REPORT OF THE SECRETARY OF AGRICULTURE AND FORESTRY AND THE SECRETARY OF HEALTH AND HUMAN RESOURCES

Report on Standards for Hemp-Derived Oils (Chapter 653, 2019 Acts of Assembly)

TO THE GENERAL ASSEMBLY OF VIRGINIA



HOUSE DOCUMENT NO. 13

COMMONWEALTH OF VIRGINIA RICHMOND 2019

REPORT ON STANDARDS FOR HEMP-DERIVED OILS

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Report on Standards for Hemp-Derived Oils

PUBLICATION YEAR 2019

Document Title

Report on Standards for Hemp-Derived Oils

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Legislative Mandate

Chapters 653 and 654 of the 2019 Acts of Assembly

Executive Summary

Chapters 653 and 654 of the 2019 Acts of Assembly direct the Secretaries of Agriculture and Forestry and Health and Human Resources ("Secretaries") to prepare a report on the appropriate standards, if any, for the production of an oil with a tetrahydrocannabinol (THC) concentration of no greater than 0.3 percent that is derived from industrial hemp. The Secretaries have determined that standards for hemp-derived oils intended for human consumption are appropriate and necessary. Recommendations for legislation or regulation to establish such standards are outlined within the Report on Standards for Hemp-Derived Oils.

Report on the Standards for Hemp-Derived Oils

Chapters 653 and 654 of the 2019 Acts of Assembly direct the Secretaries of Agriculture and Forestry and Health and Human Resources ("Secretaries") to prepare a report on the appropriate standards, if any, for the production of an oil with a tetrahydrocannabinol (THC) concentration of no greater than 0.3 percent that is derived from industrial hemp. To develop this report, the Secretaries convened on four occasions from June 2019 through September 2019. One of these meetings, on September 4, 2019, was a public meeting at which the Secretaries received comment from stakeholders on potential areas of regulation, as they pertain to industrial hemp-derived oils intended for human consumption. Notice of this meeting was posted on the Commonwealth Calendar. Representatives from the Cannabis Business Association of Virginia and Virginia Industrial Hemp Coalition as well as two industrial hemp registrants attended and provided comments on areas including product adulterants, labeling, and testing. See Appendix One for a transcript of this meeting.

BACKGROUND

While this report offers standards for an industrial hemp-derived oil, a decidedly broad category of products, industrial hemp-derived cannabidiol (CBD) oil products are currently the most common industrial hemp-derived extracts consumed. CBD is one of almost 100 cannabinoids present in the flower of the cannabis plant. CBD oil and CBD products that are intended for human consumption and derived from hemp (capsules, tinctures, oral sprays, and edibles, among others) are being sold both online and in a variety of retail locations. Consumers purchase these products for a variety of desired health benefits, and the products are often advertised as a treatment for a variety of health conditions, including anxiety and inflammation.

In the years since the enactment of federal and state laws regarding industrial hemp cultivation, the U.S. hemp industry's interest in growing hemp for its grain and fiber has shifted to an interest in growing high-CBD varieties of hemp for CBD oil and CBD product production. According to data compiled by New Frontier Data, the total sales for the U.S. hemp industry totaled \$820 million in 2017 and is expected to grow to \$1.9 billion by 2022.

The federal and state regulation of industrial hemp-derived oils has not kept pace with the hemp industry's development, leaving uncertainty as to product quality and safety. This report will outline relevant industrial hemp and food safety laws, provide examples of other states' attempts at regulating hemp-derived oils, and provide a recommendation for appropriate standards for the production of hemp-derived oils.

RELEVANT INDUSTRIAL HEMP-RELATED PROVISIONS OF FEDERAL AND STATE LAW

2014 FARM BILL

Section 7606 of the federal Agricultural Act of 2014 (Section 7606) permitted an institution of higher education or a state department of agriculture to grow or cultivate industrial hemp if (i) the industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research and (ii) the growing or

cultivating of industrial hemp is allowed under the laws of the state in which such institutions of higher education or state department of agriculture is located and such research occurs. Section 7606 defines industrial hemp, in part, as *Cannabis sativa L*. with a delta-9 THC concentration of not more than 0.3 percent.

VIRGINIA INDUSTRIAL HEMP LAW, ENACTED 2015, AMENDED 2018

The Virginia Industrial Hemp Law (Va. Code § 3.2-4112 et seq.) was enacted by the 2015 Session of the General Assembly and authorized the Commissioner of Agriculture and Consumer Services (Commissioner) to establish and oversee an industrial hemp research program directly managed by public institutions of higher education. In an effort to allow Virginia farmers to take full advantage of Section 7606, the Virginia Department of Agriculture and Consumer Services (VDACS), with the Administration's approval, successfully pursued legislation during the 2018 Session of the General Assembly that amended the Virginia Industrial Hemp Law to create a new industrial hemp research program, in addition to the existing higher education industrial hemp research program, that is managed by VDACS. The enacted legislation also replaced the industrial hemp grower licensure program with a registration program for industrial hemp growers and processors.

2018 FARM BILL

The federal Agricultural Act of 2018, which was enacted on December 20, 2018, includes numerous industrial hemp-related provisions that, in part, eliminate the aforementioned research requirement of the 2014 Farm Bill and allow for the commercial production of industrial hemp. The 2018 Farm Bill establishes a new definition of "hemp" and removes hemp from the definition of "marihuana" in the federal Controlled Substances Act. The new definition of "hemp" retains the restriction upon the THC concentration of a cannabis plant in order for that plant to be "hemp" – hemp shall not have more than 0.3 percent THC on a dry weight basis. The new definition explicitly states that all derivatives, extracts, and cannabinoids of "hemp" are also considered "hemp."

The 2018 Farm Bill also explicitly states that its hemp provisions do not affect or modify (i) the U.S Food and Drug Administration's (FDA) authority regarding the federal Food, Drug, and Cosmetic Act (FD&C Act) or the Public Health Service Act or (ii) the authority of the FDA Commissioner and U.S. Secretary of Health and Human Services pursuant to these laws.

2019 INDUSTRIAL HEMP-RELATED AMENDMENTS TO THE CODE OF VIRGINIA

Chapter 653 and 654 of the 2019 Acts of Assembly, the results of companion bills, House Bill 1839 (D. Marshall) and Senate Bill 1692 (Ruff), in part, respond to certain industrial hemprelated provisions in the 2018 Farm Bill. This legislation amended the definition of "industrial hemp" to mirror the 2018 Farm Bill's definition of "hemp," eliminated the industrial hemp research programs, and included provisions intended to clarify the legality of products derived from industrial hemp.

The legislation amended the Virginia Drug Control Act's definition of "cannabidiol oil" to exclude industrial hemp, as defined in the Virginia Industrial Hemp Law, "that is grown, dealt, or processed in compliance with state or federal law." The legislation also amends the Virginia Drug Control Act's definition of "marijuana" to exclude a hemp product, as defined in the Virginia Industrial Hemp Law, containing a THC concentration of no greater than 0.3 percent that is derived from industrial hemp that is grown, dealt, or processed in compliance with state or federal law.

FDA AND VDACS'S FOOD SAFETY PROGRAM

Federal and state food safety laws support the general requirement that an ingredient in a food product, including a dietary supplement, must be an approved food additive from an approved source. Under the FD&C Act, a food additive must be approved by FDA or be the subject of an FDA Generally Recognized As Safe (GRAS) notification before it is used in a food. To date, FDA has issued GRAS notifications for the following hemp plant parts or products: hulled hemp seed, hemp seed protein, and hemp seed oil. No other cannabis plant part or compound has been approved as a food additive.

A food manufacturer is deemed an "approved source" if it is under inspection by FDA or a state regulatory agency with authority to administer the state's food safety laws. Under the FD&C Act, the FDA adopted 21 C.F.R. Part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (GMP), with which a food manufacturer must comply in order to be deemed an "approved source." GMPs help define whether food (i) has been manufactured under conditions that are unfit for food or (ii) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or been rendered injurious to health. The GMP includes provisions related to (i) disease control and cleanliness among personnel, (ii) sanitary operations, (iii) sanitary facilities, including water supply and toilet and hand-washing facilities, (iv) equipment and utensils, and (v) processes and controls for raw materials. A manufacturer of a dietary supplement is deemed an "approved source" if it operates in compliance with 21 C.F.R. Part 111, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, which includes requirements for process documentation and requirements that ensure dose consistency.

VDACS's Food Safety Program administers Virginia's Food and Drink Law and regulations adopted thereunder and ensures that any food or beverage manufactured, produced, processed, packed, exposed, offered, possessed, or held for sale is safe for human consumption. This law and regulations, in part, require food manufacturers in Virginia to use approved ingredients from approved sources. Many of the regulations administered by the Food Safety Program adopt by reference regulations related to food for human consumption adopted by FDA under the FD&C Act. Generally, this program follows FDA's GRAS determinations when assessing whether a food ingredient is approved and deems a food manufacturer to be an approved source if it is manufacturing food in compliance with the food laws of the state in which it is manufacturing.

In June 2018, FDA approved as a drug Epidiolex (cannabidiol) oral solution for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome. The U.S. Drug

Enforcement Administration (DEA) subsequently classified "Approved Cannabidiol Drugs" as a Schedule V controlled substance while retaining its classification of both "marihuana" and "marihuana extract[s]" as Schedule I controlled substances. Under the FD&C Act, the active ingredients in an FDA-approved drug may not be introduced into the food supply or marketed as a dietary supplement. FDA has advised that it is unlawful to introduce food containing added CBD into interstate commerce or to market CBD as or in a dietary supplement because it is an active ingredient in an FDA-approved drug and was the subject of substantial clinical investigation before it was marketed as a food or dietary supplement. However, FDA's sole enforcement action addressing hemp-derived CBD products to date has been to issue warning letters to companies selling CBD products with claims that the products prevent, diagnose, treat, or cure a disease.

Following the enactment of the 2018 Farm Bill, the FDA commissioner at that time, Scott Gottlieb, M.D., issued a statement regarding FDA's regulation of products containing cannabis and cannabis-derived compounds that reiterated FDA's position on CBD but acknowledged the "proliferation of products containing cannabis or cannabis-derived substances" and Congress's interest "in fostering the development of appropriate hemp products." Commissioner Gottlieb's statement provided that FDA will "continue to evaluate and take action against products that are being unlawfully marketed and create risks for consumers," but is "committed to pursuing an efficient regulatory framework for allowing product developers that meet the requirements under [FDA's] authorities to lawfully market these types of products." To that end, on May 31, 2019, FDA held a public hearing to receive scientific data and information on products containing cannabis and cannabis-derived compounds. On July 25, 2019, FDA's Principal Deputy Commissioner, Amy Abernethy, M.D., Ph.D., testified before the Senate Committee on Agriculture, Nutrition, and Forestry at its hearing on hemp production. Deputy Commissioner Abernethy testified that FDA is evaluating options to address regulation of CBD more quickly and efficiently than the estimated three to five years it can take FDA to complete an expedited notice and comment rulemaking process. Deputy Commissioner Abernethy also testified that FDA has formed a high-level CBD Policy Working Group to coordinate FDA's "approach to CBD policy making, including considering the appropriateness of potential pathways for dietary supplements and/or conventional foods containing CBD to be lawfully marketed."¹

In May 2019, VDACS advised Registered Industrial Hemp Processors that, given both federal and state food safety-related laws, it was not able to approve the manufacture, distribution, or sale of (i) a food product or dietary supplement containing a hemp-derived extract, including CBD oil, or (ii) a hemp-derived extract intended for human consumption that is produced by a Registered Industrial Hemp Processor. In July 2019, out of concern for consumer safety and in response to concerns that Registered Industrial Hemp Processors presented to the Northam Administration following VDACS's May 2019 advisement, the Administration directed VDACS to treat hemp-derived extracts intended for human consumption as approved food additives and to place qualifying Registered Industrial Hemp Processors under food safety inspection so that inspected and approved processors may manufacture a hemp-derived extract intended for human

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https://www.agriculture.senate.gov/imo/media/doc/Testimony_Abernethy%2007.25.19.pdf

¹ Statement of Amy Abernethy, MD, PHD, Principal Deputy Commissioner, Food and Drug Administration, Department of Health and Human Services before the Committee on Agriculture, Nutrition, and Forestry, United States Senate, "Hemp Production and the 2018 Farm Bill," July 25, 2019.

consumption. Shortly after receiving this policy directive, VDACS distributed to Registered Industrial Hemp Processors an outline for its implementation thereof, which requires processors to comply with either 21 C.F.R. Part 110 or Part 111 and to ensure their hemp-derived extracts intended for human consumption comply with specific standards for microbiologicals, mycotoxins, heavy metals, residual solvents, and pesticides.

STATE REGULATION OF CANNABIS-DERIVED PRODUCTS

The FDA's establishment of a regulatory framework for the production of cannabis-derived products could take years if FDA must proceed without the enactment of a unique regulatory process under which it can address cannabis-derived products. In the absence of any federal standards for the production of cannabis-derived products, states have begun adopting their own standards. Many have production standards that include good manufacturing practices to ensure that the products are not produced under insanitary conditions. Some states have also established pesticide, heavy metal, microbiological, or residual solvent limits for hemp-derived products. As cannabis is known to absorb nutrients and chemicals from the media in which it is grown – it is a "bioaccumulator" – it is important to ensure that products derived from these plants do not contain harmful levels of these substances. Additionally, as solvents are often used to extract the CBD from the plant, it is also important to ensure that the amount of any residual solvent does not pose harm to the consumer.

Pursuant to the Virginia Drug Control Act (Va. Code § 54.1-3400 *et seq.*), the Virginia Board of Pharmacy (BOP) has adopted regulations for the production of cannabidiol oil² by permitted pharmaceutical processors. These regulations include standards prescribing the maximum levels of heavy metals (arsenic, cadmium, lead, and mercury) and mycotoxins (aflatoxin B1, aflatoxin B2, aflatoxin G1, aflatoxin G2, and ochratoxin A) as well as microbiologicals and residual solvents that may be present in cannabidiol oil.³ Florida is adopting similar standards for hemp-derived extracts.⁴ Massachusetts requires hemp-derived extracts to comply with the standards adopted in that state for medical marijuana products.⁵

RECOMMENDATIONS

The Secretaries have determined that standards for hemp-derived oils intended for human consumption are appropriate and necessary. Recommendations for legislation or regulation to establish such standards are outlined below.

 Prescribe, via legislation, that a hemp-derived extract, such as an industrial hemp-derived CBD oil, is an approved food ingredient.

² Per Va. Code §§ 54.1-3408.3 and 54.1-3442.5, "cannabidiol oil," as regulated by the Virginia Board of Pharmacy, means "any formulation of processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol per dose but not more than five percent tetrahydrocannabinol. "Cannabidiol oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law."

³ See Appendix Two, Tables 1, 2, and 3.

⁴ See Appendix Two, Tables 1, 2, and 3.

⁵ See Appendix Two, Tables 1, 2, and 3.

- Prescribe, via legislation, that a manufacturer of a hemp product containing a hemp-derived extract is an approved source, for the purpose of compliance with Virginia's food safety-related laws, if that entity complies with the food laws and regulations that pertain to the manufacturing of a hemp product containing an industrial hemp-derived extract in the state in which it is manufacturing this hemp product. Such food laws and regulations may include 21 C.F.R. Part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food or 21 C.F.R. Part 111, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. An entity manufacturing in compliance with relevant food laws and regulations will be qualified as an approved source from which (i) a retail food establishment could receive food to offer for retail sale or (ii) another food manufacturer could receive food for use in its food product.
- Prescribe, via legislation, that a hemp-derived extract intended for human consumption shall be produced from industrial hemp grown in compliance with federal or state law.
- Prescribe, via legislation, that a hemp-derived extract intended for human consumption shall have a THC concentration of no greater than 0.3 percent.
- Prescribe, via legislation, that a hemp-derived extract intended for human consumption may only be distributed and sold in the Commonwealth if the extract is the product of a batch tested by an independent testing laboratory and a certificate of analysis prepared by the independent testing laboratory is available upon request by VDACS or a consumer. An independent testing laboratory shall not have a direct or indirect interest in the entity whose product it is testing or any entity that grows, deals, or processes industrial hemp and shall be accredited by a third party accrediting body pursuant to ISO/IED 17025 of the International Organization of Standardization.
- Direct, via legislation, that the Board of Agriculture and Consumer Services adopt standards for hemp-derived extracts intended for human consumption via an expedited regulatory process that is exempt from the requirements of the Administrative Process Act but that requires a public comment period.
 - It is the recommendation of the Secretaries that the standards currently prescribed by BOP to address potential contaminants or adulterants in cannabidiol oil are appropriate for hemp-derived extracts intended for human consumption.
 - It is the recommendation of the Secretaries that only residue from pesticides that meet the requirements outlined by VDACS for use on hemp intended for human consumption may be present in a hemp-derived extract intended for human consumption.
- Direct, via legislation, that the Board of Agriculture and Consumer Services (Board) adopt labeling standards for hemp-derived extracts intended for human consumption that address information such as the cannabinoid concentration and expiration date of the product as well as the method by which to obtain specific information regarding the product. The legislation should authorize the Board to adopt these standards via an expedited regulatory process that

is exempt from the requirements of the Administrative Process Act but that requires a public comment period.

• It is the recommendation of the Secretaries that the label for a hemp-derived extract intended for human consumption shall not state that the product is intended for the diagnosis, cure, mitigation, treatment, or prevention of a disease.

ADDITIONAL CONSIDERATIONS

Both topical products and inhalants that include hemp-derived extracts are also sold online and at retail locations; however, the primary focus of the Secretaries' work for this report was hemp-derived extracts intended to be orally ingested, as VDACS currently has authority to regulate the manufacture, distribution, or sale of food and dietary supplements in Virginia and routinely conducts inspections of these manufacturing facilities.

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Public Meeting on the Report by the Secretaries of Agriculture and Forestry and Health and Human Resources

September 4, 2019

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Public Meeting on the Report by the Secretaries of 1 Agriculture and Forestry and Health and Human Resources Regarding the Appropriate Standard if Any 2 for the Production of an Oil with a 3 Tetrahydrocannabinol (THC) Concentration of No Greater Than 0.3 Percent That Is Derived from 4 Industrial Hemp

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Patrick Henry Building 1111 E. Broad Street Richmond, Virginia

September 4, 2019

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A public meeting by the Secretaries of 14 15 Agriculture and Forestry and Health and Human Resources was held at the Patrick Henry Building, 16 West Reading Room, 1111 E. Broad Street, Richmond, 17 18 19

Virginia, on Wednesday, September 4, 2019, at 2:00 p.m. before Colleen Good, Certified Court Reporter and Notary Public in and for the Commonwealth of Virginia.

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2.

JEWEL BRONAUGH, Ph.D.: Good afternoon everyone, we are going to get started. Welcome to the public meeting on the report by the Secretary of Agriculture and Forestry and Health and Human Resources on production standards for industrial hemp derived oil.

My name is Jewel Bronaugh, I'm VDACS

Commissioner and I will serve as the moderator for today. I'm happy to be joined by Dr. David Brown, Director of the Virginia Department of Health Professions.

I just welcome everyone here today. There are a lot of people who are here today because of your interest in this exciting, fast growing industry that we know as hemp.

It is clear to see that we are on the leading edge of an industry that many are watching very closely and have put a great amount of investment and hope in.

Many of us have watched this industry grow from just a few years of talking about the cultivation of hemp for fiber and grain to the extraction of hemp derived extracts for human consumption and other uses.

Today's meeting focus will be on the production standards for industrial hemp derived oil. As Chapters 653 and 654 of the 2019 Virginia General Assembly direct the Secretary of Agriculture and Forestry and the Secretary of Health and Human Resources to prepare a report on the standards, if any, for the production of an oil with a THC concentration of no greater than .3 percent that is derived from industrial hemp.

2.

The report is due to the General Assembly no later than November 1st, 2019. And this stakeholder meeting serves as a part of the process that the secretaries will use in order to complete that report that is due to the General Assembly.

So today there will be a presentation on the production standards for industrial hemp derived oil, followed by an opportunity for public comment. Today the areas for which we seek public comment include: Adulterants, labeling requirements, testing requirements, reciprocity for products manufactured under inspection in another state and any other areas that you feel have not been addressed.

Again, as Mr. Charles Green

indicated, we have a sign-in sheet to my left.

Please be sure to sign in if you wish to speak today.

2.

First we will have the Secretary of Agriculture and Forestry, Bettina Ring, who is represented by Deputy Secretary Brad Copenhaver speak after which the Secretary of Health and Human Resources, Dr. Daniel Carey, who is represented by Mr. Marvin Figaro, will both provide introductory comments and their remarks will be followed by the overview of Virginia's cannabis program that will be presented by Erin Williams at VDACS and Caroline Juran of the Board of Pharmacy.

So Deputy Secretary Copenhaver please come forward.

BRAD COPENHAVER: Thank you,

Dr. Bronaugh. First of all, I just want to say
thank you again for everyone being here today. As

Jewel said, I'm Brad Copenhaver, Deputy Secretary
of Ag and Forestry representing Secretary Bettina

Ring.

We are very happy to be taking part in this process and leading this process as representatives of Virgina's Agricultural

industry, speaking for the farmers around the Commonwealth who see hemp as a very exciting new opportunity for them, we feel like, we agree, we think that hemp could provide a lot of opportunity for the Agricultural industry, but we've also been looking at this through VDACS public safety, public health lense as well.

So we are very excited. We've had a great discussion so far with our counterparts in Health and Human Resources and we look forward to hearing your comments today. Thanks.

MARVIN FIGUEROA: Good afternoon everyone. My name is Marvin Figueroa, Deputy Secretary of Health and Human Resources. I really wanted to wear a blazer today, but I wanted to make this meeting more fun, so I decided not to wear one.

Kind of want to echo the comments of Brad, that this has been a collaborative effort between the Board of Pharmacy and VDACS, what we want to do today is to make sure that you're open and honest and you provide us with feedback, because we will take this into consideration as we form the recommendations.

And so while this has been a

collaborative process, it hasn't been the easiest process as well. There has been a lot of serious conversation behind closed doors to arrive at a place that we feel is appropriate.

2.

There is going to be some things that we still -- won't be able to iron out completely, but nonetheless we feel like we have undertaken this process with open honesty and showing that we are listening to one another. So on behalf of Daniel Carey, Dr. Daniel Carey, thank you for being here and we hope to have a good conversation. Thank you.

ERIN WILLIAMS: Good afternoon. I'm Erin Williams. I'm with the Department of Agriculture and Consumer Services. I'm in the office of Policy, Planning and Research there and I have been coordinating the agency's efforts and implement VDACS cannabis related programs, specifically Virginia's Industrial Hemp program for the past 5 years.

Caroline and I are going to go back and forth initially to provide you some background information, so I'll allow -- have her introduce herself.

CAROLINE JURAN: Good afternoon,

everyone. I'm Caroline Juran. I'm the executive director of the Virginia Board of Pharmacy and we are overseeing the pharmaceutical processor program which is a similar cannabis program, slightly different that you'll hear about in our presentation. I'm happy to be here. Thank you.

2.

ERIN WILLIAMS: So the beginning of our meeting this afternoon, what we will do is give you an overview of our respective programs and then we'll move into the opportunity to receive the comments from the public on some specific areas of regulation that we're seeing happen in other states.

Before we get into the details of our programs, what Caroline and I will do is provide the general timeline of the progression of the development of our respective cannabis related program.

Throughout the afternoon I will likely use the terms hemp and industrial hemp interchangeably. So I don't mean to make any distinction between those two when I say hemp or industrial hemp, I mean cannabis with no greater than .3 percent THC.

And that is a definition that was

initially enacted in the 2014 Federal Farm Bill which allowed for industrial hemp to be grown for research purposes.

In 2015 the Virginia General Assembly responded to those hemp related provisions in the 2014 Federal Farm Bill by enacting Virginia's Industrial Hemp Law, and that initial law created Virginia's first hemp research program that was overseen by the Department of Agriculture and Consumer Services, but their research was directly managed by public institutions of higher education.

The initial legislation in 2015 created a grower license, so to grow hemp for research purposes, you were required to obtain a license from VDACS.

CAROLINE JURAN: So also in 2015 the General Assembly enacted a law that created a provision for a physician to issue something called a written certification to a patient to possess CBD or THCA Oil.

There had been an outcry of constituents who expressed a concern to their legislatures with respect to patients, their children, for instance, that they were having to

obtain CBD or THCA oil from out of state in order to treat their child's epilepsy.

2.

So in 2015 the General Assembly created a provision that provided an affirmative defense for that patient, parent, guardian, to possess CBD or THCA oil when issued a written certification by a physician recommending the use of these oils.

Now in 2015 that's all they did.

They just created the affirmative defense. They did not create a provision for actually producing the oils in Virginia, that didn't come about until 2016.

That legislation had to be reenacted in 2017 and it did direct the Board of Pharmacy to issue up to 5 pharmaceutical processor permits here in Virginia and ask for a pharmacy to establish regulations for the health, safety and security of these processors.

Then in 2018 the General Assembly expanded this provision to allow a physician to issue a written certification for the treatment of any medical condition that the prescriber believed the patient could benefit from. So it went beyond epilepsy.

ERIN WILLIAMS: And during that same 2018 General Assembly session, the Industrial Hemp Law was amended to create a second research program that was directly managed by the Department of Agriculture because there was interest in getting, or allowing more Virginians to grow hemp, and so this second research program was created to provide an opportunity to Virginians who weren't able to partner with Universities to conduct research under the VDACS hemp research program.

2.

In 2018 the General Assembly also replaced the licensure, the grower license, with an industrial hemp grower registration and created a processor registration with the hope that that would get some hemp processing infrastructure established in Virginia.

In 2019 the Virginia Industrial Hemp Law was significantly amended to reflect the 2018 Federal Farm Bill's hemp related provisions. The Federal Farm Bill allowed for hemp to be grown commercially.

So Virginia's general assembly responded by eliminating the research program that had previously been established and essentially

allowing for commercial production of hemp. It also clarified the permissibility of the possession of hemp derived CBD oil.

2.

CAROLINE JURAN: And also in 2019 the General Assembly enacted the Drug Control Act to allow physician assistance as well as practitioners to issue written certifications to the patients for the treatment of their medical conditions or symptom control of their medical conditions.

Additionally it restricted each dose to 10 mg. of THC, that's tetrahydrocannabinoid, which is the psychoactive component of the cannabis plant.

Thirdly, it created an authority for the Board of Pharmacy to issue a new licensing category called a Registered Agent, which is an individual designated by a registered patient, parent or guardian to receive or obtain the CBD or THCA oil from the pharmaceutical processor and it mandated the Board of Pharmacy to promulgate emergency regulations allowing for the pharmaceutical processors to wholesale distribute their products between each other.

Currently the Board of Pharmacy is

working on these emergency regulations and the exempt regulatory actions.

2.

Legislation included an enactment clause that
Commissioner Bronaugh has already mentioned
directing the Secretaries of Agriculture and
Forestry and Health and Human Resources to deliver
a report to the General Assembly regarding
appropriate standards, if any, for the production
of an oil with no greater than .3 percent THC that
is derived from a hemp plant.

This enactment clause was the result of significant discussion that occurred during the General Assembly session regarding the quality of hemp derived products and consumer safety concerns surrounding those products.

So the enactment clause has given us the opportunity to convene here today to discuss what standards, if any, are appropriate for the production of these products.

What I'll do now is give you a little bit more detail about Industrial Hemp specifically and then more details about our current hemp related, as well as our current food safety related laws that VDACS administers.

Hemp has generally three different varieties. You can grow hemp for its fiber, for its grain or for its floral material. The picture on the left here is a picture of a fiber variety of hemp growing, whereas the picture on the right is one of a floral variety of hemp.

2.

Since the 2014 Federal Farm Bill was enacted, there has been a significant shift in the hemp industries interest and what varieties of hemp that they choose to grow. When the conversation initially started the hemp industry was interested in growing fiber and grain varieties of hemp.

A few years ago the interest shifted towards going floral varieties of hemp because of the cannabinoids that are present in cannabis plants.

The cannabis plant produces hundreds of cannabinoids. The hemp industry specifically at this point was interested in cannabidiol which is commonly referred to as CBD.

The cannabinoids of the plant are produced in the flowers of the plant specifically in trichomes which are little glands within the flower. CBD is often used in a variety of health

and wellness products that you find currently on the market today.

So a little bit of detail about the 2018 Farm Bill that I mentioned just a few minutes ago. This federal legislation was signed in December of 2018. It established a new definition for hemp and was very clear that hemp includes the extract and the cannabinoids of the plant.

The 2018 Farm Bill removed hemp from the definition of marijuana as it appears in the federal controlled substances list and it established a regulatory framework for the production of hemp in the U.S.

States that desire to have primary regulatory authority over hemp production in their state can submit a plan to the U.S. Department of Agriculture for approval. It's a regulatory plan that outlines how the state will regulate the production.

The U.S. Department of Agriculture also called on by the Farm Bill to establish a federal plan that farmers can operate under if they are in a state that does not have an approved plan.

2.

So the signature, the president's signature on the Federal Farm Bill was again late December 2018. The timing of that was such that Virginia's General Assembly was able to respond in 2019. Delegate Marshall and Senator Ruff had companion legislation that passed the 2019 session.

2.

Those bills had an emergency clause which meant that they went into effect the day the governor signed them, Governor Northam signed those pieces of legislation on March 21st.

The legislation eliminated Virginia's research, Hemp Research programs, essentially allowing for commercial production of the hemp here in Virginia as of March 21st.

The legislation retained the industrial hemp grower registration, retained the processor registration and it established a third registration category for industrial hemp dealers. The dealer is an entity that buys hemp crop from growers and sells it to processors.

The legislation provides that a hemp product is not marijuana under Virginia's Criminal Code, that hemp products, as long as that hemp product has no greater than .3 percent THC and is

otherwise lawful.

The legislation also provided some clarification regarding the permissibility of a hemp derived CBD oil. Specifically by amending the Drug Control Act to provide that industrial hemp is not cannabidiol oil as that term is defined in the Drug Control Act.

This is the legislation, too, that includes the enactment clause that directs the secretaries to produce a report on the standards for these products.

So again the governor signed the legislation in March, and as of August 30th VDACS has registered 1,002 industrial hemp growers, 2002 industrial hemp processors, 66 industrial hemp dealers.

Based on the reports that we are receiving from the growers who have registered and are growing and have submitted their reports, so far this growing season we have about 2000 acres planted in hemp in Virginia.

So now I'm going to give you a little bit of background about the food safety laws that the Department of Agriculture administers, and then I'll go into, which will give you some

context for how we are currently overseeing the production of hemp derived oils in Virginia.

So for the purpose of understanding the food safety related law that VDACS administers, food is a substance that is intended for human consumption and is orally ingested, and the general premise is that any substance that is intentionally added to food must be an approved food additive and must come from an approved source.

And there is a specific path through which a food additive is approved and through which a source is approved.

The Federal Food, Drug and Cosmetics Act lays out how an additive is approved.

Generally FDA can approve it, or can issue a generally recognized as safe notification for the additive.

So far FDA, the U.S. Food and Drug
Administration has issued three grass
notifications for hemp derived components. We've
got a grass notification for hulled hemp seed, for
hemp seed protein and for hemp seed oil.

To become an approved source, the manufacturer of that food additive needs to be

under inspection by a food safety regulator. So either VDACS here in Virginia or FDA, or the food program in the state in which the manufacturer is operating.

2.

So let's look at some of the hemp derived products that are currently available to understand what components would be food additives that would need to be approved.

So the top row we have, ultimately we get to a food product that, or to which hemp derived oil is added.

So we'll start with the plant. We extract the cannabinoids from the plant. If that extract is intended for human consumption, that extract is a food additive that would need to be approved.

The abstract might then be put into an oil and if that oil containing the extract is intended for human consumption, that, too, is a food additive.

And then we get to the food products, which would need to be manufactured under inspection as well.

If we look at just an oil containing an extract, often this is a product that is

marketed or labeled as a tincture, will start with the plant, we extract the cannabinoids from the plant, again that would be if it's intended for human consumption, a food additive that needs to be approved.

2.

The extract is then put into the oil which is then sold to the consumer. If that oil with the extract is intended for human consumption, again, that's a food.

So the Department of Agriculture and Consumer Services administers Virginia's Food and Drink Law and the regulations that are adopted by the Board of Agriculture and Consumer Services under that law.

The relevant regulation for our conversation today is the regulation pertaining to food for human consumption. This law, and this regulation very closely mirror the Federal Food Safety Law and the regulations adopted by the FDA under federal raw.

As we know the FDA has only approved three hemp parts as food additives and they're currently evaluating the spectrum of cannabis derived products.

For that reason while we wait for FDA

to set forth its regulator path for cannabis derived products, we wait on potential Virginia legislation addressing hemp derived oils.

The Northam administration directed the Department of Agriculture to treat hemp extracts that are intended for human consumption as approved food additives and the Department of Agriculture was directed to place qualifying registered industrial hemp processors under food safety inspection if they were intending to manufacture a hemp derived extract intended for human consumption.

So the Department of Agriculture has established criteria for hemp processors who plan to produce a hemp derived extract intended for human consumption and they include some good manufacturing requirements.

The extract that they produce must be produced from hemp grown in compliance with federal or state law. The extract shall have no more than .3 percent THC, and the criteria also establishes some specific standards for adulterants including heavy metals, mycotoxins, microbiological residual solvents and pesticides.

This is the criteria against which

the food safety program is assessing an applicant board, the ability to manufacture a hemp derived extract for human consumption and the criteria against which those products would also be assessed.

2.

Now Caroline is going to give you some additional details regarding the Board of Pharmacies Pharmaceutical processor permit program.

CAROLINE JURAN: Thank you, Erin. So with respect to the pharmaceutical processor program, as indicated earlier, the General Assembly provided for the Board of Pharmacy an authoritative to issue up to 5 permits, one per health service area as defined by the Board of Health.

It is a three phase competitive application process. We had 51 applicants originally, of course we had to widdle that down to 5 that we were going to issue conditional approval to.

We are in the second phase where we have issued conditional approval of these 5 facilities are under construction and they are slated to be ready for inspection by December of

1 2019.

2.

If they indicate compliance through that inspection process, they will be granted a pharmaceutical processor permit and then can begin operation.

As regarding fees they each paid a ten thousand dollar initial application fee. When they applied for their permit and indicate they're ready for the inspection there is a sixty thousand dollar fee, and then on an annual basis they will pay a ten thousand dollar annual renewal fee.

What we have here in Virginia is what we call a vertical operation model unlike other states who have licensed their growers separately from their processors, separate from their dispensers.

All of these activities will occur at the same site for each pharmaceutical processor, and each processor will operate under the supervision of a pharmacist in charge.

Again, the physician, physician assistant, nurse practitioner may issue the written certifications recommended in the use of the oils. Each of these individuals have to be registered by the Board of Pharmacy as do the

patients, parents, guardians in its new licensing category of registered agents.

2.

The affirmative defense for possessing these oils is through the written certification as well as the board registration issued to the patients, parents and guardians.

The law defines these two terms, cannabidiol oil and tetrahydrocannabinol acid, or THCA oil. It indicates that there must be a minimum amount of cannabidiol oil or tetrahydrocannabinol acid concentration within each product.

And they contain no more than 5 percent THC, they must be produced under current and good manufacturing practices for dietary supplements, we are anticipating various types of formulations to be produced.

These products each must be registered by the Board of Pharmacy before they may be dispensed, and as a result of that registration process they will be reported to the prescription monitoring program, so that a prescriber or a pharmacist queries a particular patient, they will see that they have been dispensed one of these two products in addition to

any other controlled substances dispensed to them.

2.

Each product must be independently laboratory tested prior to dispensing, and the categories the Board of Pharmacy has established standards for include microbiological contaminants, mycotoxins, heavy metals, residual solvents and pesticide chemical residue.

They must also perform an ingredient profile and a terpene profile for each of the products. An expiration date shall be established for each product, that is based up a validated stability testing process.

And then there are certain labeling requirements, both for the batch label of the product as well as for a patient's specific labeling.

Those types of requirements are very similar to for instance a product that would be dispensed by a pharmacy. They would include, for instance, a serial number, the name of the patient, the name of the product, the strain, any directions for use, the name of the pharmacist or initials of the pharmacist who dispensed it, contact information for the pharmaceutical processor, any cautionary statements regarding the

use of those products, the expiration date and any recommended storage conditions for those particular products.

2.

That is all I have. I will turn it back over to the Commissioner.

JEWEL BRONAUGH, Ph.D.: So thank you, Erin, and thank you Caroline for kind of a background on the progression of the Industrial Hemp Program in Virginia, the Pharmaceutical Processor Program.

We're going to move to the public comment section of today's presentation. If you wish to speak today and you have not had an opportunity to do so, we do have a sign-in sheet if you wish to speak.

I would like to just provide a little bit of guidance and direction on how we're going to move forward. So again, the purpose of this comment period is to discuss hemp derived oil production standards.

So the focus on that is to provide the public comment so that we can have feedback that Secretary Ring and Secretary Carey will include in their final report due November 1st.

So please focus your comments under that area and

on the topics in which Erin is going to highlight.

2.

Due to the limited amount of time that we have, we will not take questions today. So this is an opportunity for you to provide public comment and feedback only.

And I ask that everyone please limit your comments to between 2 to 3 minutes or less, and I assume that everyone knows this, but I ask that everyone just be respectful of each other during this time, and so Mr. Charles Green has handed me the public comment sign-in sheet, and is there anyone else who wishes to sign? Okay, sir, I'll put it right here so you can come and sign it. Thank you.

So at this point I'm going to turn it back over to Erin and she's going to highlight the areas of discussion and we call each one individually in the order that you have signed up in order to comment on that specific area that Erin highlights. Thanks.

ERIN WILLIAMS: In the absence currently of Federal FDA action regarding cannabis derived products, specifically a hemp derived oil, what we have seen nationally is states adopting their own regulations regarding production

standards for hemp derived extracts or hemp derived oils, so in preparation for today's meeting, we took a look at what other states are doing, specifically their standards regarding adulterants or what they would deem to be adulterants of these products, substances that would make a product not fit for human consumption.

So we had looked at what Florida is proposing to do, how Massachusetts is operating, and we looked at Oregon and Colorado, and they did have various standards for specific adulterants.

We looked at regulations proposed in North Carolina that at this time do no, or at least the regulations as proposed that they have published do not include specific adulterants, nor does Kentucky have any specific list of substances it would deem to be adulterants for a hemp derived product.

But what we saw generally were efforts to regulate micro toxins, we would see specific, some specific iteration that would include aflatoxin B1, aflatoxin B2, aflatoxin G1 and G2 and ochratoxin A.

Some states also prescribe standards

regarding heavy metals, among the heavy metals that we saw regulated were arsenic, cadmium, lead and mercury.

2.

Some states also provided specific standards regarding maximum levels of microbiologicals that could be found in these products to include E.coli, listeria, salmonella.

Some states had requirements for maximum total yeast and mold numbers. Some states have also established pesticide limits for these products.

At this point we will -- I would like to hear the public's comments as to the regulation of or the standards for adulterants and hemp derived oils.

JEWEL BRONAUGH, Ph.D.: Dylan Bishop, did you have a comment you wish to make on adulterants of concern? And please feel free to stand where you are.

DYLAN BISHOP: Good afternoon,
distinguished panel. My name is Dylan Bishop, I
represent the Cannabis Business Association of
Virginia. Since that's a mouthful, I'll just
refer to it shorthand as Cannabis VA.

We represent growers large and small,

processors, dealers and also ancillary businesses like laboratory testing outfits, so on and so forth.

2.

So we polled our members and I particularly talked to our members that run laboratory testing outfits since they are subject matter experts, and in particular they wanted to address the pesticide testing.

The pesticide testing requirements that are both in the pharmaceutical processor regulations and the guidance given by VDACS on hemp derived oils for human consumption, it's pretty big. It doesn't provide a specific list. It says if you need to test for pesticides then do this but not do that, but are labeled as such.

Other states such as Maryland just gave their testing requirements for medical cannabis, I think it was June 14th of this year, but they just specifically listed the pesticides. There were, you know, of concern to the State and our testers constantly are saying we don't know which pesticides to test for with the guidance given to us particularly in the VDACS guidance for hemp derived oils for human consumption is pretty convoluted at best.

So if we could get just a specific list of pesticides with the active ingredients in those pesticides it would really be to the benefit of our laboratory testing outfits who cater to these markets in the Commonwealth.

2.

Also with regard to microbiological standards, both in the Virginia pharmaceutical regulations and also the Virginia Industrial Hemp Program, the guidance given out by VDACS for hemp derived oils for human consumption list by reference section 1111 of the U.S. Pharmacopeia.

Our laboratory technicians and scientists think that those standards are unduly low or restrictive. For example, the U.S. Pharmacopeia calls for total aerobic microbial counts for non (inaudible) preparations be less then a thousand Colony Forming Units or CFUs.

We would think that that is a little restrictive, might be unduly burdensome and really goes a little bit too far if we're only concerned about a normal patient population that doesn't have a severely incapacitated immune system with something like HIV or AIDS.

What we would suggest is follow guidelines similar to the Maryland Medical

1 Cannabis Commission's Technical Authority for 2. medical cannabis testing that would include 3 standards that are, that would require a hundred thousand CFU program or less of total aerobic 5 microbial count, ten thousand CFU program or less 6 of total combined yeast and molds, one hundred or 7 less CFU per gram of E.coli, and salmonella 8 testing standard of non detected purgy (phen) for 9 none found in the testing sample. JEWEL BRONAUGH, Ph.D.: 10 Okay. Mr. Sam Johnston, do you wish to 11 you, Mr. Bishop. 12 comment on adulterants of concern? 13 SAM JOHNSTON: Thank you, no comment 14 on this topic. 15 JEWEL BRONAUGH, Ph.D.: All right. Tom Piccariello. 16 17 TOM PICCARIELLO: I have no comment. 18 JEWEL BRONAUGH, Ph.D.: Okay, thank 19 you. And Seth Richardson. 20 SETH RICHARDSON: Hello. Let's go down the list. Let's start with heavy metals. 21 22 represent Kingsland Partners, we are registered 23 growers and processors in the state of Virginia. 24 We have recently had product tested 25 as a CBD extract under California standards and

passed with flying colors. It's not difficult.

2.

The arguments for lower microbial -- or higher microbial limits I feel are not valid.

It just opens up the potential range of problems that could be encountered.

And so many people who are growers in this industry are learning, and I do not believe it is necessary to lower the standards for everybody to learn at this point in time. And every soil in Virginia is not suitable to grow industrial hemp on.

So under the California standards using best management practices, that's what I would encourage Virginia to follow. I know I'm not a popular person in this room at this time saying these things, but they aren't hard to achieve if you're paying attention to your protocols and procedures, your extraction procedures.

We even had an example where in one of the extracts we produced we showed minor traces of lead. In talking with Evolabs in California, they had noted that blue cobalt bottles from China had traces of lead.

So we made sure when we sent one of

the samples in, we sent it in for a bottle that was blue cobalt, and we showed .2269 milligrams or micrograms of lead, but we're a 10th of the legal limit in California, but the source was from 30 days in this blue cobalt bottle.

2.

So really it takes paying a lot of attention to your growing, your extraction, but also to the materials you're packaging your product in.

As far as pesticides I think a good standard would be any pesticide that is not OMRI, O-M-R-I, listed should be tested for because that would be prices that are suitable for food product consumption.

But again, the California models to me probably are a very good place to start as far as determining what guidelines Virginia needs to follow and they're not difficult.

Everybody, says oh, California, we can't meet those standards, I think it's very possible.

JEWEL BRONAUGH, Ph.D.: Thank you

Mr. Richardson. Is there anyone else who wishes
to speak, who did not sign up but wishes to speak
on this specific area?

ERIN WILLIAMS: So another common area that we saw hemp products or specifically hemp oils being regulated in other states pertains to the labeling that appears on the packaging.

2.

So we have one category of labeling requirements that is derived from current federal regulations that would include, and would be required of all packaged food, include product name, the net weight, an ingredient statement and the name and address of the manufacturer, distributor or packer of that product.

Then we also saw labeling requirements that were specific to hemp products that would include the number of milligrams of certain cannabinoids per serving in that product, a statement as to the THC concentration of the product, some requirements pertain to an expiration date for the product, prohibitions against specific statement on that label regarding that product.

And then there was often some requirements regarding the label including a batch number and information for or a method by which a consumer could obtain information regarding that batch.

JEWEL BRONAUGH, Ph.D.: All right, returning to my list. Mr. Bishop, do you wish to make a comment about labeling requirements?

2.

DYLAN BISHOP: Again, Dylan Bishop of behave of Cannabis VA, the association would like to see labeling requirements, certain cannabidiols we would like to see required, would be the total THC and the total CBD, this would not include the THCA or CBDA.

I think that falls in line with how VDACS does its testing out in the field. It's post decarboxylation which takes, from my elementary understanding of chemistry, its takes that THCA and THC and it all transforms into a total THC count.

So if that's the way the Commonwealth is going to do its testing, I think that our private sector companions ought to do it as well just to keep things uniform.

Cannabis VA would also like to see dosages listed on the labeling requirements. This would include the serving of dosage size and then a maximum daily serving or dosage.

Again, we would like to see the ingredients and then also stability information.

That would include manufacturing date, the best buy date or shelf life and then also an expiration date for a use within X number of days of opening. This would maintain the consumer safety and without being overly burdensome to our processors and manufacturers. Thank you.

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JEWEL BRONAUGH, Ph.D.: Thank you, Mr. Bishop.

Mr. Johnston?

SAM JOHNSTON: Thank you. My name is Sam Johnston, representing the Virginia Industrial Hemp Coalition. I'll just say that, and this might apply to some of the other matters that are coming up, with respect to the FDA process underway now. I believe that labeling is one of the matters that they're going to be opining on in their ruling.

And so I could encourage recommendations to the General Assembly to basically narrow the -- we anticipate that those labeling provisions will be appropriate.

We would hope that the recommendations will not go beyond that, but I will also say given that November 1 is the deadline for the Secretaries to present and maybe you know, but I don't know when, and we anticipate that the FDA is expected to do interim rule making given that the final rule making is probably going to take quite some time.

2.

So in the event that that interim rule making occurs after November 1st, it may well be that you're going to have to revise some of what you say to the General Assembly, having reviewed that ruling.

So I just would expect that that would be the case and we will be notified, but I hope that we will strongly sort of be directed to a certain extent by what the FDA says and not be more restrictive than that. Thank you.

JEWEL BRONAUGH, Ph.D.: Thank you, Mr. Johnston. Mr. Piccariello.

SETH RICHARDSON: Tom Piccariello.

I'm with ChyloCure a hemp processing facility in Blacksburg, Virginia. I'm here with Jim Politis, he's my partner, I think you all know him.

I just have two comments. One is on the prohibition against any product that is intended for the diagnosis, cure, medication, treatment or prevention of a disease, that is a statement that says what you can't do. There might be, your policies should state some of the

things that you can do.

2.

And you can find some guidance of this if you go to DSHEA, Dietary Supplement Health and Education Act, they will provide -- they have a language in there that directs one how, what one can say about the, about what it can do. So that was just one thing, I wanted to make a point about that.

The other point is I think -- if I understand Mr. Bishop correctly, he said that the label should contain a sum of THC and THC -- THCA and THC, excuse me.

And if that's true, I think that will probably make a lot of people's product hot. The sum of THCA and THC is going to be above .3 percent, I think on almost every vine because I think right now, what I'm understanding right now, the farmers are having trouble trying to meet that .3 percent THC level without going above a CBD content of 7 percent.

They go above -- if they go up to like 10 or 12 percent with the maximum, the plant to produce, if they try to push it to that level the THC level goes up above .3, so now they're product is hot.

So there is an issue there and maybe later on I'd like to, in the general comment section, I'd like to make a comment about that THC percentage.

2.

I'm not sure this is the right forum to do that, but if I say this wrong, or it's the wrong time to say it, just tell me to sit down and go over it another time, but at the end I'd like to talk about that.

JEWEL BRONAUGH, Ph.D.: Thank you, Mr. Piccariello. Mr. Richardson.

SETH RICHARDSON: I love getting to go last. The number of milligrams in certain cannabinoids per serving, in the work we have done in looking at many different cannabinoids and their different effects, the difference between the affect of CBDA versus CBD, the difference between effective THC versus THCA, they are drastically different, and for the consumer who is consuming that product it would be important to have a threshold of testing whether it is at .01 milligrams or .001 milligrams, either per serving or per ml. on the bottle.

And this is just the beginning of the hemp industry as we look at the number of

different compounds that potentially have beneficial effects, it will be important for the consumer to have some form of understanding of that.

And the argument of products testing hot, as a general rule in the formulation of these products for public sale, you're looking at a dilution of the original stock material that should test at .3 percent.

It is concentrated in the extraction process, but as a general rule it is then diluted again into a carrier before it is dispensed.

And so the .3 concentration level poses to me no problem. Combined THC and THCA should be no problem at the .3 percent if you're paying attention to your formulation, and you would have to be using material that is testing above 1 percent that once you dilute it -- commonly when the CO2 extraction is done, we're looking at 3 to 4 percent total THC and that CO2 extracted material is then diluted in the carrier down to a level where it is below, well, well, below the .3 percent.

And when we're looking at -- that's just a good summation there. All the rest I

strongly agree with and love getting to go last.

2.

JEWEL BRONAUGH, Ph.D.: Thank you, sir. We're going to testing requirements. Is there anyone else who did not get a chance to speak who wishes to speak on labeling requirements?

ERIN WILLIAMS: We looked at some of the testing that is required or proposed to be required in these other states that have begun to regulate the products.

Testing requirements, we found batch testing requirements, we found requirements regarding expectations of the laboratories, independent laboratories that are doing testing for the industry.

We found requirements regarding the information that the manufacturer must make available to both the regulator and to the consumer, whether that be providing a certificate of analysis from the test, the test lab, or another method of conveying information regarding the product and the testing that was done on the product.

JEWEL BRONAUGH, Ph.D.: Mr. Bishop, do you have any comments pertaining to testing

1	requirements?
2	DYLAN BISHOP: Yes. Again Dylan
3	Bishop on behalf of Cannabis VA. We would like to
4	see testing requirements both of the active
5	ingredient and then the final product of course by
6	batch.
7	Again, and I'll reiterate, we would
8	also like to mandate stability testing at 6 months
9	and one year intervals and that would include
10	stability testing of the cannabinoid content,
11	microbiological impurities and then water
12	activity. Thank you, ma'am.
13	JEWEL BRONAUGH, Ph.D.: Thank you.
14	Mr. Johnston?
15	SAM JOHNSTON: No comment right now.
16	Thanks.
17	JEWEL BRONAUGH, Ph.D.: All right.
18	Mr. Piccariello.
19	TOM PICCARIELLO: I have no comment.
20	JEWEL BRONAUGH, Ph.D.: Okay.
21	Mr. Richardson.
22	SETH RICHARDSON: So when we talk
23	about batch testing, which level of the product
24	are we looking at batch testing?
25	ERIN WILLIAMS: It ranged, depending

on the state whether -- it varied, and that's a topic of discussion, too.

SETH RICHARDSON: Whether it's a batch from a grower or a batch from a processor or the batch at the level of the final product, which is where your batch number comes into effect.

Batch testing at the grower level I feel is relatively unnecessary, batch testing at the level of the processor is basically your own liability policy which if you are a good processor you should be doing that anyway.

As a, for general public safety it is highly important that that certificate analysis be available at a minimum to the regulators on request.

ability to read that testing and understand the parameters of it, really not necessary. It is a difficult hurdle for a consumer to really understand the level at which products have been tested, whether it's to .01 milligrams THC and did not show up and then the consumer so low well here is a THC free product, which is only to that level.

So it's a big question, it is up to

how to approach it especially for the consumer level.

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Labeling in terms of THC free is a big question because if you are somebody who has a form of employment where drug testing is part of your job, you want some reliability in terms of the product that you are consuming, so.

JEWEL BRONAUGH, Ph.D.: Thank you.
Yes.

Ms. Commissioner, I'd DYLAN BISHOP: like to offer a point of clarification. When I said, when we were talking about the testing requirements, it's the view of our association that both THC and THCA, CBD and CBDA would all be It was only within the labeling requirements, what the consumer would see, is in the association's opinion that just hulled THC and hulled CBD be listed, not necessarily every other THCA, CBDA, and it would be the association's assertion that for minimal standards as to what is legal or marketable or not, that would be that delta 9 THC not hulled THC, so a little distinction between the consumer facing labeling and then what is required of these agencies that would be administering and enforcing these.

JEWEL BRONAUGH, Ph.D.: Thank you,
Mr. Bishop, for that clarification. Is there
anyone else who wishes to speak? Yes.

2.

SETH RICHARDSON: May I make a point?

JEWEL BRONAUGH, Ph.D.: Yes.

SETH RICHARDSON: The difference between CBDA and CBD is drastic. An extract containing primarily CBDA will keep you awake during the day, whereas CBD will put you to sleep, a very important point for a consumer not readily understood on the market the differentiation between the two.

Tom works with CBDA products that are for pain, but if you're taking a product for pain during the day, that's one thing, if you're taking a product for pain in the evening, which now we're talking about what can we describe its uses as, it's a big difference.

And people need to begin to understand these differences between the different acid and non acid forms of the cannabinoids. The difference between THCA and THC, THC is psychoactive, THCA affects those same channels as NSAIDS, aspirin, Tylenol, and has that affect, and is non psychoactive, big difference in terms of

what you are consuming.

2.

But this is the leading edge of the industry having everybody understand the nuances, the differences, does a product have CBN in it, does it have Delta 8 in it, and much less does a product contain a wide spectrum of all these cannabinoids or just a very highly concentrated form of one of the cannabinoids.

Again, the effects, the uses, are going to become very important as we understand more about all these compounds, much less the interaction of terpenes with them and all kinds of other things we just haven't named yet, so.

JEWEL BRONAUGH, Ph.D.: Thank you,
Mr. Richardson. Is there anyone else who wishes
to speak on the testing requirements?

TOM PICCARIELLO: I would just like to follow up to make sure we understand -- again Tom Piccariello, ChyloCure. When we're talking about THC and THCA, it's really talking about the sum because THCA readily converts to THC.

So if you have a product on the shelf and it contains some THCA and contains some THC, as it sits on the shelf that THCA is (inaudible) so that's something that people should be aware of

in terms of the THCA content and the THC content.

2.

I think it's important to understand that the sum is also something that should be considered and the THC level itself is not necessarily a measure of potential psychoactivity, it's actually the sum of two.

JEWEL BRONAUGH, Ph.D.: Thank you. Anyone else? Okay, and we will move forward to reciprocity for products manufactured under inspection in another state.

reciprocity between states for products
manufactured in another state, what we see is a
general sense among food safety regulators that
their peers in the other state have inspected the
facility under the food safety regulations of that
state, the facility at which these products are
being produced. So they're looking for that
inspection to then be able to deem a manufacturer
as an approved source.

JEWEL BRONAUGH, Ph.D.: Mr. Bishop?

DYLAN BISHOP: Yes, ma'am, Dylan

Bishop on behalf of Cannabis VA. I apologize for being redundant, but you guys like to have that for the record.

1	Cannabis Business Association of
2	Virginia would like to see reciprocity agreements
3	require the products sold in Virginia to meet or
4	exceed Virginia standards.
5	We know that this is a vulnerable
6	industry, public perception is at best still
7	undecided, we would like to ensure consumer safety
8	and also protect the viability of Virginia based
9	growers and processors. Thank you.
10	JEWEL BRONAUGH, Ph.D.: Thank you.
11	Mr. Johnston.
12	SAM JOHNSTON: I would tend to agree
13	with that, with Mr. Bishop. Thank you.
14	JEWEL BRONAUGH, Ph.D.:
15	Mr. Piccariello?
16	TOM PICCARIELLO: I have no comment.
17	JEWEL BRONAUGH, Ph.D.: All right.
18	Mr. Richardson?
19	SETH RICHARDSON: No comment.
20	JEWEL BRONAUGH, Ph.D.: All right.
21	The last area, if there are any other areas that
22	you feel have not been addressed in anything that
23	we discussed today, I will start with the list and
24	ask for your feedback and we will open it up to
25	any others who wish to speak.

1 Mr. Bishop, is there anything else you wish to add? 2 3 DYLAN BISHOP: I do not believe so, if you wouldn't mind just coming back to me. 4 Ι 5 may have something later on. 6 JEWEL BRONAUGH, Ph.D.: 7 Mr. Johnston? So this is 8 Thank you. SAM JOHNSTON: 9 an issue that is a little bit outside the scope of what you do, but you might be able to help with 10 11 it. 12 As an attorney in Virginia I have 13 been made aware of some circumstances in which there has been a lack of knowledge or some 14 15 confusion on the part of law enforcement, and the 16 problem of course that I am speaking to is the lack of a field test where law enforcement can 17 18 test a hemp shipment to see whether its hemp or 19 marijuana. 20 In other words they can test to see 21 if the product has the presence of THC, but they 22 can't test to see if it exceeds the threshold of 23 0.3 percent. Now I know that the Department of 24 25 Forensic Sciences is working on this issue now,

and I know that, you know, law enforcement and the attorney general have been talking about it, but I just wanted to make you aware that this is a problem that does need a solution.

2.

And I don't know, I've heard from one source at DFS that there may be forthcoming a test that would test for the CBD to THC ratio or the THC to CBD ratio.

So for example if they test a hemp shipment and it comes out higher CBD than THC, well, that's not definitive, it doesn't tell you 0.3 percent or not but it does tell law enforcement something. It tells them that this is probably a legitimate hemp shipment if it's the ratio.

So that would, that could be something that you could encourage in whatever discussions you have with law enforcement because as of now they are -- and by the way, congratulations on hitting a thousand hemp growers in the state -- but that means there is going to be a lot shipments being trucked around, and there is going to be a lot terpenes in the air so to speak.

And you know, law enforcement, you

know we want to support law enforcement, we want them to be able to be comfortable and, you know, and have a good working knowledge of the law and be able to enforce them. Because I know that there have been instances in which for example through a bizarre set of circumstances the parents had, might be threatened with an officer for endangering, for child endangerment for providing a CBD vape to her child, who then got caught with it in school.

2.

Things like that are happening, okay. It's a problem that, you know, so to whatever extent you can help law enforcement, help the Department of Forensic Sciences advance a test that law enforcement can use in the field, and I know the USDA is working on this, too.

JEWEL BRONAUGH, Ph.D.: Thank you, Mr. Johnston. Mr. Piccariello.

TOM PICCARIELLO: Yes, it was alluded to earlier about the THC content in hemp. I'm particularly concerned about the grower, I know this is not a forum that deals with growers, so this is going to be outside of the purview of what we're talking about, but I think it's an important thing to address at mini meetings, and that is

there is going to be some issues with farmers being able to comply with .3 percent rule.

2.

I think there is going to be a lot farmers who are going to be very disappointed in what is going to happen to their product.

The .3 rule from what I understand is from a study that was done quite a few years ago, which I looked at the study and it's not a statically validatable.

So the .3 percent rule is not really based on sound science in my opinion. I think that .3 percent rule can be based on sound science and statistically validatable data.

It's not going to happen this year, I understand that, but I want the VDACS and the Board of Pharmacy to be aware that I think that we should be thinking about this, and we should be prepared for certain things that are going to be very disappointing to the farmers and maybe some of the processors, I don't know about that,

Mr. Richardson thinks the processing is okay, I tend -- I don't disagree with that, but I think the farmers could be, are going to be seriously concerned about that .3 percent rule.

I'll be more than happy to talk to

you about how I would approach this problem at another time.

JEWEL BRONAUGH, Ph.D.: Thank you.

TOM PICCARIELLO: You're welcome.

JEWEL BRONAUGH, Ph.D.:

Mr. Richardson.

2.

SETH RICHARDSON: All kinds of open fields here. And all this centers around the .3 percent, being able to test it readily in the field as necessary, which at this time is very difficult.

I have worked with scientists on atmospheric solids analysis probes where we were actually measuring ratios of CBD to THC, but it's not a field ready test and the ratio is not infallible.

As Erin and Kevin and I sat down last year in our office and went through it and trying to validate it and I was on the losing end of that one.

So a ratio is probably not the best test, the current test now is a presumptive test and presumptive means you rely on one side or the other and that further testing is necessary to find the true answer as to what is going on.

As a grower with the .3 percent we have been rigorously testing our material in the field and to date we are still under, well under the .3 percent. Most of the product runs at .2 or lower at this point.

2.

When we had a very hot week last week nothing moved when we retested. So we can look at environmental conditions and what we do know is that as temperatures cool in the fall, the longer you wait, the greater potential for your THC, total THC levels to rise. And actually it's THCA in the whole testing realm.

And there are lot of growers who would like to wait later because their CBD levels, CBDA levels will rise in their plants but at the same time there is the risk of THCA levels rising.

Currently in Virginia we're looking at what I would consider ideal growing conditions for CBDA and that is hot and dry, and the longer it stays that way, the longer it's in our favor.

And we know from testing of growers last year when we had exceedingly wet conditions we had a lot of growers, even on fiber crops, fiber and seed crops under wet conditions tested triple the level of what they thought they were

going to be at.

2.

So much of it is weather related. NC State did a set of tests where they looked at levels of nitrogen as far as effecting THCA production, found no influence, so it's not fertilizer. It's going to be hot and dry versus wet and cold.

So just like a grape crop or a wine grape crop, as we see this could be a very good year for grape growers in Virginia, same thing with hemp growers.

The genetics of the plant as we see it and use it now are in their infancy, there are so much variability, and I'm sure from the applications that have been filed and the playing reports the number of difficult cultivar strains of industrial hemp that are being grown in Virginia is probably in the hundreds, with many names that none of us know the genetic background of. I can even say that for the strainings that we grow because they are our seedling selections and our process.

So when we start looking at the genetics of it, in the near term it's difficult.

In the long term I believe we will see breeders

select plants that are more favorable to Virginia climate and to maintain that .3 percent level.

2.

Well at the same time here we are in the here and now and it's a difficult area. I would rather see some leeway on the .3 percent to .6 rather than leeway on mycotoxin microbials and lead in heavy metals.

Those are things that once they reach the consumer's hands we can't take back. We have no chance at that point as far as THCA, THC levels, those are things that processers can dilute, can have an effect on, and I know that Virginia reversed itself on food products.

I would like see some reversal for this fall's crop to allow everybody a little bit of leeway knowing that the processors have the ability to change the final outcome.

JEWEL BRONAUGH, Ph.D.: Thank you.

Is there anyone who has not had an opportunity to speak or did not sign up for public comment and wishes to make any general comments as they pertain to the production standards of industrial hemp derived oil?

KYLE SHREVE: Kyle Shreve, Madam Commissioner, of the Virginia Agribusiness

Council. I just want to thank you and represent to the Board of Pharmacy, the Department of Health and Human Services as well as the Secretary of Agriculture and Forestry, for taking the time to develop standards.

2.

I think one thing that everybody can agree on while we talk about the details is that we need some type of standard both to give producers clarity on what the rules of the road are, give the processors clarity and give consumers clarity so that there isn't any confusion.

So I really do appreciate, the industry appreciates you taking the time to get these right, to get a state action plan submitted to the USDA so that the industry has certainty, we don't keep -- I said this very similar to the Board of Agriculture and Consumer Services due to the provisions in the Farm Bill it is already being sold here in the Commonwealth and so making sure that we don't continue to fall behind in ensuring consumer safety and strengthening the industry for our farmers, for our processors and for our consumers. We really appreciate it.

JEWEL BRONAUGH, Ph.D.: Thank you,

Mr. Shreve. Farm Bureau?

BEN ROWE: Ben Rowe, speaking on behalf of the Virginia Farm Bureau. I just want to say thank you for the opportunity to be involved in this process both today and since the passage of the 2018 Farm Bill.

I would just like to say that this is a very important crop in Virginia with a lot of promise and you've seen the numbers for how many growers are out there providing them with regulatory certainty is very important.

We would like to see VDACS as the regulatory agency for the crop just like it is for wheat, corn or shellfish, all the other products grown in Virginia that go into our food, that are used in pharmaceuticals and other products, having certainty in having a standard is going to make this a safe product, not only for those taking a risk of growing it but also (inaudible) Thank you.

JEWEL BRONAUGH, Ph.D.: Thank you,
Mr. Rowe. I think that covers everything with the
presentation. If there is no one else who has
comment, then I would like to invite Deputy
Secretary Copenhaver and Deputy Secretary Figueroa

1 to make some final remarks. 2. BRAD COPENHAVER: Thank you, 3 Commissioner, and I'm speaking for both Marvin and I here. I just want to say thank you again to everyone for coming out today. We know that this 5 6 was a chunk of time out of your day, but we 7 really, really appreciate you coming to join us 8 and share your thoughts and your expertise as we 9 continue throughout this process. So again, the report is due by 10 November 1st to the General Assembly, so we're 11 12 going to continue to work over the next couple of 13 months to finalize those recommendations. 14 If you have any other questions, feel 15 free to reach out to our office and we are happy 16 to answer it and engage. So thanks again for 17 coming. 18 JEWEL BRONAUGH, Ph.D.: Thank you. (The meeting concluded at 3:20 p.m.) 19 20 21 22 23 24

25

1 CERTIFICATE OF COURT REPORTER 2

I, Colleen Good, hereby certify that I was the Court Reporter for the Public Meeting on the report by the Secretaries of Agriculture and Forestry and Health and Human Resources held at 1111 E. Broad Street, Richmond, Virginia, on September 4, 2019 at the time of the hearing herein.

I further certify that the foregoing transcript is a true and accurate record of the hearing herein.

Given under my hand this 25th day of September, 2019.

16 COLLEEN GOOD, CCR, Court Reporter

20 My Commission Expires:

21 September 30, 2023

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Appendix Two

Gram (g)

Kilogram (kg)

Microgram (ug)

Part per million (ppm)

Part per billion (ppb)

Colony Forming Unit (CFU)

Table 1

Mycotoxins					
	Aflatoxin B1	Aflatoxin B2	Aflatoxin G1	Aflatoxin G2	Ochratoxin A
VA Board of Pharmacy	<20 ug/kg	<20 ug/kg	<20 ug/kg	<20 ug/kg	<20 ug/kg
Florida	20 ppb	20 ppb	20 ppb	20 ppb	20 ppb
Massachusetts	<20 ug/kg	<20 ug/kg	<20 ug/kg	<20 ug/kg	<20 ug/kg

Table 2

Heavy Metals				
	Arsenic	Cadmium	Lead	Mercury
VA Board of Pharmacy	<10 ppm	<4.1 ppm	<10 ppm	<2 ppm
Florida	1.5 ug/g	0.5 ug/g	0.5 ug/g	3.0 ug/g
Massachusetts	Max 1500 ug/kg	Max 500 ug/kg	Max 1000 ug/kg	Max 1500 ug/kg
	[1.5 ppm]	[0.5 ppm]	[1 ppm]	[1.5 ppm]

Table 3

	Microbiologicals	Residual Solvents	
VA Board of Pharmacy	Section 1111 of the US	American Herbal Pharmacopia	
VA Board of Final macy	Pharmacopeia	for Cannabis Inflorescence	
	E.coli: none present		
Florida	Listeria: none present	US Pharmacopeia	
	Salmonella: none present		
	Aerobic Bacteria: 10 ⁴ CFU/g		
	Total Yeast and Mold: 10 ³		
	CFU/g		
Massachusetts	Total Coliforms: 10 ² CFU/g	Appears to be based on US	
Wassachusetts	Bile-tolerant Gram-neg Bact:	Pharmacopeia	
	10^2 CFU/g		
	E.coli and Salmonella:		
	Not detected in 1 g		