

Jewel H. Bronaugh, Ph.D. Commissioner

Department of Agriculture and Consumer Services Division of Animal & Food Industry Services Office of Dairy & Foods

PO Box 1163, Richmond, Virginia 23218 Phone: 804-786-3520

July 25, 2019

Dear Registered Industrial Hemp Processor:

On July 15, 2019, the Commissioner of Agriculture and Consumer Services informed those who were registered as Industrial Hemp Processors at that time that the Northam Administration provided a path forward for Registered Industrial Hemp Processors interested in producing hemp-derived extracts intended for human consumption. Section 2.2-103(A) of the Code of Virginia authorizes the Governor to formulate policies of the executive branch. Under this authority, the Northam Administration has formulated a policy for VDACS to follow in order to provide some oversight over hemp-derived extracts intended for human consumption. This letter will outline the policy and explain the steps you should follow if you would like to manufacture such a product.

Below are the policy directives that VDACS will administer:

- VDACS shall treat a hemp product containing a hemp-derived extract intended for human consumption, such as a hemp-derived CBD oil, as an approved food ingredient or approved dietary supplement.
- VDACS shall require that an entity who, in Virginia, manufactures a hemp product containing a hemp-derived extract intended for human consumption from the raw industrial hemp plant (i.e., an Industrial Hemp Processor registered pursuant to the Virginia Industrial Hemp Law) comply with the food laws and regulations pertaining to food manufacturing, including 21 C.F.R. Part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (GMP). Food shall not be labeled or marketed as supporting human health or as a treatment for a medical condition.
- VDACS shall require that an entity who, in Virginia, manufactures a hemp product containing a hemp-derived extract intended for human consumption from the raw industrial hemp plant (i.e., an Industrial Hemp Processor registered pursuant to the Virginia Industrial Hemp Law) that appears to be labeled or marketed as a dietary supplement comply with the food laws and regulations pertaining to dietary supplements, including 21 C.F.R. Part 111, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.
- VDACS shall deem as an approved source those out of state manufacturers who are manufacturing a product containing a hemp-derived extract intended for human consumption in

compliance with the food laws and regulations in the state in which the entity is manufacturing the product.

- VDACS shall require that retail food establishments offering for sale a product that contains a
 hemp-derived extract intended for human consumption offer only those products produced in
 compliance with the food laws and regulations of the state in which the product is manufactured.
- Hemp-derived extracts intended for human consumption shall meet the standards stated below, which are standards that are included in the regulations promulgated by the Virginia Board of Pharmacy for the production of the cannabidiol oil product that it regulates.

Microbiologicals	
A hemp-derived extract intended for human consumption shall satisfy the standards set forth in Section 1111 of the United States Pharmacopeia.	
Mycotoxins	
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance
Heavy Metals	
Arsenic	<10 parts per million (ppm)
Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm
Residual Solvents	
A hemp-derived extract intended for human consumption shall meet the standards and limits recommended by the American Herbal Pharmacopoeia for Cannabis Inflorescence.	

- Only residue from pesticides that meet the following requirements may be present in a hempderived extract intended for human consumption:
 - 1. The active ingredient is exempt from the requirements of a pesticide tolerance on all food crops (i.e., auxins, select biopesticides, copper, cytokinins, gibberellins, petroleum oil, phosphorous acid, pyrethrins, soap, sulfur, common consumer food commodities, edible

- fats, and oils). Information regarding food tolerances for pesticide ingredients may be found on the U.S. Environmental Protection Agency's (EPA) website; and
- 2. The label has directions for use on unspecified food crops (e.g., bedding plants); and
- 3. The pesticide is registered by EPA or exempted from registration; and
- 4. The pesticide is registered by VDACS; and
- 5. The label language is sufficiently broad to include hemp and does not specifically prohibit its use on hemp.
- Hemp-derived extracts intended for human consumption shall be produced from industrial hemp grown in compliance with federal or state law.
- Hemp-derived extracts intended for human consumption shall have a tetrahydrocannabinol (THC) concentration of no greater than 0.3 percent.
- VDACS may conduct random testing of a hemp-derived extract intended for human consumption or a product containing such an extract.
- VDACS shall not determine that an entity manufacturing, distributing, or selling a hemp-derived extract intended for human consumption or product containing this extract that complies with the directives outlined in this letter is in violation of the Virginia Food and Drink Law and regulations adopted thereunder.

VDACS's Food Safety Program administers the Virginia Food and Drink Law and regulations. Currently, the Food Safety Program is able to inspect new food businesses, including dietary supplement manufacturers, within approximately 60 days of receiving a completed application. If you intend to manufacture a hemp-derived extract intended for human consumption, you will need to apply to operate as a Manufacturer of a Hemp-Derived Extract Intended for Human Consumption. Before you apply, you should review the Virginia Food and Drink Law (Va. Code § 3.2-5100 et seq.) and applicable regulations as well as guidance for completing the application, all of which can be accessed via VDACS's Office of Dairy and Foods' webpage. You may also call the Food Safety Program office at 804-786-3520.

Section 3.2-5130 of the Virginia Food and Drink Law requires that your food processing and storage areas be inspected prior to starting your food operation. An inspection of your operation will not be conducted until all of the necessary information requested in the application has been reviewed and approved by the VDACS Food Safety Program. The Food Safety Program will notify you when it has completed its review of your application. There is an annual \$40.00 fee for operating a food processing business in Virginia. VDACS will invoice you for this fee during the billing cycle following your initial inspection. You will not be required to pay this fee at the time of your initial inspection.

Please be aware that, as required by the hemp legislation enacted by the 2019 Session of the Virginia General Assembly (i.e., Chapters 653 and 654 of the 2019 Acts of Assembly), the Secretaries of Agriculture and Forestry and Health and Human Resources are working on a report to the General Assembly regarding standards appropriate for the production of hemp-derived oils. As such, in the coming months, you may hear of possible standards that are different from those outlined in this letter. Please know that any standards drafted or discussed outside of what is outlined in this letter are intended to be recommendations to the General Assembly for its consideration during the legislative session starting in January 2020. Until further notice from VDACS, if you intend to produce a hemp-derived

extract for human consumption, you should comply with the food safety standards outlined within this letter.

Sincerely,

Ryan Davis

Program Manager

Office of Dairy and Foods

Ryan W. On-