



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

eFILED

6/28/2022 4:51:11 PM

Office of West Virginia
Secretary Of State

NOTICE OF PUBLIC COMMENT PERIOD

AGENCY: Agriculture

TITLE-SERIES: 61-30

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: Hemp Products

CITE STATUTORY AUTHORITY: §19-12E-7

COMMENTS LIMITED TO:

Written

DATE OF PUBLIC HEARING:

LOCATION OF PUBLIC HEARING:

DATE WRITTEN COMMENT PERIOD ENDS: 07/28/2022 12:00 PM

COMMENTS MAY BE MAILED OR EMAILED TO:

NAME: Jodee Martin

ADDRESS: 1900 Kanawha Boulevard, East

Charleston, WV 25305

EMAIL: rulescomments@wvda.us

PLEASE INDICATE IF THIS FILING INCLUDES:

RELEVANT FEDERAL STATUTES OR REGULATIONS: Yes

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

INCORPORATED BY REFERENCE: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

PROVIDE A BRIEF SUMMARY OF THE CONTENT OF THE RULE:

Provides for the registration and regulation of hemp products in WV.

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN THE RULE AND A STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE:

Striking sections and giving the Department to right to deny product registrations is potentially hazardous.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

none

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

none

C. ECONOMIC IMPACT OF THE RULE ON THE STATE OR ITS RESIDENTS:

none

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2022 Increase/Decrease (use "-")	2023 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

n/a

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.

61CSR30

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. -- ~~April 25, 2022~~
- 1.4. Effective Date. -- ~~April 25, 2022~~
- 1.5. Sunset Date. -- This rule shall terminate and have no further force or effect on August 1, 2032.

§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. "Cannabinoid" or "Phytocannabinoid" means any of the various naturally occurring, biologically active chemical constituents (such as cannabidiol or cannabinol) of hemp or cannabis, including those (such as THC) that possess psychoactive properties.

~~2.3. "Certificate of analysis" or "COA" means a certificate issued by a laboratory that operates under ISO 17025:2017 management and laboratory practices, describing the results of the laboratory testing of sample.~~

~~2.4.~~ 2.3. "Commercial sales" means the sale of products in the stream of commerce direct to the endpoint consumer.

~~2.5.~~ 2.4. "Commissioner" means the Commissioner of Agriculture or his or her designee.

~~2.6.~~ 2.5. "Consumable" means a hemp product intended for human and/or animal consumption.

~~2.7.~~ 2.6. "Crop" means hemp grown under a single registration.

~~2.8.~~ 2.7. "Department" means the West Virginia Department of Agriculture and its employees.

~~2.9.~~ 2.8. "Distributor" or "Seller" means any person who sells, exposes for sale, offers for sale, exchanges, barter, gives, parcels out, allots shares, or dispenses a hemp product.

~~2.10. GRAS" means generally recognized as safe. A product or ingredient is said to have obtained "GRAS status" when such status is recognized by the Federal Food and Drug Administration (FDA).~~

~~2.11.~~ 2.9. "Grower" means a person, joint venture, cooperative, or any entity that produces hemp.

61CSR30

~~2.12.~~ 2.10. "Fiber product" or "hemp fiber product" means a hemp product that is manufactured with suitable fiber for textiles, rope, paper, hempcrete, building_z or fiber materials.

~~2.13.~~ 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.

~~2.14.~~ 2.12. "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.

~~2.15.~~ 2.13. "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:

~~2.15.a.~~ 2.13.a. Hemp seed derivatives;

~~2.15.b.~~ 2.13.b. Hemp concentrates or extracts;

~~2.15.c.~~ 2.13.c. Hemp edibles and drinks;

~~2.15.d.~~ 2.13.d. Hemp tincture;

~~2.15.e.~~ 2.13.e. Hemp topicals and lotions;

~~2.15.f.~~ 2.13.f. Hemp transdermal patches;

~~2.15.g.~~ 2.13.g. Hemp fiber/fiber products;

~~2.15.h.~~ 2.13.h. Hemp seed processed such that it is incapable of germination and processed such that is suitable for human consumption;

~~2.15.i.~~ 2.13.i. Hemp seed pressed or otherwise processed into oil;

~~2.15.j.~~ 2.13.j. Hemp aerosols;

~~2.15.k.~~ 2.13.k. Hemp vaping products;

~~2.15.l.~~ 2.13.l. Smokable hemp products that are properly packaged, labeled, and sealed in a manner approved by the Commissioner; and

~~2.15.m.~~ 2.13.m. Pet treats or by-products used in animal feed;

~~2.15.n.~~ 2.13.n. The term "hemp product" or "hemp commodity" does not include:

~~2.15.n.1.~~ 2.13.n.1. Hemp that has not been processed in any form;

~~2.15.n.2.~~ 2.13.n.2. Hemp that has been minimally processed, for purposes of transfer or storage, including chopping, separating, or drying; and

61CSR30

~~2.15.n.3.~~ 2.13.n.3. Agricultural hemp seed.

~~2.16.~~ 2.14. "Informational panel" means any part of the label that is not the primary label.

~~2.17.~~ 2.15. "Intended for human consumption" means to ingest, inhale, or topically apply to the skin or hair.

~~2.18.~~ 2.16. "Licensee" means an person or business entity possessing a license issued by the Department to grow, handle, cultivate, or process hemp.

~~2.19.~~ 2.17. "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.~~ 2.18. "Manufacturer" or "processor" means a person or entity who is processing, compounding, or converting raw hemp into a hemp commodity or product.

~~2.21.~~ 2.19. "Non-detectable" means that the amount of a tested ingredient is at or below 10 parts per million.

~~2.22.~~ 2.20. "Primary label" means the part of the label to be prominently displayed to the consumer at retail.

~~2.23.~~ 2.21. "Processing" means converting agricultural commodity into marketable form.

~~2.24.~~ 2.22. "Registrant" means a person or entity that has registered hemp products with the Department.

~~2.25.~~ 2.23. "THC" means tetrahydrocannabinol and is used interchangeably with "Total THC". "Total THC" means the quantifiable amount of delta-nine THC plus 0.877% of the amount of tetrahydrocannabinolic acid in a product.

~~2.26.~~ 2.24. "THC-free" or "Non-THC" means a hemp product that contains a non-detectable or non-quantifiable amount per serving of tetrahydrocannabinol.

~~2.27.~~ 2.25. "White label" means a manufactured hemp product that is manufactured or produced by one person or entity but sold by another person or entity under their own label.

§61-30-3. Regulatory authority.

3.1. ~~The Department shall have the authority to regulate all hemp products for the purpose of consumer protection and public safety. The Department has the authority to deny product registrations it deems are potentially hazardous and/or pose a threat to consumer 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. Registration of hemp products or extracts.

61CSR30

4.1. All hemp 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 hemp product registrations 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 registrant;

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

4.2.c. The name of the product;

4.2.d. The origin of the raw hemp 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 laboratory for the lot for each product; and~~

~~4.2.g.~~ 4.2.f. 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. Beginning January 1, 2022, registration shall be due by January 1 of each year.

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

4.5.a. Beginning January 1, 2022, in lieu of the \$200.00 registration fee set forth in subsection 4.5 of this rule, a registration fee of \$100.00 per hemp product shall be paid to the Department with the submission of the application, if the hemp material(s) are grown, harvested, and manufactured in West Virginia and the products are registered with the West Virginia Grown program.

4.5.a.1. Hemp products that are registered under this subdivision must include a copy of the registrant's West Virginia processing/cultivation license, or records of where the product was cultivated and processed.

~~4.5.a.2. Hemp products that are registered under this subdivision must also include a certificate of analysis that validates the batch/lot number of the final product is that of which was manufactured from hemp grown, harvested, and manufactured by a licensed West Virginia hemp grower or processor.~~

4.5.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.

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

4.5.d. Beginning January 1, 2022, in lieu of the \$1,000 registration cap fee stated in subdivision 4.5.c of this rule, a registration cap fee of \$500.00 per registrant shall be paid for hemp products that

61CSR30

are grown, harvested, and manufactured in West Virginia, and registered with the WV Grown Program.

4.5.d.1. Hemp products that are registered under this subdivision must include a copy of the registrant's West Virginia processing/cultivation license.

~~4.5.d.2. Hemp products that are registered under this subdivision must also include a certificate of analysis that validates the batch/lot number of the final product is that of which was manufactured from hemp grown, harvested, and manufactured by a licensed West Virginia hemp processor/cultivator.~~

~~4.5.d.3.~~ 4.5.d.2. Hemp products that are registered under this subdivision must also include a copy of their certificate for registration in the WV Grown Program.

4.5.e. 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 registrant.

4.5.f. Hemp products that are of the same chemical composition but of different net quantities qualify as one product.

4.5.g. Hemp product registrations that come from an international entity shall be required to pay a foreign check fee of \$35.00.

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

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

4.7.a. Changes in the chemical composition or formula of the hemp product; or

4.7.b. Changes to health-related label claims for active ingredients.

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

4.9. As a condition of registration, all registrants 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.

5.1. All retail facilities, including online domains and websites, are required to register with the Department to sell hemp products 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;

61CSR30

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

~~5.2.d.~~ 5.2.c. 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. Registrations shall be due on January 1 annually.

5.6. 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.a. Retail establishments that solely sell products that are defined under subsection 2.10 of this rule are exempt from registration.

5.6.b. Hemp retail registrations that come from a foreign entity shall be required to pay a foreign check fee of \$35.00.

5.6.c. Retail registration excludes restaurant sales for the on-site consumption of foods and drinks containing hemp or hemp derived products. Restaurants selling take-home products are not exempt from registering as a hemp seller.

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

5.8. 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.

5.9. A distributor of hemp products that does not itself engage in retail sales is not required to register under this section.

5.10 The Department may revoke the registration of a retail facility to sell hemp products if it determines they the facility has sold products to individuals not meeting requirements of subsection 7.14 of this rule.

~~§61-30-6. Certificate of analysis. Reserved for future use.~~

~~6.1. The certificate of analysis for all 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.~~

61CSR30

~~6.2. The certificate of analysis for all hemp products shall additionally minimally include the cannabinoid profile by the percentage of dry weight which must include THC and CBD content or guarantee of a cannabinoid product derived from hemp.~~

~~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.~~

6.4. A certificate of analysis shall be provided for each finished hemp product that is registered.

~~6.5. Products that only contain hemp ingredients that have been given GRAS status by the FDA are exempt from the COA requirements listed under 6.1 and 6.2, but are not exempt from the requirement to register annually.~~

§61-30-7. Labeling.

7.1. Hemp products 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 topical absorption by humans shall be labeled in accordance with FDA guidelines for Cosmetic Products Warning Statements.

7.3. Hemp products shall not contain disease or drug 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 the West Virginia Commercial Feed Law, West Virginia Code §19-14-1 *et seq.*

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. Product labels must be clear and legible.

7.8. Labels must be printed in English.

7.9. The following labeling is forbidden:

7.9.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.

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

7.9.b.1. The use of cartoons;

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

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

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

61CSR30

7.9.d. The label cannot include the use of the word “organic” unless referencing certified organic products that have been certified as organic in accordance with the National Organic Program, as provided for by the USDA.

7.10. Labels will be considered misbranded when a WVDA analysis finds the claim is above or below 20% of the cannabinoid amount declared on the label, ~~excluding any tetrahydrocannabinols.~~

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

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

7.11.b. If the product label claim contains any amount of cannabinoid(s), the label must properly identify them.

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

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

7.12.b. Batch or lot number;

7.12.c. Instructions for use and any preparation needed, if applicable;

7.12.d. List of all ingredients in descending order by weight or volume;

7.12.e. Allergens if applicable;

7.12.f. Artificial food coloring, if applicable;

7.12.g. Expiration or use by date, if applicable;

7.12.h. Refrigeration or refrigerate after opening warnings, if perishable after opening; and

7.12.i. For edible products, sodium, sugar, carbohydrates, and total fat per serving.

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

7.12.j.1. For capsules, soft gels, or similar products the net quantity of contents statement can be weight, volume, numerical count, or a combination of numerical count and weight or volume.

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

7.13.a. Any product label claiming a guaranteed cannabinoid (if applicable) shall provide the total amount of the claimed cannabinoid content per package for all manufactured products; and

7.13.b. Cannabinoid (if applicable) content per serving for all hemp products with designated serving sizes.

7.14. Any product containing more than 0.3% of tetrahydrocannabinols, ~~or more than 0.3421% of tetrahydrocannabinolic acid,~~ must declare “NOT INTENDED FOR SALE TO PERSONS UNDER THE AGE OF 18” (or more restrictive) on the label.

7.15. Any product label claiming “THC-free” or “non-THC” shall not contain levels of THC above detectable levels as determined by the Department.

7.16. 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 subsections 7.13 and 7.14 and subdivision 7.12.i of this rule.

§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, and 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.

9.5. Samples that are found to contain contaminants in excess of the following levels shall be considered adulterated.

9.5.a. Pesticide Limits. The following list of contaminants does not constitute authorization to use or apply any of the following during Hemp cultivation or processing.

Pesticide	CAS No.	Action Level for Inhalable/Smokable Products (µg/kg)	Action Level for All Other Products (µg/kg)
Abamectin	71751-41-2	100	300
Acephate	30560-19-1	100	3,000
Acequinocyl	57960-19-7	100	2,000
Acetamiprid	135410-20-7	100	3,000
Aldicarb	116-06-3	100	100
Azoxystrobin	131860-33-8	100	3,000
Bifenazate	149877-41-8	100	3,000
Bifenthrin	82657-04-3	500	500

61CSR30

Boscalid	188425-85-6	100	3,000
Captan	133-06-2	700	3,000
Carbaryl	63-25-2	500	500
Carbofuran	1563-66-2	100	100
Chlorantraniliprole	500008-45-7	300	3,000
Chlordane	57-74-9	100	100
Chlorfenapyr	122453-73-0	100	100
Chlormequat Chloride	999-81-5	300	3,000
Chlorpyrifos	2921-88-2	100	100
Clofentezine	74115-24-5	100	500
Coumaphos	56-72-4	100	100
Cyfluthrin	68359-37-5	1,000	1,000
Cypermethrin	52315-07-8	1,000	1,000
Daminozide	1596-84-5	100	100
DDCP (Dichlorvos)	1596-84-5	100	100
Diazinon	333-41-5	100	200
Dimethoate	60-51-5	100	100
Dimethomorph	110488-70-5	1,000	3,000
Ethoprop(hos)	13194-48-4	100	100
Etofenprox	80844-07-1	100	100
Etoxazole	153233-91-1	100	1,500
Fenhexamid	126833-17-8	100	3,000
Fenoxycarb	72490-01-8	100	100
Fenpyroximate	111812-58-9	100	2,000
Fipronil	120068-37-3	100	100
Flonicamid	158062-67-0	100	2,000
Fludioxonil	131341-86-1	100	3,000
Hexythiazox	78587-05-0	100	2,000
Imazalil	35554-44-0	100	100
Imidacloprid	138261-41-3	300	3,000
Kresoxim-methyl	143390-89-0	100	1,000
Malathion	121-75-5	500	2,000
Metalaxyl	57837-19-1	300	3,000
Methiocarb	2032-65-7	100	100
Methomyl	16752-77-5	100	100
Methyl Parathion	298-00-0	100	100
Mevinphos	7786-34-7	100	100
Myclobutanil	88671-89-0	100	3,000
Naled	300-76-5	100	500
Oxamyl	23135-22-0	200	200
Paclobutrazol	76738-62-0	100	100
Pentachloronitrobenzene	82-68-8	100	200
Permethrin	52645-53-1	500	1,000
Phosmet	732-11-6	100	200
Piperonylbutoxide	51-03-6	300	3,000
Prallethrin	23031-36-9	100	400
Propiconazole	60207-90-1	100	1,000
Propoxur	114-26-1	100	100

61CSR30

Pyrethrins	8003-34-7	500	1,000
Pyridaben	96489-71-3	100	3,000
Spinetoram	187166-15-0, 187166-40-1	100	3,000
Spinosad	131929-60-7, 131929-3-0	100	3,000
Spiromesifen	283594-90-1	100	3,000
Spirotetramat	203313-25-1	100	3,000
Spiroxamine	118134-30-8	100	100
Tebuconazole	107534-96-3	100	1,000
Thiacloprid	111988-49-9	100	100
Thiamethoxam	153719-23-4	100	1,000
Trifloxystrobin	141517-21-7	100	3,000

9.5.b. Residual Solvent and Processing Chemical Limits

Solvent or Processing Chemical	CAS No.	Action Level (µg/g)
1,2-Dichloroethene		1,870
Acetone	67-64-1	5,000
Acetonitrile	75-05-8	410
Butane	106-97-8	2,000
Chloroform	67-66-3	60
Ethanol	64-17-5	5,000
Ethyl Acetate	141-78-6	5,000
Ethyl Ether	60-29-7	5,000
Heptane	142-82-5	5,000
Hexane	110-54-3	290
Isopropyl Alcohol	67-63-0	5,000
Methanol	67-56-1	3,000
Methylene Chloride	75-09-2	600
Pentane	109-66-0	5,000
Propane	74-98-6	5,000
Toluene	108-88-3	890
Trichloroethylene	79-01-6	80
Total Xylenes (ortho-, meta-, para-)	1330-20-7	2,170

9.5.b.1. The limit for ethanol does not apply to products that are intended to be orally consumed products containing alcohol.

9.5.b.2. The limit for ethanol or isopropyl alcohol does not apply to products that are intended to be topical products.

9.5.c. Toxic Metals Limits

Metal	Action Level for Inhalable/Smokable Products (µg/g)	Action Level for All Other Products (µg/g)
Cadmium	0.2	0.5

61CSR30

Lead	0.2	0.5
Arsenic	0.2	1.5
Mercury	0.1	1

9.5.d. Microbiological Limits for ingestible and inhalable products

9.5.d.1. Shiga toxin-producing *Escherichia coli* (STEC *E. coli*) and other pathogenic *E. coli*, none present.

9.5.d.2. *Listeria monocytogenes*, none present.

9.5.d.3. *Salmonella* and *Shigella*, none present.

9.5.d.4. *Clostridium botulinum* and related neurotoxins, none present.

9.5.d.5. *Staphylococcus aureus* and related toxins, none present.

9.5.d.6. Coliforms greater than 10 colony forming units per gram.

9.5.e. Mycotoxin Limits.

9.5.e.1. Total Aflatoxin (B1, B2, G1, G2) - 20 µg/kg

9.5.e.2. Ochratoxin - 20 µg/kg

9.5.f. Water Activity Limits

9.5.f.1 Dried flower products – The water activity shall not exceed 0.65 Aw.

9.5.f.2 Edible products – The water activity shall not exceed 0.85 Aw.

9.5.g. Foreign Material Limits for ingestible and inhalable products

Foreign Material	Action Level
Mold	>¼ of the total sample area covered
Insect Fragments/Eggs, Hair, Mammalian Excreta	1 count per 3.0 grams
Sand, Soil, Dirt, & Other Extraneous Material	>0.5% by weight

9.5.h. The Department shall have the ability to set acceptable maximum limits for products derived from hemp and hemp seed derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers

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

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; and

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

61CSR30

10.3. Upon the second offense within a one year period:

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

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

10.3.c. 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 one-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. For unregistered sellers, the eligibility to obtain a permit to sell hemp products shall be suspended for one year. The permit holder shall have the right to request an optional hearing.

10.4.e. For unregistered products, the ability to obtain a product permit shall be suspended for one year. The product permit holder shall have the right to request an optional hearing.

10.4.f. Embargoes and offenses shall be specific to the individual product and not the entire manufacturer's line of 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.a.3. Third offense registration violations as defined in subsection 10.4 of this rule.

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 serving size and frequency of use listed on labeling; and

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

61CSR30

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:

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 one 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 one 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 and the length of time the Suspension of Permit order will be in effect.

11.3.c.2. The suspension of permit order shall state the time that the suspension will be effective and give the reason for the suspension. In the case of a summary suspension, 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 one 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

61CSR30

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 and the length of time the "Suspension of Permit" order will be in effect.

11.4.c.2. The suspension of permit order shall state the time that the suspension will be effective and give the reason for the suspension. 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 and give the reason for the.

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 a hearing.

61CSR30

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.