West Virginia Department of Agriculture Proposed Industrial Hemp Plan

West Virginia Industrial Hemp Development Act West Virginia Code §§19-12E-1 *et seq*.

West Virginia Legislative Rule for Industrial Hemp West Virginia Code of State Rules 61-29

Date of Submission: January 23, 2020

Proposed Effective Date: October 31, 2020

Overview of program

In 2002, the West Virginia Legislature passed the Industrial Hemp Development Act, which created the framework for legalized industrial hemp in West Virginia and paved the way for the growth and cultivation of industrial hemp in the State. Following passage of the 2014 Farm Bill, which authorized states to establish pilot programs for industrial hemp research, the West Virginia Department of Agriculture (WVDA) acted swiftly to implement the pilot program, based on the authority already granted in state law.

Since the inception of this pilot program, interest and investment in industrial hemp in West Virginia has grown exponentially. From 2017 to 2019, the number of license-holders increased from 46 to 165, and the acreage registered with the program recorded a corresponding increase, quadrupling to 641 planted acres over the same time frame. For the 2020 growing season, WVDA received 456 applications to grow and/or process hemp.

WVDA's current regulations and practices under its pilot program are very similar to those required by the Interim Final Rule. This means that West Virginia is well positioned to make a smooth transition into operating under a USDA-approved hemp plan. This document is an outline of the West Virginia Department of Agriculture's Industrial Hemp Program and is WVDA's formal submission to the USDA for review and approval.

Application process

WVDA will designate a time period for interested parties to apply for an industrial hemp license. Licenses will become effective, upon approval of the submitted application, for the calendar year for which the application is made and will expire on December 31 of that year. To participate in the WVDA's industrial hemp program, the applicant must complete the most current WVDA hemp application, submit geospatial coordinates and other required information concerning land where hemp operations will be performed, provide state and federal background checks and both an application and licensing fee.

Compliance Statement

By signing and submitting his or her industrial hemp application, each applicant understands and acknowledges that he or she is being licensed to grow hemp under the limited authority granted by the USDA Interim Final Rule on Hemp, the West Virginia Industrial Hemp Development Act and the WVDA through its Hemp Program. The applicant acknowledges and agrees that the actions of all individuals employed by or contracting with the applicant, and that the operations on all sites registered to the licensee are the responsibility of the applicant and can be imputed to the applicant for purposes of regulation by WVDA. Furthermore, the applicant acknowledges and agrees to the following terms and conditions:

- Any information provided to WVDA, except criminal history records provided to WVDA, may be publicly disclosed and be provided to law enforcement agencies without further notice to the applicant;
- The applicant agrees to allow any inspection and sampling that WVDA considers necessary;
- The applicant agrees to pay for any sampling and analysis costs that WVDA considers necessary;
- The applicant agrees to submit all required reports by the applicable due-dates specified by the Commissioner; and
- The applicant agrees to update information with WVDA as changes occur to the information submitted on applications.

Validation & Review of Applications

WVDA will review each application to ensure that all requested information has been provided. If the application is deemed incomplete, the applicant will be given an opportunity to provide the missing information before the application is rejected. Any applicant convicted of a felony for a controlled substance within the past 10 years will be ineligible for licensing. Any land owned by an individual with a felony conviction for a controlled substance within the past 10 years may be ineligible for inclusion on a license. Any other felonies of which an applicant has been convicted within the preceding 10 years will also be reviewed and may result in ineligibility.

License Process

All applicants who submit complete applications and otherwise satisfy all the requirements of the program will be issued a license. The license will be specific to, and will list, locations where the licensee is permitted to grow, process, cultivate, store, or handle raw industrial hemp. Applicants are responsible for both themselves and all individuals involved with planting, maintenance, harvesting, and processing of the industrial hemp grown under their license.

Information Maintenance & Reporting

WVDA maintains files for each licensee that contain contact information, application, license, geospatial location, legal description of land, sampling invoices, sampling chain of custody, THC results, all fees collected, key participants' names and titles, state and federal background checks for applicants (including key participants, where applicable). All records are kept on file for at least 5 years. While records are kept confidential in the ordinary course of operations, some or all of those records may be subject to the state's Freedom of Information Act, W. Va. Code §§29B-1-1- et seq., and subject to disclosure upon request.

WVDA will provide USDA with contact information for each licensee covered under the plan, including: name, address, telephone number, and email address. If the licensee is a business

entity, WVDA will provide USDA with the full name of the business, address of the principal business location, full name and title of the key participants, an email address, and the business entity's FEIN number. WVDA will also provide USDA with a legal description for all land licensed for the production, storage, growing, processing, or handling of raw industrial hemp, including a geospatial location for each site. WVDA will further provide USDA updates on the status of each license, including any status changes. All information reported to USDA will be submitted in accordance with its reporting requirements. WVDA will also report hemp crop acreage to the USDA Farm Service Agency.

Site Monitoring

Site inspections will be performed the same time pre-harvest samples are collected for THC compliance testing. Authorized WVDA representatives will perform site inspections to ensure compliance with State and Federal rules for hemp production in West Virginia. For the 2018 and 2019 growing seasons, WVDA successfully sampled and tested licensed locations within West Virginia, and will continue to do so. Site inspections may also be performed for other purposes, including research, education, collection of information, and compliance verification. WVDA intends to partner with USDA agencies, land grant institutions, and others to collect production and agronomic data for developing soil amendment, pest control, and recommendations for conservation best-management practices.

Field Sampling

Each licensee must contact WVDA at least 30 days prior to harvest of their licensed crop to schedule a time for sample collection. This timeframe allows adequate time to arrange for sample collection and delivery to the WVDA or equivalently accredited USDA approved laboratory for testing. Each growing area and variety (lot) will be sampled and tested to ensure that the post-decarboxylated tetrahydrocannabinol concentration level ("total THC") does not exceed 0.3%, plus the measurement of uncertainty. Harvesting cannot occur until a WVDA representative has inspected and sampled that specific variety and/or location. Samples of hemp plant material from one growing area or variety (lot) shall not be commingled with hemp plant material from other lots. Each licensee is responsible for the costs associated with sampling and testing. Once a lot has been tested by WVDA and found to be compliant, it can enter the market.

During sampling, WVDA will collect hemp flower material from each variety or location (lot). The licensee or a designated employee shall accompany the WVDA representative throughout the sampling process. The WVDA representative shall verify the GPS coordinates of the growing area and compare them with the ones submitted by the licensee to ensure that the location was properly registered. The WVDA representative shall estimate the average height, appearance, density, plant condition, and degree of maturity of the inflorescences—or flowering buds. The WVDA representative shall visually establish the homogeneity of the stand to confirm that the growing area is of like variety. The sample size must be of adequate volume to accommodate laboratory tests and to ensure that the sample is representative of the lot. The WVDA representative will utilize a paper bag and a hand pruner for collecting sample cuttings, securely

seal each bag, and record the sample number. The WVDA representative will fill out a chain of custody form and sampling invoice for hemp samples taken at each location.

Lab Testing

The WVDA laboratory is one of ten labs in the country designated with a Level 1 status from the USDA Food Emergency Response Network. The WVDA laboratory scientists are internationally recognized for their research and method development activities. All WVDA READ Laboratories follow ISO Quality System Management Procedures, Technical Standard Operating Procedures, and Quality Manuals, and maintain a consultant pharmacist regarding all matters related to schedule 1 drugs used for controls. WVDA currently has seventeen methods that are ISO17025:205 accredited, and has further applied for its method of measuring total THC to be likewise accredited. American Association for Laboratory Accreditation (A2LA) plans to perform the laboratory audit in January 2020 for this method. The WVDA laboratory is a DEA schedule 1 laboratory.

The WVDA laboratory follows sample preparation procedures to ensure that the entire sample received by the laboratory is adequately prepared and homogenized prior to analysis (*see* Attachment 1). Once the sample is received and adequately dried, it is passed through a sieve to remove large non-grindable materials before being ground into a fine powder (*see* Attachment 2). Analysis of the homogenized sample's total THC is conducted using an Ultra-High-Performance Liquid Chromatography machine to chromatically separate and quantitate both $\Delta 9$ -THC and THC-A. The formula [%total THC = % $\Delta 9$ -THC + (% $\Delta 9$ -THCA \times 0.877)] accounts for the loss of carbon dioxide from the THC-A that results from decarboxylation (*see* Attachment 3). All samples are initially tested with several controls per batch to ensure that results are precise and accurate. If the calculated results are above 0.3%, taking into account the measurement of uncertainty, the samples are retested for confirmation.

WVDA follows a strict procedure on the calculation of measurement uncertainty for THC analysis in hemp. WVDA's method is based on the A2LA Guides for Estimation of Measurement in Testing. Reference materials are used to calculate the standard deviation. The expanded measurement of uncertainty is calculated at a 95% confidence level (*see* Attachment 4). The calculated measurement of uncertainty is indicated on each final report in a +/- format. The acceptable hemp THC level is based on the application of the measurement of uncertainty to the reported total THC content concentration level on a dry-weight basis, producing a distribution of 0.3% or less.

Violations and Enforcement

If a sample is determined to be above the acceptable limit of total THC (0.3% + MU), the licensee will be notified by certified mail, the contents of which will direct the embargo of the lot in violation, until such time destruction of the crop can be completed. Methods of crop destruction are based on scale, available equipment, and effectively rendering the crop irrecoverable. All crop destruction is witnessed by WVDA employees, and report forms for all non-compliant plants will be submitted to the USDA.

WVDA will conclude that a licensee has negligently violated the state plan if it fails to provide a legal description of the land on which the licensee produces hemp or conducts hemp operations; fails to obtain a license or other required authorization from the West Virginia Department of Agriculture; or produces cannabis containing more than the acceptable level of total THC stated in the USDA Interim Final Rule.

A licensee will be required to comply with requirements established by WVDA to correct any negligent violation, including: (1) a reasonable date by which the licensee shall correct the negligent violation; (2) any requirement stipulating that the licensee shall periodically report to WVDA the licensee's compliance with the state plan for at least two calendar years from the date of the negligent violation (depending on the Commissioner's discretion); and (3) any other requirement deemed appropriate to address the negligent violation. A licensee who negligently violates the rules of the WVDA industrial hemp plan three times within a five-year period will be ruled ineligible to produce hemp in West Virginia for a period of five years beginning on the date of the third violation. WVDA shall conduct inspections to determine the corrective action plan or any other stated requirements have been implemented by the licensee.

If WVDA determines that a licensee has intentionally violated the provisions of its industrial hemp plan, the violation and licensee will be reported to the USDA, West Virginia Attorney General, the sheriff of the county in which the violation occurred, and the local detachment of the West Virginia State Police. Cannabis containing more than the acceptable level of total THC stated in the USDA Interim Final Rule, currently 1% total THC will be considered an intentional act on the part of the licensee, and other actions may be considered intentional based on additional factors, such as the licensee's state of mind.

Appeal Process

Once a licensee has been notified of a violation based on a non-compliant crop or other issue, he or she has the right to appeal the determination within ten (10) days of the date received. The licensee may request to schedule a hearing, during which time evidence and arguments may be presented. The appeal process is guided by the West Virginia Administrative Procedures Act, W. Va. Code §§29A-5-1 *et seq.*, and the issues, once argued and briefed, are decided by the WVDA Commissioner.

Program Financing

WVDA operates as an interdisciplinary department, and many employees are cross-trained to assist with various programs; the industrial hemp program is no exception. Aside from WVDA's full-time Hemp Program Coordinator, the following employees and divisions contribute to the operation and management of the WVDA Industrial Hemp Program:

- Executive Division, including the Commissioner, Deputy Commissioner, Chief of Staff, and General Counsel;
- Plant Industries Division, including plant regulatory officers;
- Regulatory and Environmental Affairs Division, including chemists, research chemists, hemp chemists, compliance officers, laboratory technical leaders, laboratory quality managers, and others;
- Business Development Division;
- Communications Division;
- Information Technology Division; and
- Administrative Services Division.

Due to the interdisciplinary structure of the Department, WVDA is confident that it has adequate personnel to properly implement this Plan. Further, the West Virginia Legislature has provided additional appropriations, both one-time and ongoing, to fund the program, thus indicating a commitment to support the industry.

Conclusion

In accordance with federal and state laws, WVDA does not discriminate in its programs and services on the basis of race, color, religion, sex, age, national origin or ancestry, disability (including blindness), medical condition, marital status, veteran status, or political affiliation.

WVDA retains the right to update this plan in accordance with West Virginia statues, legislative rules, and USDA guidelines.