laws that apply to food and drugs. Most often this was for the purpose of allowing hemp products like CBD, but which also could result in the unintended allowance of intoxicating derivatives. When the CBD market grew saturated, some hemp producers turned to the lab to convert CBD into different forms of intoxicating THC. This led to the emergence of HSI products like delta-8 THC in 2019, and by the fall of 2020 they were appearing on store shelves in many retail outlets around the country and gaining in popularity.[23] Notably, changes that states initially made to their laws in response to the federal Farm Bill were done before intoxicants began to emerge into the marketplace and as a result, many were caught off-guard as the new market materialized.





By November 9, 2022, according to the law firm Vicente LLP, 35 states at least technically allowed HSI's, including Alabama, Alaska,[24] Arizona, Arkansas, Colorado,[25] Delaware, Georgia, Wisconsin, Idaho, Indiana, Maine, Massachusetts,[26] Michigan, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming. However, only a handful specifically addressed HSI's, while most states simply did not address hemp intoxicants when permitting hemp-derived products, and as result, intoxicants were allowed.

Of the 35 jurisdictions that allowed HSI's, 26 adapted their state laws to align with the federal government without specifically addressing HSI's.[27] Six of these 35 jurisdictions adopted regulations tailored to hemp extracts, including HSI's, by late 2022.[28]

Among the 18 states that ban HSI's, 16 did so by expressly prohibiting HSI's during the course of modifying their state hemp laws. The remaining two, Delaware and Arizona, had existing controlled substances laws that were broad enough to include all forms of THC irrespective of its source, and their law did not change once hemp laws had otherwise been amended.

Between the 2022 and 2023 legislative years, state lawmakers proposed numerous bills to allow, regulate, or ban HSI's. Some proposals would simply have imposed an age limit for retail sales (Alabama, Kentucky), while others would have created an entire licensing and regulatory system for HSI's including Kentucky, Minnesota and Tennessee, which Kentucky and Minnesota adopted.[29] Many states had proposals that would only have allowed HSI's within their regulated cannabis programs, and limited the hemp regulatory systems to have lower THC-containing products. Other states proposed or adopted parallel systems to regulate HSI's and marijuana separately (Florida, Arizona). Several others did in fact direct various task forces to consider regulatory models or solutions, including Colorado, Oregon, and Washington. Louisiana simply modified its existing regulatory system in various ways, while other states such as Indiana, and Arkansas have or are considering proposals to ban HSI's completely, although their effectiveness is yet to be seen.

Irrespective of current law, HSI's are pervasive in every jurisdiction in the country and have generated an estimated $2 billion in revenue in two years.[30] They are both cheap and easy to produce, and consumers increasingly have access to them. It is recommended that states adopt regulatory programs that are easy for producers to join, ensuring that the products consumers access will have gone through a regulatory system that includes regulations governing manufacturing, testing, advertising, and THC content, and consumers are not placed at unnecessary risk—and they understand what they are consuming.


# Hemp-Synthesized Intoxicants (HSI's)

## The Science of Hemp-Synthesized Intoxicants

Intoxicating cannabinoids like those found in the Cannabis sativa L. plant interact with the endocannabinoid system at the molecular level.[31] The plant produces at least 90 cannabinoids,[32] with varying effects depending on the specific molecule and its ability to attach to receptors in the endocannabinoid system. For example, delta-9 THC, the primary intoxicating cannabinoid found in marijuana, connects to the CB-1 receptor and produces a euphoric effect or high.[33] There are others that are known, including delta-8, and others yet to be discovered, that also lead to an intoxicating effect.

Intoxicating cannabinoids act as agonists for the CB-1 receptor, meaning they produce a psychogenic effect, or high. Delta-8 THC is less potent than delta-9 THC, while delta-10 THC and delta-11 THC have different potencies due to their effectiveness in connecting to the receptor. We have yet to fully explore the entire range of phytocannabinoids, or understand which ones are intoxicating. However, key feature of varieties of THC is that they have different psychogenic effects based on their affinity to bind to the CB-1 receptor. These new forms of THC have different levels of potency.

## How HSI's Are Manufactured

Hemp-Synthesized Intoxicants, such as delta-9 THC and delta-8 THC, are produced through semi-synthetic methods, including isomerization and functionalization.


Isomerization involves modifying an existing molecule, generally CBD, into an intoxicant like delta-8 THC, delta-9 THC, or delta-10 THC. The process starts by extracting CBD from hemp biomass, dissolving it in a solvent, and exposing it to an acidic catalyst and heat. This changes the bonds in CBD to create intoxicating molecules with different physical effects on the consumer. **However, some processing agents, such as heptane, are known toxins and must be removed before consumption and critically, producers often do not because of a lack of regulatory oversight. In all cases, a complex mixture of synthetic compounds are created, of which we have little if any toxicity information, which raises serious concern when mixtures are not cleaned following the conversion process.**

Functionalization, another method to create HSI's, changes the surface chemistry of a cannabinoid to add new functions or properties. This method involves processes like reduction and acetylation. Reduction is used to create HHC by subjecting concentrated THC to high pressure, hydrogen atoms, and a catalyst. Acetylation is employed to create cannabinoids like THC-O, synthesized through a chemical process using acetic anhydride.

These production methods are dangerous and require specialized equipment and experienced chemists in regulated environments. Unfortunately, many HSI products are manufactured and distributed by unregulated labs with little oversight, posing health and safety concerns.[34]

# When Delta-9 THC is an HSI

Delta-9 THC is appearing with increasing frequency and popularity as a hemp-derived consumer product. Delta-9 THC is generally found in limited amounts in the hemp plant per harvest—it is part of the very definition of hemp and what distinguishes it from marijuana. When we refer to HSI's, we are often referencing minor cannabinoids such as delta-8 THC or delta-10 THC. However, delta-9 THC itself is one of the many intoxicants that can be produced through conversion processes. Large-scale hemp producers can even accumulate naturally-occurring delta-9 THC across vast hemp harvests, despite delta-9 THC[35] appearing in only trace amounts in any given plant.


As a result, we commonly see products sold online that are hemp-derived, but which exclusively contain concentrated forms of delta-9 THC. For now, it appears hemp-derived delta-9 THC products fall outside the scope of the Controlled Substances Act for the same reasons the other HSI's do—because the production process began with hemp plant stock, and delta-9 THC is a phytocannabinoid. The upshot is that HSI's contain all the same intoxicants that are found in marijuana—except in greater quantities than the trace amounts found in nature—and they fall outside the Controlled Substances Act.

## Separating Farming from Manufacturing and Distribution; Process Limitations to Address

Another unintended consequence of the change in definition was the burden it placed on farmers and processors who work with plant stock and pre-consumer processing. In addition to better accounting for the types of consumer products and regulating those product types, changes should be made to the definition of hemp that will make it feasible for farmers and producers to remain within the limits of the law but also ensure that HSI's are not produced through a loophole. They need the ability to practically work with plant stock and employ essential processing techniques without risking unintended technical violations of the law.

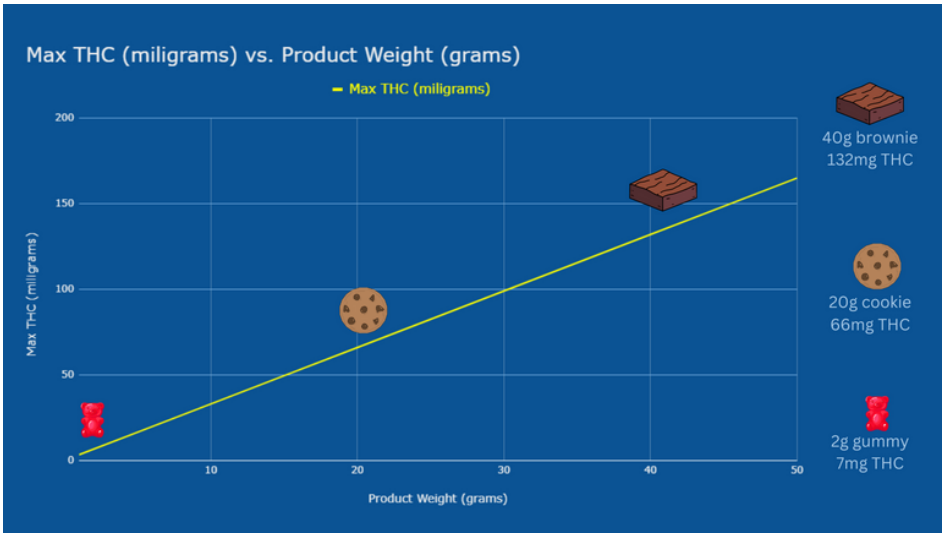
Farmers and processors face a similar problem. In the case of farming, commonly available hemp varieties used for CBD production can cross the 0.3% THC threshold per harvest, even when well short of the amount needed to lead to intoxication.[36] Nonetheless, the amount of delta-9 THC present may be enough to require destruction of the entire crop under state law—a devastating loss for a farmer. As we now know, the real intoxicant production from hemp plant stock begins in a laboratory and well after farming is complete, which is not currently limited in any significant way. Limiting farmers to plant material that must always remain below the 0.3% threshold is unfairly burdensome.


Similarly, processors that extract compounds in the plant—just as vanilla is extracted from a vanilla bean—end up with a concentration of chemicals. When the definition of hemp refers not only to the plant but to anything derived from hemp, this limitation is also a significant burden. The law should recognize that processors who derive chemicals from the plant should be regulated and limited, but the practical limitations of running an extraction operation should be taken into account.

**For this reason, we recommend that the threshold for hemp be raised to 1% on a dry weight basis only for raw plant material, or a reasonable THC limit in milligrams for "work in process hemp extract" to relieve the burden on both farmers and processors.** When it comes to intoxicants, regulators must focus on meaningful ways to impose limitations on the post-harvest processes that create intoxicants, intoxicating finished products, distribution channels, and retail where there is currently no regulation and for which lies outside the purview of a regulated cannabis market.

## The Abuse of the 0.3 Delta-9 THC Limit in Hemp

Another unintended consequence is that the percentage-based restriction has been regularly misapplied to non-plant material products such as edibles, beverages, tinctures, and vaporized products. These products are often measured in grams, while the presence of delta-9 THC is measured in thousandths of a gram, or milligrams. In the case of an edible product, 0.3% of the total weight of the edible is an enormous amount of THC, which far exceeds potency limits in regulated marijuana programs. For instance, most marijuana programs in the US limit the presence of delta-9 THC to either 5 or 10 mg per serving. However, if the limit were simply based on "less than 0.3% dry weight," in the case of a .5 ounce gummy, it would take over 43 mg of THC to exceed the weight limit, over 4 times the serving size of a regulated marijuana product.


The combination of deriving delta-9 THC from hemp and then adding it to consumer products in some amount up to 0.3% of the dry weight of the product has resulted in de facto legalization even in states that prohibit marijuana products.[37] A cursory search online finds dozens of companies selling these products. **In many states in which marijuana products are considered illegal for adults, the exact same intoxicants—hemp-derived delta-9 THC and other intoxicating cannabinoids—are readily available to consumers of any age, online, in local retail shops, and even farmer's markets.**

Because intoxicants made with hemp fall outside many regulations, it is possible products containing intoxicants could show up in places outside gas stations, convenience stores, and through the Internet. For instance, under Minnesota's law, it may be possible for vendors to sell products such as beverages more broadly at retail outlets, including even stadiums and sporting events.[38] As a practical matter, TTB should be forward-thinking and adopt a regulatory system similar to alcohol that accounts for cannabis beverage on that basis alone.

**We strongly urge members of Congress and state legislatures to amend their definitions of hemp to better account for the wide range of consumer products and uses, including intoxicants. This should include serving sizes for package limits of THC in milligrams, in addition to dry weight percentages for raw plant material.**


# Testing HSI's

HSI's face concerns regarding their safety primarily due to the synthetic production process that requires and creates toxic chemicals. These chemicals may remain in the product if not properly removed after the conversion process. Many manufacturers do not take specific measures to remove residual chemicals, and few states require testing for product purity. The FDA has already identified numerous individual cases involving HSI's, with reports of people experiencing hallucinations, vomiting, losing consciousness, or even death[39] after consuming such products.[40]

As of early 2023, only Connecticut, Louisiana, Minnesota, and Virginia have implemented specific product testing requirements for hemp-synthesized intoxicants. However, even when testing is required, the processes used may not be sufficient to guarantee consumer safety due to the presence of unknown chemicals in these products. A large number of these chemicals are simply not known to researchers, and whether they cause harm and how they can be detected in different labs with different equipment is not widely understood.

High Pressure Liquid Chromatography (HPLC) is the most common analytical technique used for testing HSI's and consumer products that contain them. However, due to limitations in the technology, results can overlook byproducts created unintentionally during synthesis from CBD into another cannabinoid. The signals from these synthetic byproducts can be found "hiding" behind ("co-eluting with") other chemical signals. This can lead to false results, with samples looking more pure than they are.

Because of this, Certificates of Analysis (COAs) for these products are often unreliable, and fail to identify the presence of contaminants. For this reason, a Gas Chromatography (GC) device should also be used, which is capable of resolving the signals for several of the byproducts that can be missed by HPLC. Note that the GC would not be a replacement for the HPLC, but rather should be used in addition to the HPLC.


Unfortunately, there is no standardized process for creating these synthetic compounds. As a result, each producer, with their individualized synthetic process, would yield a different profile of contaminants based on their specific synthetic conditions. Without that standardization, a complete understanding of the chemical composition for each of these complex synthetic mixtures will most likely require multiple orthogonal approaches for evaluation (analysis by both HPLC and GC), or more advanced 2-dimensional chromatographic techniques (e.g. GCxGC-TOF or LC with Ion Mobility Mass Spectrometry).[41]

A further complication for routine testing of these complex mixtures is that certified reference standards are not available for most of the multitude of synthetic byproducts produced during these syntheses. The chemical structures for at least 15 of these synthetic byproducts, which are not found in nature, have only recently been made available, and have not yet been tested for any toxicity or intoxicating properties. Importantly, it is not simply a matter of requiring testing – **manufacturing processes must be standardized in order to minimize the number of possible contaminants** to identify in samples, and research must begin, likely in coordination with multiple state jurisdictions, to identify the chemical structures of the many other byproducts that appear in formulations to they can be added to testing requirements.

**Federal and state regulators should work together to develop a system for identifying harmful chemical residues and other contaminants that can be applied uniformly across all jurisdictions that allow regulated access.**[42] This may need to be considered alongside best manufacturing practices to limit the range of possible contaminants. Once a product can be verified to be free from chemical residues or other contaminants, it will be better suited for retail consumption.


# Serving Sizes, Potency, and Informing Consumers

Consumers face challenges when predicting the potency of new intoxicants, including different types of THC, which can have varying degrees of potency compared to the familiar delta-9 THC usually found in marijuana. Overconsumption of these products can present significant health risks. Colorado, the first state to implement a marijuana legalization program, faced issues with consumers being confused about the potency of edible products, leading to overconsumption incidents.[43] As a response, lawmakers established serving sizes for products containing delta-9 THC.[44]

Similarly, **it is essential that hemp-synthesized intoxicants also have serving sizes that are uniform and enable consumers to anticipate the potency of the product.** As with regulated marijuana programs, packaging should include a limit to the total amount of intoxicant allowed per package, and the amount that is available per serving suggestion, and these must be accurately reflected on the label. These fundamental requirements must be in place for the protection of consumers.

For hemp-synthesized intoxicants, it is essential for regulators to establish a framework for package and serving sizes that accounts for the unique challenges of HSI's, in that different forms of THC have different levels of potency, and product formulations can contain multiple intoxicants derived from hemp. A proposed labeling system under consideration by ASTM International would consist of the Total Intoxicating Cannabinoid Content (TICC),[45] representing the aggregate concentration of intoxicating cannabinoids in a serving. This would account for all intoxicants.

In addition, such a system could also include a Delta-9 Equivalency (DNE) which we propose here, a metric comparing the intoxicating potential of the product to a standard dose of delta-9 THC, which serves as a reference point. When used in conjunction with serving sizes and TICC, this system would help consumers make informed decisions and avoid accidental overdoses when trying new or unfamiliar products.


In the table below,[46] the potency of an HSI can be expressed as a ratio or percentage compared to delta-9 THC, with the ratio representing the equivalent amount of the intoxicating consumer product needed to produce the same or similar effect:

**Example Delta-9 THC Equivalency Chart (based on 5mg per serving of delta-9 THC)**

| | Delta-9 Equivalents (DNE's) | DNE Oral Dose in mg Non-intoxicating | DNE Oral Dose in mg Intoxicating | DNE oral Dose in mg Std Single Serving |
|---|---|---|---|---|
| Delta 9-THC | 1 | 1 | 10 | 5 |
| Delta-8 THC | 0.66 | 1.5 | 15 | 7.5 |
| Delta-10 THC | 0.5 | 2 | 20 | 10 |
| HHC (Hexahydrocannbinol) | 0.8 | 1.25 | 12.5 | 6.25 |
| THC-O acetate | 3 | 0.33 | 3.3 | 1.65 |

Notes: doses oral formulations only

Column B represents relative potencies for Delta-9 THC and hemp-derived isomers and analogues

Column C represents a non-intoxicating dose in mg most normal adults

Column D represents an intoxicating dose in mg in most normal, non-chronic using adults

Column E represents an "average serving size" of a single 5 mg Delta-T9 THC gummy or its DNE in other hemp-derived formulations

As with any intoxicant, including alcohol, consumers will adjust their consumption based on their experience and comfort level. By using a framework like the Total Intoxicating Cannabinoid Content (TICC) and Delta-9 Equivalency (DNE), consumers can make informed decisions about their intoxication levels. This approach can help prevent accidental overdoses and potential health risks that may follow when trying new or unfamiliar hemp-synthesized intoxicating products.

It is important to note that this framework requires significant investigation and real-world validation from researchers and consumers to ensure its reliability, and will likely take time to develop. But, the concept of moving to an understanding of intoxication of products with consumers is necessary. To avoid confusion and inconsistency, it is essential that this system be developed and applied nationally through a federal cannabis legalization with TTB as the primary regulator, as ATACH has commented previously, rather than through ad-hoc adoption by individual states. Consistent labeling standards across states will enable consumers to read a label and understand its meaning, regardless of their location, just as they do with alcohol.

# Market

Labs that experimented with converting CBD into delta-8 isolate found an immediate wholesale market[47] and new product manufacturers emerged. HSI products initially gained traction through CBD distribution channels (rather than through licensed marijuana companies or the illicit market), and CBD consumers who were familiar with traditional marijuana products became the earliest adopters.

The lack of regulatory oversight and consumer demand for intoxicating cannabinoids encouraged producers to develop a wide array of HSI products, often marketed as "marijuana lite."[48] The market grew quickly, with hemp-synthesized intoxicant products netting $2 billion in sales between 2020 and 2022.[49] Despite predictions that the industry would face regulatory backlash,[50] neither state nor federal regulators have taken significant enforcement action against sellers, except where limited by state law.

In some cases and as previously mentioned, some of the products contain larger amounts of delta-9 than permitted under state marijuana laws, or they are available in states that otherwise ban marijuana products, such as Indiana. These include infused edibles, concentrates such as tinctures, beverages, and vape cartridges, and raw hemp plant material which is sprayed or dipped in an intoxicant solution, dried, and then lighted and inhaled by consumers. The most common type of product used to ingest HSI's is the edible gummy.

**It is worth noting that while the hemp industry saw a steep decline in hemp plants cultivated in 2022 overall, the market in cannabinoids derived from hemp continued to grow.** [51]

# Recommendations

ATACH believes that there is a significant primary role to be taken in response to the emergence of hemp derived intoxicants by both the federal government and by states. HSI's are a new type of intoxicant that are gaining popularity due to consumer demand and wide availability, they are easy to produce, and they can carry significant risk when not properly regulated. They are now part of the ever widening landscape for law enforcement and state regulators to be given education and the tools to properly address.

There are several areas of federal reform we suggest to minimize the current health and safety threat, which will help set conditions for a regulatory approach to minimize harmful products entering the marketplace.

To summarize the sections below, **the federal government should adopt a revised definition of hemp in the 2023 Farm Bill which accounts for all categories of hemp products, cannabinoids, and importantly, those that are intoxicating and can be synthetically produced, as well as a revised delta-9 THC threshold for farmers and processors. We also recommend a federal mandate to create an equivalency standard such as Total Intoxicating Cannabinoid Content (TICC) calculating IDHCs as a delta-9 equivalent (DNE), adopted through federal regulation to further delineate intoxicating products from nonintoxicating products.** This will help separate regulatory pathways of the two distinct product categories (intoxicants like THC, and non-intoxicants like CBD), better safeguard non intoxicating products, alert consumers of intoxicating products of the product potency, and prepare for eventual federal legalization of intoxicating cannabis products. For the same reasons as adopting an equivalency standard, **we also recommend the federal government actively support normalized testing standards and labeling requirements of cannabinoid products** so that hemp manufacturers fall within the purview of federal regulation and not outside of it. It is our desire that any Farm Bill considerations clarify the regulatory landscape around IDHC products, and not cause additional confusion that could be further exploited.

**In the States section below, we further recommend that state lawmakers immediately impose age restrictions on HSI's, amend their state definitions of hemp similar to our recommendation for a federal amendment of regulating by finished product, adopt additional sensible normalized regulatory provisions that move products into the regulated channel, and feature licensing, testing, and labeling, as well as any additional standards needed to account for lab-derived products that can carry unique risks. States should impose labeling requirements based on equivalency standards to better delineate pathways to the regulated market, inform consumers about these products, and act in conformity with newly adopted federal definitions and regulations of non intoxicating products to ensure that intoxicating products fall within the purview of a regulated market.**

# Federal

1. Modifications to the 2023 Farm Bill need to close the hemp-synthesized intoxicant "loophole," and advance public health and safety through a regulatory framework, including:

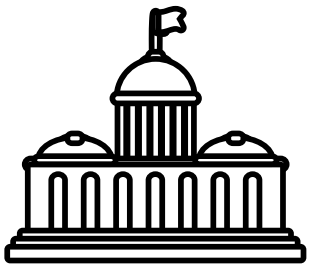
    a. Modifying the definition of "hemp" to regulate by finished product and delineate intoxicating from non-intoxicating products.
    b. Adding a definition and regulatory oversight for "work in process hemp extract" that is not intended for sale to consumers to facilitate reasonable safeguards for hemp processing of nonintoxicating cannabinoids and hemp farmers, allowing the threshold level of delta-9 THC for work in process extract only to be 1% rather than 0.3% on a dry weight basis – which should only be applicable to biomass – and establishing regulations over finished product to separate intoxicating from non intoxicating products.
    c. Establishing primary federal regulatory authority for intoxicating products through TTB, rather than FDA, that contemplates the eventual federal legalization of intoxicating cannabis products and ensures that all intoxicating products will fall within a taxed and regulated system. Nonintoxicating products should fall under the purview of FDA and regulatory channels for non-intoxicating cannabinoid product channels must be adopted immediately. This is consistent with ATACH's position on the Cannabis Administration and Opportunity Act (CAOA).

2. TTB and FDA must account for intoxicating and non-intoxicating products through an equivalency standard such as Total Intoxicating Cannabinoid Content (TICC) calculating IDHCs as a delta-9 equivalent (DNE), which should be adopted through federal regulation to further delineate intoxicating products from nonintoxicating products and recognizes the facts on the ground in state regulatory programs.

3. The FDA should be available to advise on testing standards, label contents through MOU with TTB just as we have advocated through federal regulation of marijuana, and help develop an appropriate set of labels for consumers and manufacturing standards.

4. State crime labs should receive technical assistance for acquisition, operation, and necessary training for appropriate testing equipment for enforcement.

# States



1. Establish a regulatory framework that brings HSI's into the purview of a regulated cannabis market. As with our recommendations for changes to the definition of hemp in the 2023 Farm Bill, states should amend their state definitions of hemp to close the hemp-synthesized intoxicants loophole, recognize the challenges and limitations hemp processing, and advance public health and safety through a regulatory framework that favors regulation by finished product. Like the federal definition of hemp, state laws should also:

a. Modify the definition of “hemp” to regulate by finished product and delineate intoxicating from non-intoxicating products.
b. Add a definition for “work in process hemp extract” that is not intended for sale to consumers to facilitate reasonable safeguards for hemp farming and allowing the threshold level of delta-9 THC for work in process extract only to be 1% rather than 0.3% on a dry weight basis, and adopt regulations for finished products to separate intoxicating from non intoxicating products.

2. If not already provided for under state law, the state should establish a regulatory framework to ensure that intoxicating cannabis products are taxed, tested, and regulated, including the following:

a. Impose age limit of 21 or over for retail sales, with strict criminal penalties for knowingly selling or providing to minors.
b. Testing methods should be developed and mandated. Labs should be required to participate in proficiency testing in a program that is designed to look for HSI known contaminants.
c. Require licensing for any business who manufactures regulated intoxicating products intended for consumption:
d. Require licensees meet GMP,
e. Manufacturers should be responsible for meeting all testing standards before products may be made available for retail sale.
f. Penalties should apply for unlicensed manufacturing, which we believe should reflect the penalties that apply for the unlicensed manufacture of alcohol for sale in the same jurisdiction. In addition, health and safety threats caused by unknown ingredients or contaminated products should be a separate cause of action.
g. Include reasonable licensing requirements to fit into existing structures for retail outlets authorized to sell intoxicating products, or where there are none have state law adopt law to do so.
h. Keep fees and taxes low to encourage participation and reduce the illicit market.
i. Adopt the uniform delta-9 THC equivalent standard for all HSI products and their labels.
j. Testing standards should be as comprehensive and normalized as possible, including:
    i. Standards that apply to marijuana product testing—including those for residual solvents or heavy metals which could be present due to the cultivation process, and,
    ii. Additional standards that account for the array of authorized manufacturing methods and the residual chemicals that can appear using conversion methods, and which should be identified and removed prior to sale or distribution.

k. Accurate labeling. Consumers must be informed on contents and potential risks. Accordingly, we recommend that labels contain the following information:

i. "Contains an intoxicating substance" and associated warnings related to impairment
ii. TICC, calculated through a delta-9 THC equivalency, so that consumers can understand product potency, along with serving size to delineate intoxicating from non intoxicating products.
iii. In the case of intoxicating products, "Not FDA approved"
iv. An estimate of the length of time it typically takes for the product to take effect;
v. A disclosure of ingredients:
    1. Possible allergens,
    2. Every compound that is intoxicating, and
    3. Whether or not the product contains unknown compounds (if allowed by state law);
    4. A nutritional fact panel where applicable;
vi. Requiring that edible intoxicating hemp products be clearly identifiable, when practicable, with a standard symbol indicating that it contains and intoxicant;

l l. Packaging should require opaque, child-resistant packaging, which must be designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly as defined by 16 C.F.R. 1700.20 (1995);

m. Engage in public education

i. HSI's can contain a dangerous mix of chemicals if not regulated;
ii. State licensed businesses are the best option currently for consumers because they are subject to oversight

p. Establish clear causes of action based on hazardous consumer products. The potential harm that could be caused by poorly manufactured products is significant, and false statements, misleading labels, or dangerous ingredients place individual consumers directly in harm's way. The state Attorney General should be empowered to bring legal actions against manufacturers that manufacture or vendors who sell products that are shown to be harmful, including those that contain contaminants beyond trace amounts, or which are otherwise sold illegally in the state.

q. Support state law enforcement. The state should allocate funding for proper analytical equipment, staffing for it, and law enforcement training related to HSI's and applicable law. Enforcement should reorient from criminal drug laws to those centered on business practices and product health and safety concerns.

# Conclusion

HSI's are popular, they are extremely prevalent, and because it is easy to produce contaminated products, they are dangerous to consumers if they are not produced according to normalized standards within an appropriate regulatory regime. Both state and federal regulators have a significant role to play in the wake of their emergence into the marketplace, and failure to take action will place individuals at further risk. A normalized regulatory approach is urgently needed in practically every jurisdiction but a handful that have already implemented solutions. At the very minimum, states should immediately impose age restrictions on HSI products and limit HSI's to their regulated program where available.

**The purpose of marijuana legalization programs, at their heart, is not the liberalization but the regulation of intoxicants from the cannabis plant. Ideally, that is where HSI regulation should also take place—within the context of a marijuana regulatory program.** But critical support from regulators at the Federal level must also be part of the regulatory framework, including amending the definition of “hemp” and establishing licensing and testing standards, among others. For those states facing an HSI boom, ATACH strongly urges states to adopt marijuana legalization programs without delay if they do not already have one, and HSI's should be included in the regulatory framework.

For those that are not yet ready to adopt a marijuana regulatory framework, they should look to put regulation in place that addresses HSI's specifically. Such an approach will provide a basic framework for regulators and law enforcement to protect public health and safety and provide consumer protection.

# Endnotes

1. While not the focus of this paper, non-intoxicating cannabinoids carry many of the same challenges when used in consumer goods, particularly those intended for human consumption. Just as intoxicating cannabinoids should be regulated under a sensible approach similar to alcohol, non-intoxicating cannabinoids such as CBD, when taken as a supplement, should be regulated under a regime like that for dietary ingredients.
2. See Defining Hemp: A Fact Sheet, Updated March 22, 2019, available at https://crsreports.congress.gov/product/pdf/R/R44742
3. For instance, the definition of cannabis offered by the National Institute of Health's National Cancer Institute is the same as marijuana. See at https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cannabis
4. Section 297A of the Agricultural Marketing Act of 1946 (AMA). Note that a cannabis plant does not contain delta-9 THC (other than in trace amounts), but rather it contains another form of the molecule, THCa. The intoxicating delta-9 THC is not created until THCa is heated, a process called decarboxylation. The definition contained in the Agriculture Marketing Act also includes a method for testing THCa in order to predict how much delta-9 THC it will convert into, once it is carboxylated, which is omitted here for brevity.
5. 2022 Minn. Stat. ch. 18K, § 18K.02.
6. It is worth noting that without adequate studies, the actual intoxicating potential of these cannabinoids are not understood and consumers rely on manufacturers claims and anecdotal evidence. In addition, products that are advertised as containing isolates of particular cannabinoids often contain a complicated mix of synthetically-produced substances, despite claims made on the label.
7. As mentioned earlier, the cannabis plant does not contain more than trace amounts of delta-9 THC, but rather THCa, which is converted into delta-9 THC once it is heated. The amount of delta-9 THC is calculated based on conversion formulas that have been developed to allow for reasonable predictability.
8. 21 U.S.C. Section 802(16) defines marijuana "to mean[ ] 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, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination."

9. https://www.astm.org/workitem-wk84589
10. Congressional Research Service, Comparing Hemp Provisions in the 2014 and 2018 Farm Bills, 1-2 (Dec. 2, 2021).
11. 7 U.S.C. 1639o(1) (defining hemp).
12. https://www.ams.usda.gov/sites/default/files/HempExecSumandLegalOpinion.pdf
13. United States. Food and Drug Administration. Letter to Congress. January 2023. https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol
14. While within the Farm Bill's definition, products remain illegal under the Federal Food, Drug, and Cosmetics Act.
15. Letter from Terrence L. Boos, Drug & Chem. Evaluation Section Chief, Drug Enf't Admin., U.S. Dep't of Justice, to Donna C. Yeatman, Exec. Sec'y, Ala. Bd. of Pharmacy (Sept. 15, 2021).
16. AK Futures LLC v. Boyd Street Distro, LLC, 35 F.4th 682 (9th Cir. 2022)
17. It is worth noting, however, that in clarifying its decision, the Ninth Circuit noted "the record reveals little else about the manufacturing process" other than AK Futures' statements that it "regularly tests its products for potency and regulatory compliance purposes, and screens for heavy metals, pesticides, and other contaminants." Not included in the record on appeal was how AK Futures manufactured its delta-8 THC (i.e., most likely using a chemical process to convert CBD derived from hemp into delta-8 THC).
18. Title 21 United States Code (USC) Controlled Substances Act, Section 812(c) Schedule I(c)(17)
19. https://albop.com/oodoardu/2021/10/ALBOP-synthetic-delta8-THC-21-7520-signed.pdf
20. Dario Sabaghi, Delta-8 And -9 THC-O Are Controlled Substances, DEA Says, Forbes, Feb 16, 2023, https://www.forbes.com/sites/dariosabaghi/2023/02/16/delta-8-and9-thc-o-are-controlled-substances-dea-says/?sh=17057410754f
21. In May of 2023, the DEA released a presentation that included significant new information on hemp-synthesized intoxicants, entitled Drug & Chemical Evaluation Section, available at https://www.deadiversion.usdoj.gov/mtgs/supply_chain/conf_2023/Boos.pdf
22. In reaching this conclusion, the DEA cited citing 21 U.S.C. 812, Schedule I(c)(17); 21 CFR 1308.11(d)(31), and Implementation of the Agriculture Improvement Act of 2018, 85 FR 51639, 51641 (2020)

23. Jessica S. Kruger, and Daniel J. Kruger, "Delta-8-THC: Delta-9-THC's nicer younger sibling?" Journal of Cannabis Research, January 4, 2022, https://doi.org/10.1186/s42238-021-00115-8
24. Alaska's law does include mg THC cap.
25. Colorado's addresses artificial cannabinoids, but not specifically intoxicants
26. Massachusetts included guidance specific to D8 but did not include any other HSI
27. These include Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Maine, Massachusetts, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, West Virginia, Wisconsin, Wyoming, and the District of Columbia.
28. These states include Connecticut, Louisiana, Maryland, Michigan, Minnesota, Virginia. It is possible that in the case of Virginia and perhaps others, the intent was to allow CBD products to be derived from hemp, but which has laws that were broad enough to include intoxicants.
29. John Schroyer, "Minnesota hemp edibles law ushers in new rivals, upends marijuana market," MJBiz Daily, August 15, 2022, https://mjbizdaily.com/minnesota-hemp-edibles-law-might-hurt-medical-marijuana-market/
30. Brightfield group report - https://global-uploads.webflow.com/596691afde3c5856d866ae50/639a681a25fc196d623644f8_How%20Big%20of%20a%20Threat%20is%20Delta-8_%20(1).pdf
31. See Biological Product Definitions, What is a biological product?, Food and Drug Administration, https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf
32. Christelle M. Andre, Jean-Francois Hausman, Gea Guerriero, "Cannabis sativa: The Plant of the Thousand and One Molecules," Front. Plant Sci., 04 February 2016, https://doi.org/10.3389/fpls.2016.00019
33. Debra A. Kendall and Guillermo A. Yudowski, Cannabinoid Receptors in the Central Nervous System: Their Signaling and Roles in Disease, Front Cell Neurosci., 04 January 2017, https://doi.org/10.3389/fncel.2016.00294
34. It is worth noting that while this paper is focused on intoxicating hemp-derived cannabinoids, our concerns related to harmful residual chemicals could easily apply to all synthetically-derived products made from the plant, including non-intoxicating cannabinoids such as CBD and others. This particular issue relates more to manufacturing practices than the intoxicating nature of the products.
35. When in the natural plant, THC appears in the form THCa, which is converted into delta-9 THC once it is decarboxylated. By convention, many simply refer to delta-9 as appearing in the plant, which is a misnomer.
Krishna Ramanujan, "Hemp goes 'hot' due to genetics, not environmental stress," Cornell Chronicle, July 28, 2021, https://news.cornell.edu/stories/2021/07/hemp-goes-hot-due-genetics-not-environmental-stress#:~:text=But%20when%20hemp%20contains%20more,can%20lose%20their%20entire%20crop.

36. Krishna Ramanujan, "Hemp goes 'hot' due to genetics, not environmental stress," Cornell Chronicle, July 28, 2021, https://news.cornell.edu/stories/2021/07/hemp-goes-hot-due-genetics-not-environmental-stress#:~:text=But%20when%20hemp%20contains%20more,can%20lose%20their%20entire%20crop.
37. See for instance https://hometownherocbd.com/collections/delta-9-gummies
38. David Mantey, Minnesota Could Be First State to Allow THC Beverage Sales at Stadiums, Concerts, Cannabis Equipment News, June 7, 2023, https://www.cannabisequipmentnews.com/manufacturing/article/22864161/minnesota-could-be-first-state-to-allow-thc-beverage-sales-at-stadiums-concerts
39 Lauren Silver, Mother charged with murder after child dies from ingesting delta-8 THC gummies, officials say, Fox 23 News, October, 21, 2022, https://www.fox23.com/trending archives/mother-charged-with-murder-after-child-dies-from-ingesting-delta-8-thc-gummies-officials-say/article 47d65e36-6b32-5b6e-9f5f-2e6ef0d2c598.html
40. https://khn.org/news/article/hemp-delta-8-marijuana-laws-health-concerns/ ; see also https://pubs.acs.org/doi/10.1021/acs.chemrestox.1c00388
41. However, it is likely that the instrumentation and technical expertise for these more advanced analytical techniques would be prohibitively expensive for routine testing.
42. It is likely this process will take several years and will require regulatory agencies to work with researchers and states that similarly regulate in order to gather the data needed. In addition, chemical manufacturers will need to commercialize certified reference standards for these chemicals, so that they can be reliably identified and quantitated by testing labs, which has only just begun to create standards for the hundreds of compounds that result from these syntheses.
43. Anthony Zurcher, Maureen Dowd's marijuana-induced freak out, 4 June 2014, https://www.bbc.com/news/blogs-echochambers-27704837
44. The Associated Press, Colorado works on new rules for edible marijuana, April 30, 2014, https://www.denverpost.com/2014/04/30/colorado-works-on-new-rules-for-edible-marijuana/
45. https://www.astm.org/workitem-wk84589
46. While based on available research, the figures used in this chart must be fully vetted and considered before promulgation in a rule, and until then should be seen as placeholders used for illustrative purposes only.
47. Laura Drotleff, "Delta-8 THC a 'market response' to lack of FDA guidance on CBD, hemp industry says," Hemp Industry Daily, May 18, 2021, https://hempindustrydaily.com/delta-8-thc-a-market-response-to-lack-of-fda-guidance-on-hemp-derived-cbd/
48. Michael Kaplan, Delta-8-THC is legal—but is it safe? What to know about 'weed lite', New York Post, March 5, 2021, https://nypost.com/2021/03/05/delta-8-thc-is-legalbut-is-it-safe/

49. Brightfield group report - https://global-uploads.webflow.com/596691afde3c5856d866ae50/639a681a25fc196d623644f8_How%20Big%20of%20a%20Threat%20is%20Delta-8_%20(1).pdf
50. Laura Drotleff, Delta-8 THC a 'market response' to lack of FDA guidance on CBD, hemp industry says, Hemp Industry Daily, May 18, 2021, https://hempindustrydaily.com/delta-8-thc-a-market-response-to-lack-of-fda-guidance-on-hemp-derived-cbd/
51. Andrew Long, "US hemp plantings plummet in 2022 as production shifts to northern states," MJBiz Daily, May 9, 2023, https://mjbizdaily.com/hemp-planting-plummets-in-2022-as-production-shifts-to-northern-states/?utm_medium=email&utm_source=newsletter&utm_campaign=MJD_20230509_NEWS_Daily

# Appendix A

## History of hemp regulation prior to the 2014 and 2018 Farm Bills

Hemp regulation has existed in the United States since the 1600's, when the plant was primarily cultivated as a fiber crop. During the period as a British agrarian colony on the East Coast, the Virginia Company directed the mandatory production of at least 100 plants for export by royal decree. Similarly, Spanish authorities on the West Coast cultivated hemp as a fiber crop. Importantly, "hemp," "Indian hemp," "Cannabis," "Cannabis indica," "Cannabis sativa," and "Cannabis sativa L." all referred to the same plant as an agricultural product during the period. The modern distinction between industrial hemp and marijuana had not yet been introduced.

Hemp, a versatile crop, has been used for fiber production for centuries. However, its use in Western medicine began in the early 1800s. In contrast, medical practitioners in China and India have used hemp in medical preparations and foodstuffs for thousands of years, such as Bhang. In 1839, Sir William O'Shaughnessy discovered the medicinal properties of cannabis while working in India. By 1850, the US Pharmacopeia began to list hemp/cannabis preparations for medicinal use, and it also became a popular recreational drug for adults.

During the 1860s, the USDA treated hemp/cannabis as any other crop, even offering federal assistance such as research into marketable uses, production statistics, and crop reports. States such as Kentucky and Missouri became known for their hemp production, and even Kansas advertised land suitable for hemp cultivation under the 1862 Homestead Act.

However, starting in the early 1900s, the government began regulating hemp/cannabis use as an intoxicant. This began in states like New York, where laws aimed at adult use of hemp/cannabis derivatives were enacted. In 1906 and 1914, the federal government began regulating medical cannabis products for revenue purposes. They used the Pure Food and Drugs Act and the Harrison Narcotics Act to do this under the Food & Drug Agency, the modern FDA predecessor.

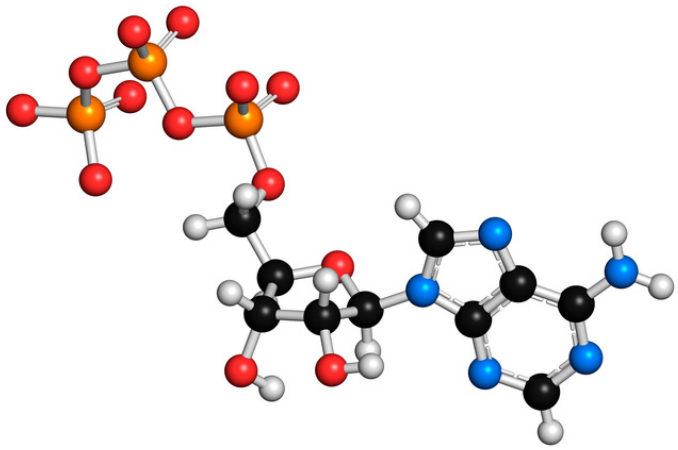
In 1937, the Marihuana Tax Act was introduced, which effectively ended hemp production in the US. Although aimed at eliminating narcotic use, the Act ended all hemp production. Production briefly resumed during World War II for use in wartime materials, but production ended fully by the 1950s.

The Marihuana Tax Act was later challenged, and in 1969, the US Supreme Court declared it unconstitutional. However, Congress re-criminalized all hemp/cannabis production under Schedule I of the Controlled Substances Act in 1970. This legal status remained until the 2014 and 2018 Farm Bill modifications to the Controlled Substances Act.

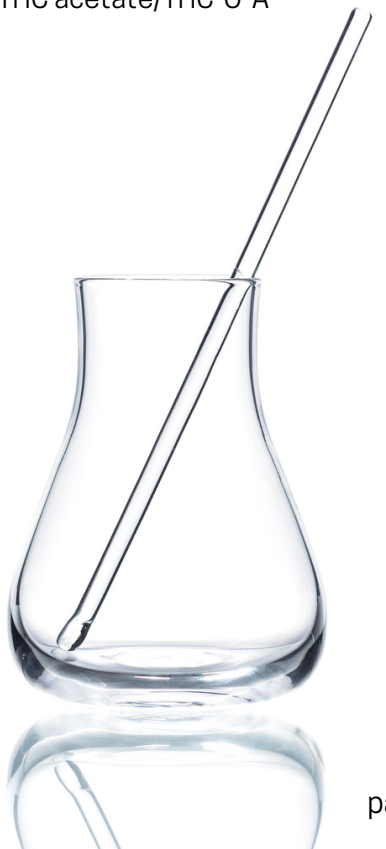
1 Robert Detrich, Hemp: American History Revisited: The Plant with a Divided History 1-9, 14, 16 (2003).
2. Id at 16.
3. J.N. Bowman, "Notes on Hemp Culture in Provincial California," (Berkeley, 1943); Hubert Howe Bancroft, History of California, Vol. 1, p 717 and Vol. 2, pp. 178-81, (The History Co., San Francisco 1886); reprinted as Volumes XVIII and XIX of the Works of Hubert Howe Bancroft (Wallace Herberd, Santa Barbara CA, 1963); Dale H. Gieringer, "The Forgotten Origins of Cannabis Prohibition in California," Contemporary Drug Problems, Vol 26 #2, Summer 1999.
4. Mitch Earlywine, Understanding Marijuana: A New Look at the Scientific Evidence 9-16 (2002); RICHARD J. BONNIE & CHARLES H. WHITEHEAD, THE MARIHUANA CONVICTION: A HISTORY OF MARIJUANA PROHIBITION IN THE UNITED STATES 1–5 (University Press of Virginia 1974)
5. O'Shaughnessy's discovery was reviewed in the New York Journal of Medicine in 1843. N.Y. J. Med. 1(3):390-398 (November 1843); see also "Remarks on Indian Hemp," N.Y. J. Med. 2:273 (March 1844).
6. E.g., PHARMECOPŒIA OF THE UNITED STATES (3d Decennial Rev., Philadelphia, J.B. Lippincott & Co. 1851); Charles Baduelaire, Les Paradis Artificiels (1860). Fitz Hugh Ludlow, The Hashish Eater (1857); Our Fashionable Narcotics, N.Y. Times, Jan. 10, 1854, at 4.
7. Renee Johnson, Congressional Research Service, Hemp as an Agricultural Commodity 10 (Jan. 19, 2012) (RL 32725); U.S.Dep't Agriculture, Bulletin No. 404, Hemp Hurds as Paper-Making Material (1916)
8. Homestead Act, 12 Stat. 392 (May 20, 1862); General Circular, Bureau of Immigration, Topeka, Kansas, March 11, 1867
9. E.g., New York's Towns-Boylan Act of 1914.
10. See Harrison Narcotics Act, Pub. L. No. 223, 38 Stat. 785 (Dec. 17, 1914); Pure Food & Drug Act, Pub. L. 59- 384, 34 Stat. 768 (June 30, 1906).
11. Marihuana Tax Act of 1937, Pub. L. 75-238, 50 Stat. 551 (Aug. 2, 1937).
12. Renee Johnson, Congressional Research Service, Hemp as an Agricultural Commodity 10 (Jan. 19, 2012) (RL 32725)
13. E.g., USDA's 1942 short film "Hemp for Victory"; Renee Johnson, Congressional Research Service, Hemp as an Agricultural Commodity 10-11 (Jan. 19, 2012) (RL 32725).
14. Leary v. United States, 395 U.S. 6, 17 (1969).
15. Controlled Substances Act, Pub. L. 91-513, 84 Stat. 1236 (Oct. 27, 1970) (codified at 21 U.S.C. ch. 13); see also generally Gonzales v. Raich, 545 U.S. 1 (2005).

# Appendix B

## Partial list of known HSI's



Delta-6a10a
Delta-7-THC
CBNO
D9-THCPO
D8-THCPO
D10-THCPO
HHCP
HHCPO
THC-B
HHCjd
HHCjdO
Delta-8 THC
Delta-9 THC
Delta-10 THC
Hexahydrocannabinol - HHC;
Hexahydrocannabinol Acetate - HHC-O
Tetrahydrocannabinol acetate ester THCo/THC-O/THC-O Acetate/ THC acetate/THC-O-A
Tetrahydrocannabiphorol (THCp)
Tetrahydrocannabivarin (THCv)
Tetrahydrocannabinolic acid (THCa)
Tetrahydrocannabihexol - THC-H
Delta 8-THC-O-A
Delta 10-THC-O-A



# Appendix C

## Example Health Incidents

Since the 2020 explosion of HSI's across the country and states are being inundated. Increases in poison control and emergency room visits are happening nationally and at the state level.

There is a national concern about delta 8 products. The CDC stated: “Syndromic surveillance data from emergency departments participating in the CDC’s National Syndromic Surveillance Program (NSSP) show an increase in visits with a mention of delta-8 THC or some variation in the chief complaint text in recent months. More than 4,400 active emergency facilities that represent portions of 49 states and Washington, DC contribute data to NSSP, accounting for approximately 71% of all U.S. non-federal emergency departments.”

The FDA stated: “The FDA received 104 reports of adverse events in patients who consumed delta-8 THC products between December 1, 2020, and February 28, 2022. Of these 104 adverse event reports: 77% involved adults, 8% involved pediatric patients less than 18 years of age, and 15% did not report age. 55% required intervention (e.g., evaluation by emergency medical services) or hospital admission.” Cases were high in 2021. “In 2021, The American Association of Poison Control Centers (AAPCC) introduced a product code specific to delta-8 THC into its National Poison Data System (NPDS), allowing for the monitoring of delta-8 THC adverse events*. From January 1 to July 31, 2021, 660 delta-8 THC exposures were recorded with the new product code, and one additional case was recoded as a delta-8 THC exposure from October 2020. Eighteen percent of exposures (119 of 661 cases) required hospitalization, and 39% (258 of 661 cases) involved pediatric patients less than 18 years of age.” That was just in the span of 7 months. There is also data for all of 2021. “National poison control centers received 2,362 exposure cases of delta-8 THC products between January 1, 2021 (i.e., date that delta-8 THC product code was added to database), and February 28, 2022. Of the 2,362 exposure cases: 58% involved adults, 41% involved pediatric patients less than 18 years of age, and 1% did not report age. 70% required health care facility evaluation, of which 8% resulted in admission to a critical care unit; 45% of patients requiring health care facility evaluation were pediatric patients. One pediatric case was coded with a medical outcome of death.”

There is also concern at the state level. In Virginia, "The director of the University of Virginia's Blue Ridge Poison Center said he's seeing an increase in calls involving synthetic THC products with the same intoxicating effects as marijuana…the center announced a 30% increase in calls related to its consumption over the last year, largely linked to edibles shaped like popular candies." In Tennessee, "The Tennessee Poison Control Center answered 115 calls from people concerned about consuming Delta 8 — a legal form of THC — last year, its medical director said." In Florida, "the Florida Poison Control Center in Jacksonville is warning parents about the uptick in calls they're getting related to Delta-8 gummies…All three of Florida's poison control centers have noted a rise in marijuana calls. Just under 300 calls were made in one week earlier this month, the centers report." In North Carolina, "So far this year, as of July, the North Carolina Poison Control Center reported 157 cases related to delta-8, according to the Winston-Salem Journal." In Wisconsin, "Gundersen Health System is reporting an increase in patients reacting badly to a legal form of cannabis: hemp-derived Delta 8…'We have noticed, especially recently, a sharp increase in the number of patients who have been poisoned with THC products — especially Delta 8 THC,' Orozco said." In Wyoming, "One of the biggest threats currently facing Cody students is Delta 8 and other smokable hemp products. These products have put multiple students in the emergency room this school year…Blatt said in her time as vice principal, she has never seen this. 'This is my seventh year, and I've never sent anyone to the emergency room, let alone five or six kids because their vitals were so low and they were incoherent,' she said."

In Virginia, the first death of delta-8 toxicity occurred. "The Virginia case involves a 30-year-old mother who was charged with felony murder and felony child neglect in the death of her son last May. The death was officially ruled an accident attributable to "delta-8-tetrahydrocannabinol toxicity" by the Office of the Chief Medical Examiner Central District of Virginia. The mother was charged last month."

Unsuspecting adults are affected by delta 8. For example, a bus driver. Jinhuan Chen, a commercial bus driver in Connecticut, "has been charged with 38 counts of reckless endangerment after blacking out behind the steering wheel while snacking on gummies he says he didn't know were infused with THC." "Chen was driving 38 passengers from the Mohegan Sun Casino on March 13 when he stopped the bus on the side of Interstate 95 in Stratford. Police said they found Chen slumped unconscious in the driver's seat, next to an open package of Smokies Edibles Cannabis Infused Fruit Chews."

Youth are also affected. “Poison control centers are issuing a warning to parents after seeing a spike in calls from families because their young children have gotten a hold of Delta-8 gummies. The products in many forms look like candy, especially to kids, but they contain Delta-8 THC, a derivative similar to the main ingredient in marijuana – which can cause a mild high. For young kids, the effects can be dangerous.” For example, “Amina Serir didn’t know if her two-year-old daughter, Maya, would ever recover after she ate what looked like Apple Jacks cereal, containing high levels of Delta-8…Serir says the small package of cereal had ended up in a basket of snacks the family had brought home from an area pool…Maya fell asleep and her lips were turning blue. They rushed her to the ER, where she was placed on oxygen. 30 hours later, she finally woke up. But she was a long way from being back to normal.” Additionally, “A mother in the New River Valley is taking action, after her toddler was hospitalized after accidentally eating a gummy containing Delta-8 THC.” In Omaha, “An Omaha woman has been cited for child abuse after her son got into her THC gummies and became sick…the boy had eaten Delta 8 brand THC gummies belonging to the boy's mother”.

- Youth/Children
  - CA kids in school
  - https://www.ksl.com/article/50404716/fourth-grade-student-in-california-shared-cannabis-candies-resembling-skittles
  - A fourth-grade student handed out cannabis candy that resembled Skittles to other students at a school in Sacramento.

* for a more comprehensive review of articles citing to the HSI marketplace impact on children

Labeling inconsistencies can cause problems. For example, “Edibles made from the hemp plant, which contain a weaker level of THC known as Delta 8, 9 or 10, are legal in North Carolina.” Whereas, “Edibles laced with THC, the chemical that gives marijuana its narcotic effect, are illegal in North Carolina. Still, products have found their way into stores. That's why correct labels and packages are key. Buyers must look carefully to know what they are getting, and whether it is even legal in the state.” It is not just delta 8 versus marijuana that is an issue. Labeling creates an issue when it comes to children as well. “A Secretary of State-led enforcement has swept $224,000 worth of THC-infused gummies and snacks that mimic the look of legitimate snack brands off store shelves in North Carolina. The counterfeits had labels that resembled Skittles, Cheetos, Lifesavers, and Girl Scout Cookies.” “THC-infused snack packaging includes markings that indicate the snacks contain THC in them. Marshall noted that these markings could be overlooked and troublesome due to many counterfeit products resembling brands geared toward kids.”

Labeling inconsistencies are prevalent. “CBD Oracle, a website that reviews hemp-derived products including CBD as well as delta-8 THC products, sent 51 different delta-8 products to FESA Labs, a licensed testing outfit in Santa Ana, California, to see if potency levels and other metrics printed on the products’ labels were accurate…And according to CBD Oracle’s results, delta-8 product manufacturers routinely mislabel their gummies, vaporizer cartridges, and other products…Of the products tested, 77 percent had less delta-8 THC than advertised. One, a Blue Dream concentrate from a company called Binoid, contained only a third of the advertised delta-8.” Another study exposed labeling inconsistencies. “a January 2022 study by University of Rochester researchers in the journal Chemical Research in Toxicology used three different testing methods to analyze the chemical content of 27 vaporizers from 10 brands containing hemp-derived psychoactive Delta-8 THC. For starters, potency was off, again: none of the products had accurate Delta-8 labeling.”

With the public health crisis reaching a fever pitch, the adverse effect reports flooding the FDA resulted in the FDA working jointly with the Minnesota Board of Pharmacy in an investigation and lawsuit. “The US Food and Drug Administration (FDA) reportedly received complaints about ‘serious adverse events’ relating to Northland Vapor’s ‘Death by Gummy Bears’ delta-8 THC products. The Minnesota Board of Pharmacy has said that one of these complaints included the report of a death however the FDA has not determined that the products caused the adverse events. Consequently, the FDA contacted the Minnesota Board of Pharmacy to conduct a joint investigation.” “The Minnesota Board of Pharmacy and the FDA began an inspection at Northland Vapor’ manufacturing warehouse in Moorhead, Minnesota on 8 November 2022. Various edible cannabinoid products were found and were reportedly the same as those for sale on the companies’ websites and at their retail location. It is estimated the retail value of these products is worth more than $7 million.” “On December 5, 2022, the Minnesota Board of Pharmacy filed a lawsuit against three affiliated Minnesota hemp companies seeking condemnation and destruction of several million dollars worth of gummy edibles. Ironically named ‘Death by Gummy Bears,’ they allegedly contained 100 milligrams of hemp-derived THC per gummy and were intentionally marketed in a manner that is appealing to children.” “To protect the public, the Minnesota Board of Pharmacy has embargoed this product and has said that it is seeking an order from the court to destroy the noncompliant product as well as an order from the court to prevent Northland Vapor from manufacturing and selling edible cannabinoid products that violate state law.” “The Board has said that the FDA investigation is ongoing.”