VIRGINIA HEALTHY ALTERNATIVES ASSOCIATION

August 2, 2022

The Honorable Matthew J. Lohr
Secretary of Agriculture and Forestry
Commonwealth of Virginia

Public Comments: Task Force to Analyze Industrial Hemp Extracts and Other Substances Containing Tetrahydrocannabinol (THC) Intended for Human Consumption

Dear Secretary Lohr,

Thank you for the opportunity to submit written public comments to the Task Force to Analyze Industrial Hemp Extracts and Other Substances Containing Tetrahydrocannabinol (THC) Intended for Human Consumption. I appreciate the opportunity to provide this input, and while I gave comments at the task force's July 7 meeting, I am thankful for the chance to follow up and expand on those remarks based on what was shared in the meeting.

I am the President of the Virginia Healthy Alternatives Association (VHAA) and the owner of a small business called VGI Brands. We employ around 30 people in Chesterfield County. The VHAA was formed to ensure that every Virginian has access to healthy alternatives to the products offered by large pharmaceutical companies, and we represent a wide range of members in the hemp products industry.

These comments will focus on both the legal and regulatory environment for hemp-derived products across the United States, including recent court decisions and our thoughts on the 2022 budget language that was recently enacted and a list of recommendations for regulatory action moving forward. Furthermore, we encourage the task force to review comments submitted by our colleagues in the laboratory and testing sector for both a technical explanation of the properties of various cannabinoids and a review of the necessity for regulated third-party laboratory testing of products.

United States Regulatory Environment

Across the entire nation, individual states are grappling with the same question that we are in Virginia. Absent clear federal laws, other than the fact that hemp-derived products with a delta-9 THC concentration of less than 0.3% are legal, states are all regulating these products in different ways. Our organization's goal is to support robust regulation that informs consumers and provides a high level of trust and protection, especially with regard to children, while supporting the viability and growth of the hemp industry here in the Commonwealth.

In the July 7, 2022 meeting of the Task Force, staff from the Virginia Department of Agriculture and Consumer Services (VDACS) gave an informative overview of how some other states have chosen to regulate these hemp-derived products. However, this overview does not tell the full story of the regulatory environment nationwide. These comments will address the current federal regulatory stance, recent judicial rulings related to these products, and an additional state which could serve as a successful model for Virginia.

Federally, these products have been legal since the passage of the 2018 Farm Bill, but there are differing interpretations among regulatory agencies regarding their authority and responsibilities related to hemp-derived products intended for human consumption. The U.S. Food and Drug Administration (FDA) has claimed that hemp-derived oils and other derivatives are not approved food ingredients, except for in very limited circumstances where those derivatives, such as hemp seeds, are "Generally Recognized as Safe" or GRAS.[1] FDA's enforcement of this stance has mostly consisted of sending letters to companies selling certain to products that are making illegal health claims that can mislead and confuse consumers.[2] Virginia has chosen to ignore this FDA interpretation since 2019 when Governor Northam directed the agency to consider hemp-derived oils as approved food ingredients, and legislation in 2020 further mandated this designation. Despite FDA's inaction, Virginia has very real authority to regulate these products which are intended for human consumption.

The U.S. Drug Enforcement Agency (DEA) has stated that in light of the language of the 2018 Farm Bill, all hemp-derived cannabinoids, as long as they are under 0.3% total delta 9-THC, are not controlled substances and are not illegal under federal law. In a September 2021 letter to the Alabama Board of Pharmacy, a DEA official explained, "The Controlled Substances Act, however, excludes from control 'tetrahydrocannabinols in hemp (as defined under section 1639o of Title 7).' Hemp, in turn, is defined as '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.' 7 U.S.C. 1639o(1). Accordingly, cannabinoids extracted from the cannabis plant that have a delta 9-THC concentration of not more than 0.3

[1] https://www.fda.gov/news-events/fda-voices/fda-committed-sound-science-based-policy-cbd & https://www.fda.gov/media/131878/download

[2] https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products

percent on a dry weight basis meet the definition of 'hemp' and thus are not controlled under the CSA.[3]"

A recent ruling by the U.S. Court of Appeals Ninth Circuit further supports this interpretation of the 2018 Farm Bill. According to *The National Law Review*, in a recent trademark violation case involving delta 8-THC products, "The Ninth Circuit found that the plaintiff was likely to succeed on the merits of its trademark claim "because its delta-8 THC products are not prohibited by federal law, and they may therefore support a valid trademark." In so doing, the Ninth Circuit pointed to the plain text of the 2018 Farm Bill and found the Δ8-THC in the plaintiff's products appear to fit comfortably within the statutory definition of 'hemp.'"[4]

Absent a change in federal law, it is becoming clearer that current statute allows, or at the very least does not disallow, products derived from hemp as long as they do not contain a total delta 9-THC concentration of greater than 0.3%.

Several states have taken action with regard to the regulation of hemp-derived products intended for human consumption, including by inhalation. VDACS staff presented three states, Oregon, Colorado, and New York, as examples in the July 7 task force meeting, but each of these states also has a legal, regulated adult-use cannabis market (with New York's currently being finalized) making them poor comparisons to the Commonwealth's current posture. Traditional medical or adult-use cannabis producers have long seen hemp products as strong competitors in the marketplace as consumers continue to demand a wide variety of safe, regulated cannabis products.

While this question is still being answered in several states, my organization recommends Virginia review Florida's laws and regulations for hemp derived products.

Florida

Florida has become a national leader in its regulation of hemp-derived products intended for human consumption, either orally or via inhalation. The state regulates the products via its Department of Agriculture and Consumer Services (FDACS). Section 581.217, Florida Statutes, gives FDACS regulatory authority over Hemp and Hemp Extract intended for Human Consumption. As part of the State Hemp Program, FDACS Division of Food Safety has adopted Rule 5K-4.034, Florida Administrative Code.[5]

In a guide released by FDACS for hemp and hemp products producers, FDACS has outlined the various regulatory requirements, and several of these are very similar to both what VDACS requires under its authority via § 3.2-5145.2 and the new language within § 59.1-200, but there are a few important differences as well.

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[3] https://albop.com/oodoardu/2021/10/ALBOP-synthetic-delta8-THC-21-7520-signed.pdf, accessed via https://www.yahoo.com/now/us-doj-dea-clarifies-position-120600928.html

[4] https://www.natlawreview.com/article/weeds-thicken-making-sense-ninth-circuit-s-decision-finding-delta-8-legal-under

[5] https://www.fdacs.gov/content/download/89947/file/Hemp-Extract-for-Ingestion-and-Inhalation.pdf

The first is that Florida, in addition to regulating products intended to be consumed orally, also regulates those products intended to be consumed via inhalation. FDACS not only requires ingredients come from an approved source as VDACS does for food products, it also requires those manufacturers making products for inhalation be under inspection as well. In addition, Florida has extremely robust packaging and labeling requirements. In addition to requiring child-proof packaging, it requires the packaging to "minimize exposure to light" that could alter its contents' chemical composition. Labels must contain very specific information and warning labels verbatim. See these requirements for oral ingestion products and for inhalation in Exhibits 1 and 2 on the following pages.

Florida also has released specific guidance regarding delta 8-THC and other similar cannabinoids. In a notice posted on the FDACS website, the agency states, "At this time any hemp product intended for human or animal ingestion or inhalation which is sold in Florida must comply with all Florida statutes and rules. Any hemp or hemp extract products offered for sale or sold in Florida must comply with all labeling rules and have a certificate of analysis that shows a total THC (THCA x .8777 + THC Delta 9 = total THC) content of 0.3% or less. Any hemp or hemp extract product that does not comply with all statutes and rules is subject to enforcement and possible destruction by the Florida Department of Agriculture and Consumer Services."[6]

With these inspection, labeling, and testing requirements, Florida both ensures that the industry is properly regulated and that consumers are protected, and that the industry can remain viable and operate under clear guidelines.

[6] https://www.fdacs.gov/Cannabis-Hemp/Hemp-CBD-in-Florida and https://www.fdacs.gov/content/download/94040/file/Delta8.pdf

Exhibit 1 – Florida Labeling Requirements for Products Intended to be Ingested

HEMP EXTRACT LABELING GUIDELINES INGESTION

1. Existing labeling requirements for packaged products include the following:

- The identity of the product (this is not the same as the brand name).
- A list of ingredients (including sub-ingredients) in order of abundance.
- The business name and address of the manufacturer, packer, or distributor (also referred to as the Responsible Party).
- An accurate declaration of the quantity of the net contents in both SI and U.S. Customary units, such as milliliters (ml) and fluid ounces (fl. oz).
- A Nutrition Facts panel, unless exempt.
- Servings per container and the serving size.
- The label, and advertisement, shall not contain claims indicating the product is intended for diagnosis, cure, mitigation, treatment, or prevention of disease rendering it a drug as defined in 21 U.S.C. 321(g)(1).

2. In addition to the above requirements, Hemp Extract intended for human consumption must be distributed and sold in a container that includes:

1. A scannable barcode or quick response code linked to the certificate of analysis of the hemp extract 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,
5. The number of milligrams of each marketed cannabinoid per serving.

Nutrition Facts

30 servings per container
Serving size
1 dropperful (1mL)
Calories per serving 10

Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
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% • Iron 0mg 0%			
Potassium 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.

(Labels for example purposes only.)

Exhibit 2 – Florida Labeling Requirements for Products Intended to be Consumed by Inhalation

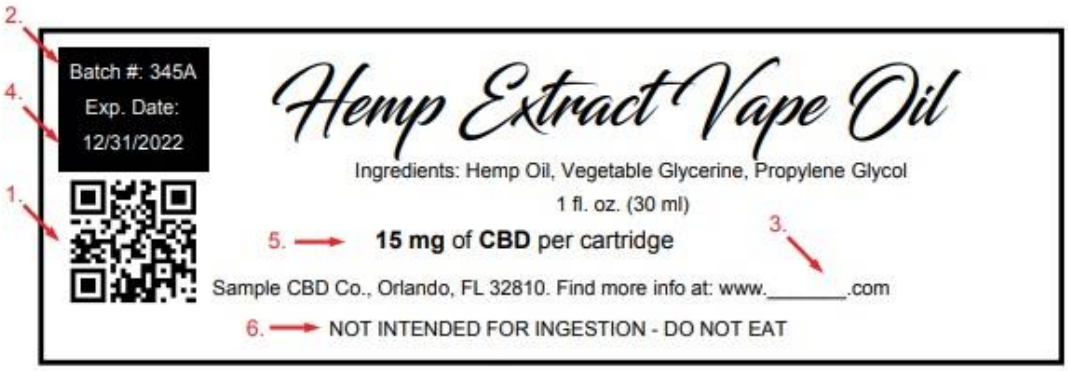
HEMP EXTRACT LABELING GUIDELINES
INHALATION

1. Existing labeling requirements for packaged products include the following:

- The identity of the product (this is not the same as the brand name).
- A list of ingredients (including sub-ingredients) in order of abundance.
- The business name and address of the manufacturer, packer, or distributor (also referred to as the Responsible Party).
- An accurate declaration of the quantity of the net contents in both SI and U.S. Customary units, such as milliliters (ml) and fluid ounces (fl. oz).
- The label, and advertisement, shall not contain claims indicating the product is intended for diagnosis, cure, mitigation, treatment, or prevention of disease rendering it a drug as defined in 21 U.S.C. 321(g)(1).

2. In addition to the above requirements, Hemp Extract intended for Inhalation must be distributed and sold in a container that includes:

1. A scannable barcode or quick response code linked to the certificate of analysis of the hemp extract 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,
5. The number of milligrams of each marketed cannabinoid per serving/container,
6. The statement "Not Intended for Ingestion - Do Not Eat".



(Label for example purposes only.)

2022 Action and Beyond

Our organization was encouraged to see several policies for which we advocated end up in the final language that passed the 2022 General Assembly in HB 30 regarding hemp-derived products containing THC. These include:

- Sales restricted to only those consumers age 21 and above;
- Child resistant packaging;
- Clear labeling requirements, including how much and the potency of each cannabinoid in the product;
- Testing requirements for each product by independent laboratories accredited pursuant to standard ISO/IEC 17025 of the International Organization of Standardization by a third-party accrediting body;
- Protections for intellectual property, which will prevent dangerous copycat products from being marketed and sold to children and other consumers who may be unaware of what these products contain.

We appreciate the leadership of the Youngkin Administration on this issue and appreciate the Attorney General's quick action regarding those copycat and counterfeit products that are on the shelves. We stand ready to assist in any way we can in helping this industry get up to speed on the new requirements and weeding out the bad actors.

While our organization sincerely disagrees with the interpretation of the Virginia Department of Agriculture and Consumer Services (VDACS) regarding hemp-derived THC intended for human consumption, we also desire to continue to be a partner in this conversation. We believe that the language passed in HB 30 clarifies the legality of hemp-derived alternatives to delta 9-THC, which have also been federally legal since the passage of the 2018 Farm Bill.

We will continue to advocate not only for these products to remain on the shelves in a safely regulated manner, but we also desire additional requirements that will further ensure the safety of these products and earn the trust of consumers across the Commonwealth. Some examples of these additional requirements are below:

- Licensing requirements for each retail, wholesale, and manufacturing location;
- Designate who may enter stores (i.e. adults only;
- Requirements of where products should be kept and displayed (i.e. behind the counter)
- Additional items on the label, such as place of manufacturing and batch numbers; customer service number; and
- Large warning label on each package with the emergency call number and particular warning language. For example, this could read, "WARNING: THESE PRODUCTS CONTAIN THC DERIVED FROM INDUSTRIAL HEMP. THESE PRODUCTS ARE INTENDED FOR USE BY ADULTS 21 YEARS OF AGE AND OLDER. KEEP OUT OF REACH OF CHILDREN. CONSUMPTION OF THC IMPAIRS COGNITION AND YOUR ABILITY TO DRIVE AND MAY BE HABIT FORMING. THC SHOULD NOT BE USED WHILE PREGNANT OR BREASTFEEDING. EFFECTS OF HEMP

DERIVED PRODUCTS MAY BE DELAYED UP TO TWO HOURS. PLEASE USE EXTREME CAUTION."

Thank you once again for the opportunity to provide public comments. We look forward to continuing to engage with the task force and its members. These issues are extremely complex, but we are confident that Virginia can craft a positive solution for the future—one that both protects and informs consumers and that allows the hemp and hemp products industry to flourish.

Sincerely,

Yan Gleyzer, VHAA President