



The Patchwork of State Hemp Laws

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AGENDA

- Review: Current Status of Hemp
 - 2018 Farm Bill
 - USDA Approved Hemp Plans
- Development of State Regulatory Frameworks for Hemp Products
 - Trends in State CBD Regulations
 - State Requirements for Hemp Foods/Dietary Supplements
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Review: Current Status of Hemp

2018 Farm Bill

- Removed hemp and its byproducts from the definition of “Marijuana” in the Controlled Substances Act.
- U.S. Department of Agriculture (USDA) established a national regulatory framework for the commercial production of hemp in the United States.
- All State and Tribal hemp plans are to be submitted to the USDA for review and approval.
- Offers protections for interstate transportation of hemp and hemp products.
- Required the USDA to establish a plan to monitor and regulate the production of hemp in those States or Indian tribes that do not have an approved State or Tribal plan.

Current Status of Hemp

- **USDA approved hemp production plans**
 - 24 states + Puerto Rico and the U.S. Virgin Islands have received approval
 - 2 state plans currently under review
 - 20 states have elected to continue to operate under existing 2014 pilot programs
 - 3 states have received USDA Hemp Producer Licenses
 - 1 state with pending state legislation

Development of State Regulatory Frameworks for Hemp Products

Development of State Regulatory Frameworks for Hemp Products

- About ½ of U.S. states have explicitly amended laws/regulations to allow the use of hemp-derived ingredients in foods and/or dietary supplements.
- USDA's review and approval of state hemp plans does not encompass state requirements for processing and manufacturing finished hemp products.
 - Plan review only relates to cultivation of hemp, not processing or beyond
- The FDA's exclusionary clause position and conclusion that CBD is not GRAS means that the FDA has not weighed in on a number of the issues the states are addressing in their hemp product regulatory framework.

Development of State Regulatory Frameworks for Hemp Products

- The FDA has taken a largely hands-off enforcement approach, but don't confuse availability with legality.
- The result of this approach is a patchwork of state laws (ranging from “ingestibles and topicals are allowed” to “ingestibles only” to “all cannabinoid products are illegal”).
- To ensure product safety, quality, and uniformity, a national framework needs to exist. Yes, some states have robust CBD requirements. The patchwork created by the various state requirements creates a nightmare for the industry – there is no way to simultaneously comply with all requirements.
- Who is in a better position to promulgate uniform cannabinoid-infused food and beverage product requirements – FDA or state departments of health?
- It's not a matter of if FDA will regulate cannabis, it's a matter of when.

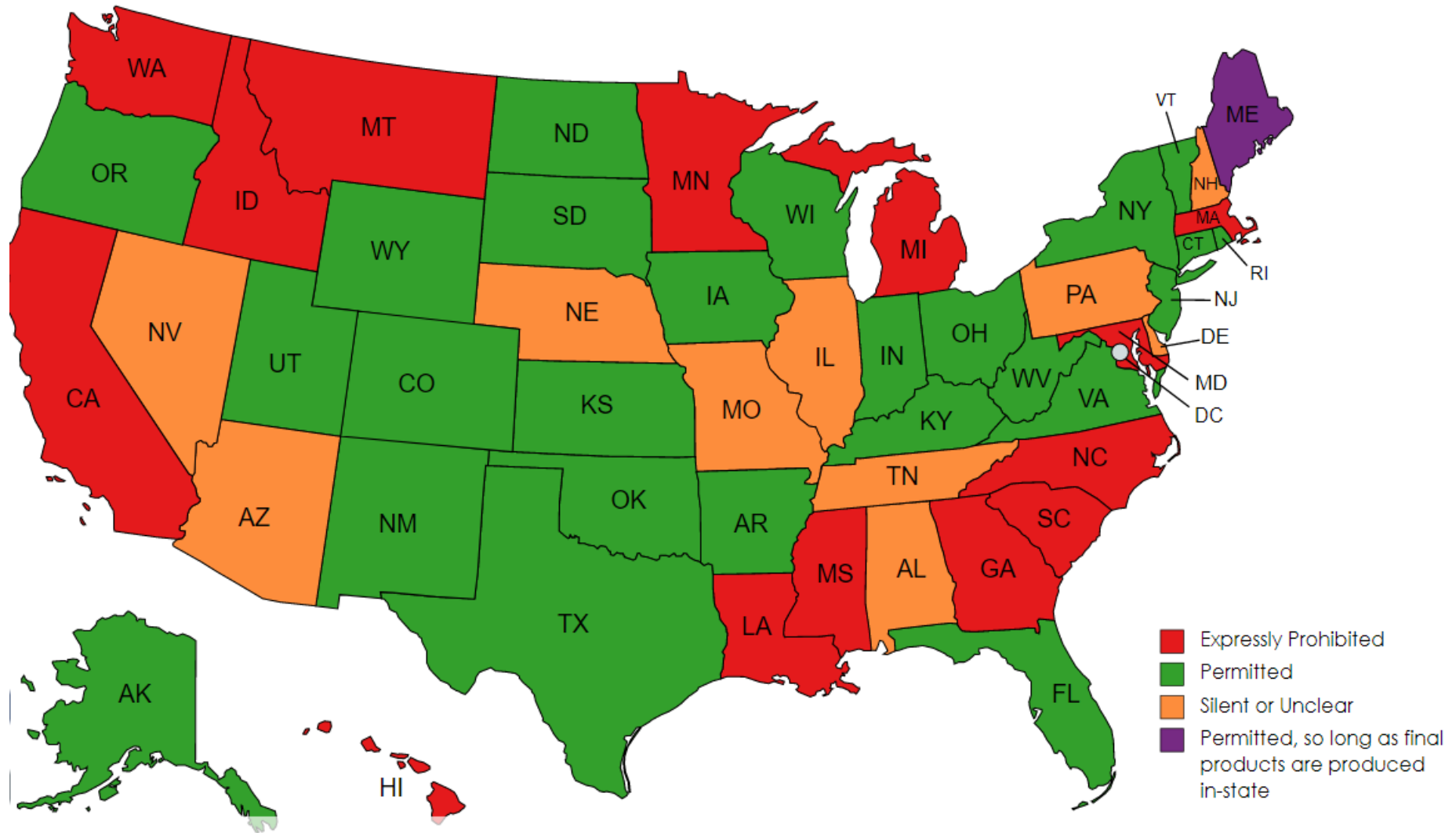
“People are using these products. . . . We’re not going to be able to say you can’t use these products. It’s a fool’s game to try to even approach that.”

-Former FDA Commissioner Dr. Stephen Hahn

Trends in State CBD Regulations

- A growing number of states including Alaska, Iowa, Louisiana, Michigan, New Hampshire, Texas and others, require retailers (and often manufacturers and distributors) of hemp products to register or obtain a handler's license with the state to lawfully sell consumable hemp products within the state.
- Common trends in labeling requirements — in addition to the applicable FDA labeling requirements for the product type — often include scannable QR codes that link to detailed product information (batch numbers, dates, certificates of analysis), quantities of cannabinoids per serving, specific labeling with respect to THC and other cannabinoid content.
- An increasing number of state hemp laws expressly prohibit synthetic cannabinoids or intoxicating cannabinoids, controlled substance analogues or cannabinoids created through isomerization (including Delta-8 THC).
- While more states are trending towards regulation of CBD products in 2021, certain product types like smokable hemp (which often includes vaporizers) are often prohibited or restricted.

Hemp in Human Food and Dietary Supplements



State Requirements for Hemp Foods/Dietary Supplements

- States affirmatively regulating foods, dietary supplements, and other products containing hemp-derived ingredients, including CBD and other cannabinoids have established, to varying degrees, requirements for:
 - Registration for processors, manufacturers, warehouses, and retailers
 - Product registration and sampling
 - Product testing, approved testing laboratories and information required to appear on Certificate of Analysis
 - Contaminant limits and other product standards
 - Labeling
 - Limitations on advertising, claims, and other promotional practices

State Case Studies

State Case Study: Colorado

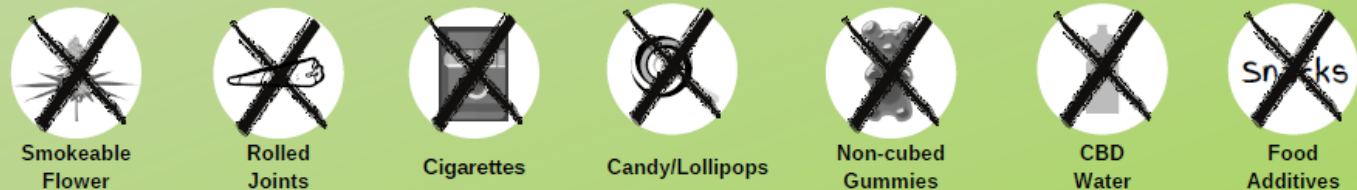
- Colorado was one of the first states to create a regime to regulate hemp-derived ingredients/cannabinoids in foods and dietary supplements.
- All plant material, extracts, cannabinoid compounds, concentrates, isolates, resins, or derivatives that are to be used in food, dietary supplement and cosmetic manufacturing must come from a state that has an established and approved hemp program or a country that inspects or regulates hemp under a food safety program or equivalent criteria to ensure safety for human consumption.
- All hemp product manufacturers must register with CDPHE.
- In addition to THC potency testing, rules require hemp products be tested for over 100 pesticides, microbials, heavy metals and residual solvents.
- Packaging and labeling requirements: Product packaging shall be food-grade or GRAS and labeling shall be performed in accordance with 21 C.F.R. 101, subparts A–G and the department’s labeling requirements for hemp food products, which includes:
 - Product identity statement, THC content, net weight statement, list of ingredients, allergen identification, FDA warning statement, and a code or numbering system that identifies the date and location of manufacturing and packaging so the products can easily be tracked in the event of a recall. No health claims are permitted.
- No age restrictions on who can purchase, consume, or ingest CBD products.

State Case Study: Utah

- Requires hemp processors and retailers to be licensed.
- Requires individual product registration, including separate registrations for each flavor of the same product.
- Hemp products must be in “medicinal dosage” form (cannot be marketed as food products)
 - Doesn't mirror FDA product categories/forms exactly
 - Very specific/limiting for certain forms (shape of gummies – must be cubed/rectangular without sugar coating)



Most Common NON-APPROVED Medicinal Dosage Forms



State Case Study: Florida

- Processing, manufacturing, distributing, and retailing of ingestible and inhalable CBD products all require a Hemp Food Establishment Permit.
 - Retail hemp food establishments: Food establishments that prepare and/or sell prepackaged food consisting of or containing hemp extract, which includes CBD or other cannabinoids, to the end consumer.
 - Wholesale hemp food establishments: Food establishments that manufacture, process, pack, hold or prepare food consisting of or containing hemp extract, which includes CBD or other cannabinoids, and sell that product to other businesses.
- Food consisting of or containing Hemp or Hemp Extract must be obtained from an Approved Source (hemp extract manufacturer must meet local, state, or federal food safety standards from the jurisdiction of origin).
 - Any products sold online must be manufactured in a facility that is subject to a food safety inspection program and meets their inspection requirements.
- Regulations require tests for numerous pesticides, residual solvents, heavy metals, biological pathogens and select toxins.

Labeling Requirements for Prepackaged Food products

- Statement of Identity / Food product name and description
- Product weight / measurement in both metric and US measurement terms
- Manufacturer's - or packer or distributor - details (name, address, contact)
- List of ingredients (including sub-ingredients) in order from most to least
- Allergen or prescribed warnings
- Nutrition Facts Panel or Supplements Facts Panel, unless exempt



Labeling for Food Products Containing Hemp Extract

Food products containing Hemp Extract must be distributed and sold in a container with:

1. A scannable barcode or quick response code linked to the certificate of analysis of the Hemp Extract batch by an independent testing laboratory;
2. The batch number;
3. The internet address of a website where batch information may be obtained;
4. The expiration date; and
5. The number of milligrams of each marketed cannabinoid per serving. If cannabinoids are marketed, the milligrams per serving of the specific cannabinoid must be listed and the serving size shall be declared on the label.



Nutrition Facts		Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
30 servings per container Serving size 1 dropperful (1mL) Calories per serving 10		Total Fat 1g	1%	Total Carbohydrate 0g	0%
		Saturated Fat 1g	5%	Dietary Fiber 0g	0%
		Trans Fat 0g		Total Sugars 0g	
		Polyunsaturated Fat 1g		Includes 0g Added Sugars	0%
		Monounsaturated Fat 0g		Sugar Alcohol 0g	
		Cholesterol 0mg	0%	Protein 0g	0%
		Sodium 0mg	0%		
		Vitamin D 0mcg	0%	Calcium 0mg	0%
		Potassium 0mg	0%	Iron 0mg	0%

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.



State Case Study: Louisiana

- HB 640 was passed during the 2021 Legislative Session, amending CBD laws in the state effective August 1, 2021.
- Manufacturers and distributors of hemp consumable products must register each individual product and have labels pre-approved by the Department of Health.
 - Consumable hemp products cannot be labeled as “dietary”
- All consumable hemp processors, wholesalers, and retailers must obtain a permit.
 - Explicitly includes “remote retailers” who sell CBD products online, even if they do not have a physical in-state presence.
- Consumable hemp products may only be sold to individuals 18+

Hemp Ingredients and the Marijuana Market

- Some states have also passed laws to allow for hemp and hemp-derived ingredients to be sold into the recreational marijuana market
 1. **Oregon**
 - ODA registered hemp growers can transfer raw industrial hemp to OLCC licensed processors that have a hemp endorsement and to OLCC-licensed wholesalers. You must apply and be approved for an OLCC hemp certificate to be able to make those transfers.
 2. **Washington**
 - Hemp-derived CBD may only enter the regulated marijuana market as an additive for the purposes of enhancing overall CBD concentration in marijuana concentrates, useable marijuana, and marijuana-infused products. See WAC 314-55-109.
 - Stand-alone CBD products, regardless of concentration, are not authorized for sale in licensed marijuana retail locations, unless they meet the definition of a “Cannabis Health and Beauty Aid”.
 3. **Colorado**
 - Licensed marijuana retailers may only sell a hemp product that it receives from a CDPHE registrant and that has passed all required testing
 - Stores are prohibited from accepting and/or selling plant material from an industrial hemp plant.



Navigating the Patchwork of State Regulations

- CBD regulations on both the state and federal levels are constantly evolving. It can therefore be incredibly difficult to properly assess and ensure that hemp and hemp-derived products are complying with all applicable regulatory requirements.
- However, companies in this industry can substantially lower the risk of state and federal enforcement actions against them by taking the following steps:
 - Ensure that products comply with all applicable FDA regulations, including, but not limited to, refraining from making unlawful health claims about products containing CBD.
 - If you choose to add CBD to food or dietary supplements, ensure that production and sales are confined solely to states in which such products are legal and, even then, understand that there is still federal legal risk associated with such actions.
 - Review and follow all applicable state regulations concerning CBD products, including, but not limited to, complying with all labeling and testing requirements.
 - Ensure that all CBD products, and the hemp crop from which the CBD was derived, were tested by a reputable, independent laboratory. Additionally, maintain all certificates of analysis and documentation regarding the testing processes.
 - Ensure that claims set forth in all labeling, packaging, marketing, and advertising of CBD accurately reflect any test results and are otherwise fully substantiated before the claims are made.

FDA Enforcement

- Enforcement to date:
 - Primarily limited to the issuance of warning letters.
- Aimed at companies with products making health claims on labels/advertising/social media claiming to prevent, diagnose, treat, or cure serious diseases, such as cancer.
- Usually tied to claims to treat serious medical conditions.
 - Opioid Addiction
 - COVID-19 Treatment
 - CBD touted as a “cure” for Covid-19: “CBD CAN PREVENT AND CURE THE CORONAVIRUS!”

The Future of CBD Regulation

- Rise in CBD Lawsuits
 - Lawsuits claiming products contain less CBD than labeled or advertised.
 - Lawsuits claiming CBD products are ineffective or unsafe.
 - Lawsuits claiming products are deceptively labeled or advertised.
 - Lawsuits claiming products are unlawful and therefore worthless.
- How will state and federal agencies share responsibilities?
 - Federal officials can benefit from states' experiences.
- FDA should promulgate rules so there is one national standard for product development, manufacturing, labeling, and testing.
- States should oversee licensing

Questions?



Thank you!