



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Agriculture

RULE TYPE: Legislative

TITLE-SERIES: 61-30

RULE NAME: Hemp Products

CITE AUTHORITY: §19-12E-7

The above proposed Legislative rules, following review by the Legislative Rule Making Review Committee, is hereby modified as a result of review and comment by the Legislative Rule Making Review Committee. The attached modifications are filed with the Secretary of State.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Norman Bailey -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 61
LEGISLATIVE RULE
WEST VIRGINIA DEPARTMENT OF AGRICULTURE

SERIES 30
HEMP PRODUCTS

§61-30-1. General.

1.1. Scope. -- This legislative rule provides for the registration and regulation of hemp products sold within the State of West Virginia.

1.2. Authority. -- W. Va. Code §19-12E-7

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Sunset Date. -- This rule shall terminate and have no further force or effect five years from the effective date.

§61-30-2. Definitions.

2.1. "Cannabidiol" or "CBD" means the compound by the same name derived from the hemp variety of the Cannabis sativa L. plant.

2.2. "Certificate of analysis" or "COA" means a certificate issued by a third-party laboratory that operates under ISO 17025:2005 management and laboratory practices, describing the results of the laboratory testing of sample.

2.3. "Commercial sales" means the sale of products in the stream of commerce retail wholesale and online.

2.4. "Commissioner" means the Commissioner of Agriculture or his or her designee.

2.5. "Consumable" means a hemp product intended for human and/or animal consumption.

2.6. "Crop" means hemp grown under a single registration.

2.7. "Department" means the West Virginia Department of Agriculture and its employees.

2.8. "Grower" means a person, joint venture, or cooperative that produces hemp.

2.9. "Fiber product" or "hemp fiber product" means a hemp product that is manufactured with suitable fiber for textiles, rope, paper, hempcrete, or building or fiber materials.

2.10. "Handler" means a person, joint venture, or cooperative that receives hemp for processing into commodities, products or agricultural hemp seed.

2.11. "Handling" means processing or storing hemp plants for any period of time on premises owned, operated, or controlled by a person licensed to cultivate or process hemp. "Handling" also includes

processing or storing hemp plants in a vehicle for any period of time other than during its actual transport from the premises of one licensed person to cultivate or process hemp to the premises of another licensed person. "Handling" does not mean possessing or storing finished hemp products.

2.12. "Harvest lot" means a quantity of hemp harvested in a distinct timeframe that is:

2.12.a. Grown in one contiguous field or growing area; or

2.12.b. Grown in a portion or portions of one contiguous field, or one growing area.

2.12.c. All of the same variety.

2.13. "Hemp" means all parts and varieties of the plant Cannabis sativa L. and any part of the plant, including the seeds of the plant and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not with no greater than 0.3% tetrahydrocannabinol, or the THC concentration for hemp defined in 7 U.S.C. § 5940, whichever is greater.

2.14. "Hemp product" or "Hemp commodity" means any product derived from, or made by, processing hemp plants or plant parts, that are prepared in a form available for commercial sale. This includes, but is not limited to:

2.14.a. Hemp seed derivatives;

2.14.b. Hemp concentrates or extracts;

2.14.c. Hemp edibles and drinks;

2.14.d. Hemp tincture;

2.14.e. Hemp topicals and lotions;

2.14.f. Hemp transdermal patches;

2.14.g. Hemp fiber/fiber products;

2.14.h. Hemp seed processed such that it is incapable of germination and processed such that is suitable for human consumption;

2.14.i. Hemp seed pressed or otherwise processed into oil;

2.14.j. Hemp aerosols;

2.14.k. Hemp vaping products;

2.14.l. Smokable hemp products that are properly packaged, labeled, and sealed in a manner approved by the Commissioner; and

2.14.m. Pet treats or by-products used in animal feed, if applicable by federal law.

2.14.n. The term "hemp product" or "hemp commodity" does not include:

2.14.n.1. Hemp that has not been processed in any form;

2.14.n.2. Hemp that has been minimally processed, for purposes of transfer or storage, including chopping, separating, or drying; and

2.14.n.3. Agricultural hemp seed.

2.15. "Informational panel" means any part of the label that is not the primary label.

2.16. "Intended for human consumption" means to ingest, inhale, or topically apply to the skin or hair.

2.17. "Laboratory" means the West Virginia Department of Agriculture laboratories.

2.18. "Licensee" means an individual or business entity possessing a license issued by the Department to grow, handle, cultivate, or process hemp.

2.19. "Lot" means any amount of hemp product of the same type and processed at the same time using the same ingredients, standard operating procedures, and batches.

2.20. "Manufacturer" or "processor" means a registrant who is processing, compounding, or converting raw hemp into a hemp commodity or product.

2.21. "Primary label" means the part of the label most likely to be displayed to the consumer at retail and is typically on the front or top of the package.

2.22. "Produce" means the planning, cultivation, growing, or harvesting of hemp.

2.23. "Processing" means converting agricultural commodity into marketable form.

2.24. "Registrant" means an individual or business that has registered with the Department to sell and/or distribute hemp products. The term "registrant" also includes manufacturers of hemp products whose products are registered with the Department.

2.25. "THC" means tetrahydrocannabinol and is used interchangeably with "Total THC". "Total THC" means the quantifiable amount of delta-nine THC plus the amount of tetrahydrocannabinolic acid in a product.

§61-30-3. Regulatory authority.

3.1. The Department shall have the authority to regulate all hemp products and extracts for the purpose of consumer protection and public safety.

3.2. Rules governing the requirements for licensing, cultivating, testing, processing, supervision, production, and sale of raw hemp in West Virginia are found in 61 C.S.R. 29.

3.3. The rules provided in this rule are in addition to any requirements imposed by the United States Department of Agriculture, the federal Food and Drug Administration, or any other federal agency with regulatory authority over hemp products.

§61-30-4. Manufacturer registration of hemp products or extracts.

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4.1. The manufacturer of all hemp products, including hemp fiber products, available for distribution in West Virginia shall register annually with the Department. This includes products manufactured in West Virginia, another state, or another country.

4.2. Application for manufacturer registration shall be made to the Department on a form provided by the Department, and shall include the following information:

4.2.a. The name and address of the applicant;

4.2.b. The name and address of the person whose name shall appear on the label, if other than the applicant's;

4.2.c. The name of the product;

4.2.d. The name and address of the origin of the raw hemp product with which the final product was manufactured;

4.2.e. A complete copy of the label that will appear on the product;

4.2.f. A certificate of analysis from a third-party laboratory for the lot for each product; and

4.2.g. The associated registration fee.

4.3. Registrations shall expire on December 31 of the year for which the registration was issued, regardless of the date the registration is received.

4.4. A registration fee of \$200.00 per hemp product shall be paid to the Department with the submission of the application for the manufacturer of hemp products.

4.4.b. A renewal fee of \$200.00 per hemp product shall be submitted to renew a product's registration. Renewal fees shall be accompanied by a form provided by the Department identifying the product to which the fee corresponds.

4.4.c. The annual fee for hemp product registrations shall be capped at \$1,000 per manufacturer for products that are manufactured and sold in West Virginia.

4.4.d. The annual fee for hemp product registrations that are white labeled by a West Virginia vendor for sale in West Virginia shall be capped at \$1,000 per vendor.

4.4.e. Hemp fiber products, such as rope, fiber, hempcrete, paper, and other industrial uses, are exempt from the \$200.00 annual fee and certificate of analysis but are subject to all other registration requirements.

4.4.f. Hemp products that are not consumed, inhaled, ingested, absorbed, come in contact with the skin, or otherwise have an effect on the health of humans or animals are exempt from the \$200.00 annual fee and certificate of analysis but are subject to all other registration requirements.

4.5. The Department may deny or delay registrations and renewals that are incomplete.

4.6. A new registration is required for any of the following:

4.6.a. Changes in the hemp product;

4.6.b. Changes to the directions for use; or

4.6.c. Changes to label claims.

4.6. The person registering the product is responsible for the completeness and accuracy of all information submitted.

4.7. A retailer may register a product in lieu of the manufacturer if the product is not registered.

4.8. As a condition of registration, all manufacturers are required to retain documentation for each product lot demonstrating the source of the hemp that was utilized to manufacture the hemp product, including documentation that the product was grown by a licensed hemp grower. Such documentation shall be made available to the Department upon request.

§61-30-5. Registration to distribute and sell hemp products or extracts.

5.1. All retail facilities are required to register with the Department to sell hemp products or extracts in West Virginia.

5.2. Application to sell and distribute hemp products shall be made to the Department on a form provided by the Department and shall include the following information:

5.2.a. Name and address of the applicant's retail store; or, if the applicant is selling at an on-line store, this must be indicated on the form;

5.2.b. Name and home address of the responsible party;

5.2.c. A list of items intended for sale, including the product name and brand; and

5.2.d. The associated registration fee.

5.3. A registration fee of \$100.00 shall be paid to the Department with the submission for application to sell and distribute hemp products in West Virginia.

5.4. A registration fee shall be paid annually. Registrations shall expire on December 31 of the year for which the registration was issued, regardless of the date the registration is received.

5.5. Retail establishments that sell only products that they manufacture themselves are exempt from the requirement to pay the fee to distribute, but are not exempt from the requirement to register annually.

5.6. The Department may deny or delay registrations for incomplete applications.

5.7. Retail facilities that register with the Department will be provided a verification document, in the form of a certificate or otherwise, for display at the retail location, which will indicate that the retail facility is an authorized location for the sale and/or distribution of hemp products.

§61-30-6. Certificate of analysis.

6.1. The certificate of analysis for all products, excluding hemp fiber products, shall minimally include the following information:

6.1.a. A batch or lot number identification;

6.1.b. The date the certificate of analysis was received;

6.1.c. The method of analysis for each test conducted; and

6.1.d. The product name.

6.2. The certificate of analysis for all products containing CBD or THC products shall additionally minimally include the following test results:

6.2.a. The cannabinoid profile by the percentage of dry weight which must include THC and CBD content;

6.2.b. Solvents;

6.2.c. Pesticides;

6.2.d. Microbial contaminants; and

6.2.e. Heavy metals.

6.3. The Department, or its designee, may conduct audits of third-party laboratories providing certificates of analysis, without notice, at the Department's discretion.

§61-30-7. Labeling.

7.1. Hemp products that contain CBD for human consumption as a food or dietary supplement shall be labeled in accordance with FDA guidelines for food or dietary supplement labeling.

7.2. Hemp products produced for absorption by humans shall be labeled in accordance with FDA guidelines for Cosmetic Product Warning Statements.

7.3. Hemp products shall not contain medical claims on the label that are not approved by the FDA.

7.4. The product lot on the label must be traceable to the plant origin.

7.5. Hemp products meant for animal consumption shall be labeled and comply with all other applicable federal laws and regulations.

7.6. Hemp seed products intended for cultivation shall be labeled in accordance with the West Virginia Seed Law, West Virginia Code §19-16-1 et seq.

7.7. Edible product labels must include the words "Cannabis-Infused".

7.8. Product labels must be clear and legible.

7.9. Labels must be printed in English.

7.10. The following labeling is forbidden:

7.10.a. Unless at least 51% of the hemp in the product is grown in the state of West Virginia, the hemp product cannot be labeled as a West Virginia hemp product.

7.10.b. The product cannot be attractive to children. This includes, but is not limited to:

7.10.b.1. The use of cartoons;

7.10.b.2. The use of images popularly used to advertise to children; or

7.10.b.3. The imitation of a candy label.

7.10.c. The label cannot include false or misleading information. This includes untrue or unproven information that leads consumers to have an inaccurate impression.

7.10.d. The label cannot include the use of the word “organic” unless the product has been certified as organic in accordance with the National Organic Program, as provided for by the USDA.

7.11. Labels will be considered misbranded when a WVDA analysis finds the claim is above or below 20% of the amount declared on the label.

7.12. The following requirements must be met for the primary label:

7.12.a. The product must be identified with the generic or common name;

7.12.b. If the product contains CBD or THC, the label must properly identify them; and

7.12.c. The net weight or volume of the contents of the package, in both metric and US customary units must be displayed.

7.13. The following requirements must be met for the information panel:

7.13.a. Manufacturer’s name and contact information;

7.13.b. Manufacturing or packaging date;

7.13.c. Batch or lot number;

7.13.d. Instructions for use and any preparation needed;

7.13.e. List of all ingredients in descending order by weight or volume;

7.13.f. Allergens if applicable;

7.13.g. Artificial food coloring, if applicable;

7.13.h. Expiration or use by date, if applicable;

7.13.i. Refrigeration or refrigerate after opening warnings, if perishable after opening; and

7.13.j. For edible products, sodium, sugar, carbohydrates, and total fat per serving.

7.14. The cannabinoid content, in milligrams, may be posted on either the primary or informational panel, and must include:

7.14.a. THC or CBD (if applicable) content per package for all manufactured products; and

7.14.b. THC or CBD (if applicable) content per serving for all edibles and concentrates, with designated serving sizes.

7.15. A QR code, or similar tool, may be used in lieu of labeling requirements on the physical label's informational panel for all required information except that required by sections 7.13.a and 7.14.

§61-30-8. Handling and transport.

8.1. It is lawful in West Virginia to transport and possess CBD and THC products, so long as the THC content does not exceed that permitted by law.

8.2. Hemp products may be legally transported across state lines and exported to foreign countries in a manner that is consistent with federal law and laws of respective foreign countries.

8.3. For time- and temperature-controlled products for human consumption, sellers must meet FDA guidance for maintaining safe handling, storage, and preservation of the product.

§61-30-9. Inspection and testing.

9.1. The Department shall conduct random inspections of hemp products distributed or made available for distribution in the state.

9.2. The Department shall periodically sample, analyze, and test hemp products distributed within the state for compliance with registration, labeling requirements, product safety, and the certificate of analysis, if applicable.

9.3. The Department may conduct inspection of hemp products distributed or available for distribution for any reason that the Department deems necessary.

9.4. Samples taken by the Department shall be the official samples.

§61-30-10. Enforcement actions on unregistered sellers and product manufacturers.

10.1. If the seller or a manufacturer does not renew its registration annually, the Commissioner is authorized to take enforcement actions against the seller or manufacturer as set forth in this section.

10.2. Upon the first offense:

10.2.a. The seller or product manufacturer will be notified in writing that they must register with the Department;

10.2.b. The seller or product manufacturer will be given 14 days to register with the Department; and

10.2.c. If the seller or product manufacturer does not register with the Department in the allotted time, their hemp products shall be embargoed and removed from the shelves in accordance with section 12 of this rule.

10.3. Upon the second offense within a five-year period:

10.3.a. The seller or product manufacturer will be notified in writing that they must register with the Department;

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10.3.b. The seller or product manufacturer will be given 14 days to register with the Department, and will then be subject to the regular registration fee in addition to a penalty;

10.3.c. The seller or product manufacturer will be required to pay a penalty of \$250.00; and

10.3.d. If the seller or product manufacturer does not register with the Department in the allotted time, the hemp products shall be embargoed and removed from the shelves in accordance with section 12 of this rule.

10.4. Upon a third offense in a five-year period:

10.4.a. The seller or product manufacturer will be notified in writing that they must register with the Department;

10.4.b. The product shall be embargoed and removed from shelves in accordance with section 12 of this rule;

10.4.c. The seller or product manufacturer shall be required to pay a penalty of \$250.00; and

10.4.d. A hearing will be held to suspend the holder's permit to sell hemp products.

§61-30-11. Enforcement actions on products violations and related penalties.

11.1. The Commissioner may assess a violation of West Virginia Code §19-12E-7 *et. seq.* or this rule.

11.2. Violations shall be broken into classes, dependent on the severity. Violations are classified as follows:

11.2.a. Class I violations are flagrant violations and include, but are not limited to:

11.2.a.1. Hemp products that are unsafe or adulterated or show cause for immediate human or animal health concern; and

11.2.a.2. Hemp products that contain more than the THC content authorized by law.

11.2.b. Class II violations are violations in which the person acted in a faulty or careless manner and include, but are not limited to:

11.2.b.1. Falsification of information on an application;

11.2.b. 2. No dosage listed on labeling; and

11.2.b.3. Failure of the product to meet label claims.

11.2.c. Class III violations are negligent violations and include but are not limited to:

11.2.c.1. Improper labeling; and

11.2.c.2. Misbranding.

11.3. Class III (Negligent) Violations.

11.3.a. Upon the first Class III violation being committed by a manufacturer:

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11.3.a.1. The Commissioner shall send a written "First Notice" to the registrant. This notice shall notify the registrant that a violation of West Virginia Code §19-12E-7 *et. seq.* of this rule and the enforcement policy established by this section of the rule has been violated.

11.3.a.2. The manufacturer shall be assessed a \$100.00 penalty for the Class III violation.

11.3.a.3. The manufacturer shall be given 30 days to fix the Class III violation and must provide evidence to the Department that the violation has been corrected.

11.3.b. If a second Class III violation has been committed on the same products within a 5-year period, the Commissioner shall send a written "Second Notice" to the registrant. The registrant must develop a written plan to correct the violation(s) and implement it within 7 days after the Second Notice has been sent. An additional \$100.00 penalty will be assessed for the second Class III violation of a product.

11.3.c. If a third Class III violation has been committed on the same product within a five-year period, the Commissioner will issue an immediate "Suspension of Permit".

11.3.c.1. The "Suspension of Permit" order will give the reason for the order, the length of time the Suspension Permit order will be in effect, and a specific time and place for a hearing.

11.3.c.2. The suspension shall state the effective time of the suspension the reason for it, and a specific time and a place for a hearing, except in the case of a summary suspension, in which the Commissioner may give the manufacturer an opportunity to request a hearing in the matter subsequent to the notification of the suspension.

11.4. Class II (Faulty or Careless) Violations.

11.4.a. Upon the first Class II violation being committed by a manufacturer:

11.4.a.1. The Commissioner shall send a written "First Notice" to the registrant. This notice shall notify the registrant that a violation of West Virginia Code §19-12E-7 *et. seq.* of this rule, and the enforcement policy established by this section of the rule.

11.4.a.2. The manufacturer shall be assessed a \$200.00 penalty for the Class II violation.

11.4.a.3. The manufacturer shall be given 30 days to fix the Class II violation and must provide evidence to the Department that the violation has been alleviated.

11.4.b. If a second Class II violation has been committed on the same products within a 5-year period, the Commissioner shall send a written "Second Notice" to the registrant. The registrant must develop a written plan to correct the violation(s) and implement it within 7 days after the Second Notice has been sent. An additional \$200.00 penalty will be assessed for the second Class II violation of a product.

11.4.c. If a third Class II violation has not been resolved within a specified time frame, the will issue an immediate "Suspension of Permit".

11.4.c.1. The "Suspension of Permit" order will give the reason for the order, the length of time the "Suspension of Permit" order will be in effect and a specific time and place for a hearing.

11.4.c.2. The suspension shall state the time that the suspension will be effective, give the reason for the suspension, and specify a time and a place for a hearing to be held in the matter, except that in the case of a summary suspension, the Commissioner may give the manufacturer the opportunity to request a hearing in this matter subsequent to the notification of the suspension.

11.5. Class I (Flagrant) Violations.

11.5.a. Upon the first Class I violation being committed by a manufacturer:

11.5.a.1. The Commissioner shall notify the registrant that the product has been embargoed. This notice shall notify the registrant that a violation of West Virginia Code §19-12E-7 et. seq. of this rule and the enforcement policy established by this section of the rule.

11.5.a.2. Embargo of products shall follow in accordance with Section 12 of this rule.

11.5.a.3. The manufacturer of a product with a Class I violation shall be assessed a penalty of \$250.00.

11.5.b. The embargo notice will establish the date effective, give the reason of the suspension and specify a time and a place for a hearing to be held in the matter.

11.6. A person who performs a recall by voluntarily removing product from sale or distribution in an effective manner, so as to limit the potential harm to the health and well-being of the public, may be eligible for exemptions from the normal enforcement policy. The Commissioner shall consider the facts of each case when making a decision on an exemption.

11.7. The Commissioner may suspend the standard enforcement policy in cases where such action is necessary to protect the public health, safety, and welfare.

§61-30-12. Embargos.

12.1. Embargo orders.

12.1.a. When the Commissioner has reasonable cause to believe any lot of hemp product is being manufactured distributed offered for sale exposed for sale or used in this state in violation of the provisions of this rule a written embargo order may be issued and enforced warning the custodian of the hemp product not to manufacture, distribute, use, remove, or dispose of it in any manner until the embargo is released by the Commissioner or by court order.

12.1.b. When the embargo is issued, the Commissioner shall affix a tag or other marking to the hemp product, warning that such product is under embargo and shall notify the custodian of the right to request an immediate hearing.

12.1.c. The Commissioner shall release the hemp product so embargoed when said product has been brought into compliance with this article and its rules.

12.1.d. The Commissioner shall have the authority to issue an embargo against a perishable product even if the result is the involuntary disposal of the product.

12.1.e. The Commissioner may take action to seize and condemn any product if not brought into compliance with this rule within the aforesaid time frame.

12.2. Condemnation and Confiscation

12.2.a. Any hemp product not in compliance with the provisions of this rule shall be subject to condemnation and confiscation on complaint of the Commissioner to the circuit court of the county in which the product in question is located. Jurisdiction is hereby conferred upon the circuit courts to hear and determine such matter.

12.2.b. If the court finds that the hemp product is in violation of the provisions of this rule and should be confiscated, the court shall order the condemnation and confiscation of such product and its disposition in a manner consistent with the quality of such product which is not in violation of any other laws of this state: Provided That the owner thereof must first be given an opportunity to process or relabel such hemp product or dispose of the same in full compliance with the provisions of this rule.

12.3. Injunctions

12.3.a. Upon application by the Commissioner, the circuit court of the county in which the violation is occurring, has occurred, or is about to occur, may grant a temporary or permanent injunction restraining any person from violating or continuing to violate any of the provisions of this rule.

12.3.b. An injunction shall be issued without bond.