TITLE 61 LEGISLATIVE RULE WEST VIRGINIA DEPARTMENT OF AGRICULTURE

SERIES 30 HEMP PRODUCTS Select Plant-Based Derivative Products

§61-30-1. General.

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

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

1.3. Filing Date. -- April 13, 2023

1.4. Effective Date. -- May 1, 2023

1.5. Sunset Date. -- This rule shall terminate and have no further force or effect on August 1, 2033.

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

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

2.5. "Consumable" means a hemp-select plant-based derivative product intended for human and/or animal consumption.

2.6. "Crop" means hemp or *Mitragyna speciosa* grown under a single registration.

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

2.8. "Distributor" or "Seller" means any person who sells, exposes for sale, offers for sale, exchanges, barters, gives, parcels out, allots shares, or dispenses a hemp select plant-based derivative product.

2.9. "Grower" means a person, joint venture, cooperative, or any entity that produces <u>select plant-based derivatives</u> hemp.

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

2.11. "Handling" means processing or storing hemp <u>or *Mitragyna speciosa*</u> plants for any period of time on premises owned, operated, or controlled by a person licensed to cultivate or process hemp <u>or *Mitragyna speciosa*</u>. "Handling" also includes processing or storing hemp <u>or *Mitragyna speciosa*</u> 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 <u>or *Mitragyna speciosa*</u> to the premises of another licensed person. "Handling" does not mean possessing or storing finished hemp <u>or *Mitragyna speciosa*</u> products.

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.

2.13. "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:

2.13.a. Hemp seed derivatives;

2.13.b. Hemp concentrates or extracts;

2.13.c. Hemp edibles and drinks;

2.13.d. Hemp tincture;

2.13.e. Hemp topicals and lotions;

2.13.f. Hemp transdermal patches;

2.13.g. Hemp fiber/fiber products;

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

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

2.13.j. Hemp aerosols;

2.13.k. Hemp vaping products;

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

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

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

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

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

2.13.n.3. Agricultural hemp seed.

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

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

2.16. "Kratom" means any portion of the specified strain of botanical Mitragyna speciosa.

2.17. "Kratom product" means any product manufactured from any part of the *Mitragyna speciosa* plant, containing the alkaloids mitragynine and 7-hydroxymitragynine and intended or marketed for consumption.

<u>2.18.</u> "Licensee" means any person or business entity possessing a license issued by the Department to grow, handle, cultivate, or process hemp <u>or Mitragyna speciosa</u>.

2.17. 2.19. "Lot" means any amount of hemp <u>or *Mitragyna speciosa*</u> product of the same type and processed at the same time using the same ingredients, standard operating procedures, and batches.

2.18. 2.20. Manufacturer" or "processor" means a person or entity who is processing, compounding, or converting raw hemp or *Mitragyna speciosa* into a hemp-commodity or product.

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

2.20. 2.21. "Primary label" means the part of the label to be prominently displayed to the consumer at retail.

2.21. 2.22. "Processing" means converting agricultural commodity into marketable form.

2.22. <u>2.23.</u> "Registrant" means a person or entity that has registered hemp <u>or *Mitragyna speciosa*</u> products with the Department.

2.23. 2.24. "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.

2.24. 2.25. "THC-free" or "Non-THC" means a hemp product that contains a non-detectable or nonquantifiable amount per serving of tetrahydrocannabinol.

2.25. <u>2.26.</u> "White label" means a manufactured hemp <u>or *Mitragyna speciosa*</u> 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. <u>The Department has the authority to regulate all hemp and kratom products for the purpose of consumer protection and public safety</u>. 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 and kratom products or extracts.

4.1. All hemp <u>and kratom</u> 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 <u>and kratom</u> 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 or *Mitragyna speciosa* 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. 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 for each hemp and kratom 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 <u>and kratom</u> 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.b. A renewal fee of \$200.00 per for each hemp and kratom 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 <u>and kratom</u> 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 <u>and kratom</u> products that are grown, harvested, and manufactured in West Virginia, and registered with the WV Grown Program.

4.5.d.1. Hemp <u>and kratom</u> 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 <u>and kratom</u> 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 <u>and kratom</u> product registrations that are white labeled by a West Virginia vendor for sale in West Virginia shall be capped at $\frac{1,000}{2,000}$ per registrant. <u>White labelers</u> <u>must use West Virginia grown hemp in order to be eligible for the cap of \$2,000</u>.

4.5.e.1. The white labeler is subject to all fines and enforcement actions related to the white labeled products.

4.5.f. Hemp <u>and kratom</u> products that are of the same chemical composition but of different net quantities qualify as one product.

4.5.g. Hemp <u>and kratom</u> 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 or kratom 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 <u>for a minimum</u> <u>of two years after the final product manufacture date</u> for each product lot demonstrating the source of the hemp <u>or kratom</u> that was utilized to manufacture the hemp <u>or kratom</u> product, including documentation that the product was grown by a licensed hemp <u>or kratom</u> grower. Such documentation shall be made available to the Department upon request.

4.10. Kratom products shall be exempt from registration requirements until January 1, 2025.

§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;

5.2.c. The associated registration fee.

5.2.d. For hemp products listed under West Virginia Code §19-12E-12(c)(6A-F)- letter of good standing with the West Virginia state tax division.

5.2.e. For products listed under West Virginia Code §19-12E-12(c)(6A-F)- SSN, FEIN, or ITIN ID.

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 8.14 of this rule.

§61-30-6. Reserved for future use. Registration to distribute and sell kratom products.

6.1. All retail facilities, including online domains and websites, are required to register with the Department to sell kratom products in West Virginia.

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

6.2.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;

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

6.2.c. The associated registration fee;

6.2.d. Letter of good standing with the West Virginia state tax division; and

6.2.e. SSN, FEIN, or ITIN ID.

<u>6.3.</u> A non-refundable application fee of \$1,500 shall be paid to the department to manufacture, process, distribute, or sell kratom products in West Virginia.

6.4. An annual registration fee of \$300.00 shall be paid to the Department with the submission for application to manufacture, process, sell or distribute kratom products in West Virginia.

6.5. 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.

6.6. Registrations shall be due on January 1 annually.

6.7. Retail establishments that sell only kratom 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.

<u>6.8. Kratom retail registrations that come from a foreign entity shall be required to pay a foreign check fee of \$35.00.</u>

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

6.10. 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 kratom products.

6.11. The Department may revoke the registration of a retail facility to sell kratom products if it determines the facility has sold products to individuals not meeting requirements of subsection 8.14 of this rule.

§61-30-7. Displays, Advertising, and Marketing

7.1. For establishments selling hemp and kratom derived products intended for consumption, items shall be displayed only in areas that the store staff can see in direct sight.

7.2. For establishments, stores at fairs and festivals, farmers markets, etc., products must be in a controlled environment and not accessible to children.

7.3. No advertising on television programs, radio stations, websites or print publications are that allowable where audiences include more than 30 percent of people under the age of 21.

7.4. The distribution of free samples of hemp and kratom derived products intended for consumption is prohibited (except for products distributed in an "adult-only facility").

§61-30-7. §61-30-8. Labeling.

7.1. 8.1. Hemp <u>and kratom</u> 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. 8.2. Hemp and kratom products produced for topical absorption by humans shall be labeled in accordance with FDA guidelines for Cosmetic Products Warning Statements.

7.3. 8.3. Hemp and kratom products shall not contain disease or drug claims on the label that are not approved by the FDA.

7.4. 8.4. The product lot on the label must be traceable to the plant origin.

7.5. <u>8.5.</u> 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. <u>8.6.</u> 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. <u>8.7.</u> Product labels must be clear and legible.

7.8. <u>8.8.</u> Labels must be printed in English.

7.9. <u>8.9.</u> The following labeling is forbidden:

7.9.a. <u>8.9.a.</u> Unless at least 51% of the hemp <u>or kratom</u> 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. 8.9.b. The product cannot be attractive to children. This includes, but is not limited to:

7.9.b.1. <u>8.9.b.1.</u> The use of cartoons;

7.9.b.2. 8.9.b.2. The use of images popularly used to advertise to children; or

7.9.b.3. <u>8.9.b.3.</u> The imitation of a candy <u>or food</u> label.

7.9.c. <u>8.9.c.</u> The label cannot include false or misleading information. This includes untrue or unproven information that leads consumers to have an inaccurate impression.

7.9.d. <u>8.9.d.</u> 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. <u>8.10.</u> <u>Hemp product labels Labels</u> will be considered misbranded when a <u>WVDA</u> <u>Department</u> analysis finds the claim is above or below 20% <u>10%</u> of the cannabinoid amount declared on the label. <u>Kratom product labels will be considered misbranded when a Department analysis finds the claim is above or below 10 20% of the alkaloid amount declared on the label. <u>This shall remain effective through January 1, 2025.</u></u>

7.11. 8.11. The following requirements must be met for the primary label:

7.11.a. 8.11.a. The product must be identified with the generic or common name; and

7.11.b. <u>8.11.b.</u> If the product label claim contains any amount of cannabinoid(s) <u>and/or</u> mitragynine or 7-hydroxymitragynine, the label must properly identify them.

8.11.c. 7-hydroxymitragynine may not be sold in concentrations higher than two percent.

7.12. <u>8.12.</u> The following requirements must be met for the information panel:

7.12.a. 8.12.a. Manufacturer's name and contact information;

7.12.b. 8.12.b. Batch or lot number;

7.12.c. 8.12.c. Instructions for use and any preparation needed, if applicable;

7.12.d. <u>8.12.d.</u> List of all ingredients in descending order by weight or volume;

7.12.e. 8.12.e. Allergens if applicable;

7.12.f. <u>8.12.f.</u> Artificial food coloring, if applicable;

7.12.g. <u>8.12.g.</u> Expiration or use by date, if applicable;

7.12.h. <u>8.12.h.</u> Refrigeration or refrigerate after opening warnings, if perishable after opening; and

7.12.i. 8.12.i. For edible products, sodium, sugar, carbohydrates, and total fat per serving.

7.12.j. <u>8.12.j.</u> 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. <u>8.12.j.1.</u> 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. <u>8.13.</u> The cannabinoid content, in milligrams, may be posted on either the primary or informational panel, and must include:

7.13.a. <u>8.13.a.</u> 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. <u>8.13.b.</u> Cannabinoid (if applicable) content per serving for all hemp products with designated serving sizes.

7.14. <u>8.14.</u> Any product containing <u>hemp derived cannabinoids or kratom derivatives</u> more than 0.3% of tetrahydrocannabinols, must declare on the label, "NOT INTENDED FOR SALE TO PERSONS UNDER THE AGE OF <u>21</u>; <u>18</u>" Keep out of reach of children. Consult your physician before use if you are pregnant or taking any medication" and "Use of this product may impact drug testing results." (or more restrictive) on the label.

<u>8.14.a.</u> It is unlawful to manufacture, package, import, distribute, or sell any hemp derived or kratom product without the required warning statements. The warning statement shall be printed in English in a conspicuous and legible type on the outer packaging,

8.14.b. A temporary provision shall be made until January 1, 2025, on the above subsection 8.14 statement requirement on packaging, so long as the seller prominently displays a sign with the warnings listed until all labels and packaging are compliant.

7.15. <u>8.15.</u> 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. <u>8.16.</u> 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 <u>8.13</u> and 7.14 <u>8.14</u> and subdivision 7.12.1 <u>8.12.1</u> of this rule.

§61-30-8. §61-30-9. Handling and transport.

8.1. 9.1. It is lawful in West Virginia to transport and possess <u>kratom</u>, CBD and THC products, so long as the THC content does not exceed that permitted by law.

8.2. 9.2. Hemp <u>and kratom</u> 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. 9.3. 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. §61-30-10. Inspection and testing.

<u>9.1.</u> <u>10.1.</u> The Department shall conduct random inspections of hemp <u>and kratom</u> products distributed or made available for distribution in the state.

9.2. <u>10.2.</u> The Department shall periodically sample, analyze, and test hemp <u>and kratom</u> products distributed within the state for compliance with registration, labeling requirements, and product safety, if applicable.

9.3. <u>10.3.</u> The Department may conduct inspection of hemp <u>and kratom</u> products distributed or available for distribution for any reason that the Department deems necessary.

9.4. <u>10.4.</u> Samples taken by the Department shall be the official samples.

<u>10.5.</u> Unofficial samples submitted by law enforcement, any agents other than the commissioner, or by consumers, must be submitted to the Department's laboratory, but are subject to associated fees as set by the commissioner.

9.5.<u>10.6.</u> Samples that are found to contain contaminants in excess of the following levels shall be considered adulterated.

9.5.a. <u>10.6.a.</u> Pesticide Limits. The following list of contaminants does not constitute authorization to use or apply any of the following during Hemp <u>or kratom</u> 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

	61CS		
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
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

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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
Pyrethrins	8003-34-7	500	1,000
Pyridaben	96489-71-3	100	3,000
Spinotorapp	187166-15-0,	100	3,000
Spinetoram	187166-40-1		
Calina and	131929-60-7,	100	3,000
Spinosad	131929-3-0		
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. 10.6.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. <u>10.6.b.1</u>. The limit for ethanol does not apply to products that are intended to be orally consumed products containing alcohol.

9.5.b.2. <u>10.6.b.2.</u> The limit for ethanol or isopropyl alcohol does not apply to products that are intended to be topical products.

9.5.c. <u>10.6.c.</u> 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
Lead	0.2	0.5
Arsenic	0.2	1.5
Mercury	0.1	1

9.5.d. 10.6.d. Microbiological Limits for ingestible and inhalable products

9.5.d.1. <u>10.6.d.1.</u> Shiga toxin-producing *Escherichia coli* (STEC E. coli) and other pathogenic *E. coli*, none present.

9.5.d.2. <u>10.6.d.2.</u> *Listeria monocytogenes,* none present.

9.5.d.3. 10.6.d.3. Salmonella and Shigella, none present.

9.5.d.4. <u>10.6.d.4.</u> Clostridium botulinum and related neurotoxins, none present.

9.5.d.5. <u>10.6.d.5.</u> *Staphylococcus aureus* and related toxins, none present.

9.5.d.6. <u>10.6.d.6.</u> Coliforms greater than 10 colony forming units per gram.

9.5.e. 10.6.e. Mycotoxin Limits.

9.5.e.1. 10.6.e.1. Total Aflatoxin (B1, B2, G1, G2) - 20 μg/kg

9.5.e.2. <u>10.6.e.2.</u> Ochratoxin - 20 µg/kg

9.5.f. 10.6.f. Water Activity Limits

9.5.f.1 10.6.f.1. Dried flower products – The water activity shall not exceed 0.65 Aw.

9.5.f.2 <u>10.6.f.2</u>. Edible products – The water activity shall not exceed 0.85 Aw.

9.5.g. 10.6.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. <u>10.6.h.</u> The Department shall have the ability to set acceptable maximum limits for products derived from <u>kratom</u>, hemp, and hemp seed derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers

\$61-30-10. <u>§61-30-11.</u> Enforcement actions on unregistered sellers, <u>distributors</u>, and products <u>product</u> manufacturers (excluding select plant-based derivatives as described in section 12 of this rule)</u>.

<u>10.1.</u> If the seller, <u>distributor</u>, 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. <u>11.2.</u> Upon the first offense:

10.2.a. <u>11.2.a.</u> The seller, <u>distributor</u>, or product manufacturer will be notified in writing that they must register with the Department; and

10.2.b. <u>11.2.b.</u> The seller, <u>distributor</u>, or product manufacturer will be given 14 days to register with the Department; <u>and</u>

<u>11.2.c.</u> If the seller, distributor, 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. <u>11.3.</u> Upon the second offense within a one year five-year period:

10.3.a. <u>11.3.a.</u> The seller, <u>distributor</u>, or product manufacturer will be notified in writing that they must register with the Department;

<u>11.3.b.</u> The seller, distributor, 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;

<u>10.3.b.</u> <u>11.3.c.</u> The seller, <u>distributor</u>, or product manufacturer will be required to pay a penalty of $\frac{250.00}{500.00}$; and

<u>10.3.c.</u> <u>11.3.d.</u> <u>If the seller, distributor, or product manufacturer does not register with the</u> <u>Department in the allotted time, the</u> The hemp products shall be embargoed and removed from the shelves in accordance with section 12 of this rule.

<u>10.4.</u> Upon a third offense in a one-year five-year period:

10.4.a. <u>11.4.a.</u> The seller, <u>distributor</u>, or product manufacturer will be notified in writing that they must register with the Department;

10.4.b. <u>11.4.b.</u> The product shall be embargoed and removed from shelves in accordance with section 12 of this rule;

10.4.c. The seller, distributor, or product manufacturer shall be required to pay a penalty of $\frac{11.4.c.}{250.00}$; 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.

<u>11.4.d.</u> The permit shall be suspended for one year. An informal hearing can be requested to consider reinstatement of a suspended permit.

<u>11.5.</u> Law enforcement or any agents other than the commissioner shall work in consultation with the Department prior to and post investigations of any retail establishment, distributor, or manufacturer.

§61-30-12. Enforcement actions on unregistered sellers, manufacturers, and products.

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

12.2. Upon the first offense:

<u>12.2.a.</u> The seller, distributor, or product manufacturer will be notified in writing that they must register with the Department; and

<u>12.2.b.</u> The seller, distributor, or product manufacturer will be given 15 business days from date of attempted delivery of notice to register with the Department.

12.3. Upon the second offense (first violation) within a one-year period:

<u>12.3.a.</u> The distributor, seller and/or product manufacturer will be notified in writing that they must register with the Department;

<u>12.3.b.</u> The distributor, seller and/or product manufacturer will be required to pay a fine of \$1,000; and

<u>12.3.c.</u> The hemp products shall be embargoed and removed from the shelves in accordance with section 12 of this rule.

<u>12.3.d.</u> Any person in violation of this section shall be guilty of a crime and subject to criminal penalties in accordance with section 19E-12E(m)(o)

12.4. Upon a third offense (second violation) in a one-year period:

<u>12.4.a.</u> The distributor, seller and/or product manufacturer will be notified in writing that they must register with the Department;

<u>12.4.b.</u> The product shall be embargoed and removed from shelves in accordance with section <u>12 of this rule;</u>

<u>12.4.c.</u> The distributor, seller and/or product manufacturer shall be required to pay a penalty of <u>\$5,000; and</u>

<u>12.4.d.</u> For unregistered sellers and/or distributors, the eligibility to obtain a permit to sell hemp and kratom products shall be suspended for one year. The permit holder shall have the right to request an optional informal hearing.

<u>12.4.e.</u> 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.

<u>12.4.f.</u> Embargoes and offenses shall be specific to the individual product and not the entire manufacturer's line of products.

<u>12.4.g.</u> Any person in violation of this section shall be guilty of a crime and subject to criminal penalties in accordance with section 19E-12E(m)(o)

<u>12.4.h.</u> Law enforcement or any agents other than the commissioner shall work in consultation with the Department prior to and post investigations of any retail establishment, distributor, or manufacturer.

§61-30-11. <u>§61-30-13</u>. Enforcement actions on products violations and related penalties.

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

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

11.2.a. 13.2.a. Class I violations are flagrant violations and include, but are not limited to:

11.2.a.1. 13.2.a.1. Hemp and kratom products that are unsafe or adulterated or show cause for immediate human or animal health concern; and

 $\frac{11.2.a.2.}{13.2.a.2.}$ Hemp products that contain more than the THC content authorized by law-;

<u>13.2.a.2.1.</u> Products sampled by the laboratory are subject to the determination of flagrant violation by the commissioner

11.2.a.3. 13.2.a.3. Third offense registration violations as defined in subsection 10.4 11.4 of this rule-; and

13.2.a.4. Improper labeling, as defined in subdivision 8.9.b and subsection 8.14 of this rule.

<u>11.2.b.</u> <u>13.2.b.</u> Class II violations are violations in which the person acted in a faulty or careless manner and include, but are not limited to:

<u>11.2.b.1.</u> <u>13.2.b.1.</u> Falsification of information on an application;

11.2.b.2. <u>13.2.b.2.</u> No serving size and frequency of use listed on labeling; and

<u>11.2.b.3.</u> Failure of the product to meet label claims.

<u>11.2.c.</u> <u>13.2.c.</u> Class III violations are negligent violations and include but are not limited to:

11.2.c.1. 13.2.c.1. Improper labeling; and

11.2.c.2. 13.2.c.2. Misbranding.

11.3. <u>13.3.</u> Class III (Negligent) Violations.

11.3.a. 13.3.a. Upon the first Class III violation being committed by a manufacturer:

<u>11.3.a.1.</u> <u>13.3.a.1.</u> 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.

 $\frac{11.3.a.2.}{13.3.a.2.}$ The manufacturer shall be assessed a $\frac{100.00}{200.00}$ penalty for the Class III violation.

<u>11.3.a.3.</u> 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.

<u>11.3.b.</u> <u>13.3.b.</u> 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 <u>10 business</u> days after the Second Notice has been sent. An additional <u>\$500.00</u> \$100.00 penalty will be assessed for the second Class III violation of a product.

<u>11.3.c.</u> 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."

<u>11.3.c.1.</u> 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.

<u>11.3.c.2.</u> <u>13.3.c.2.</u> 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 <u>an informal</u> hearing in the matter subsequent to the notification of the suspension.

<u>11.4.</u> <u>13.4.</u> Class II (Faulty or Careless) Violations.

<u>11.4.a.</u> <u>13.4.a.</u> Upon the first Class II violation being committed by a manufacturer:

<u>11.4.a.1.</u> <u>13.4.a.1.</u> 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.

 $\frac{11.4.a.2.}{13.4.a.2.}$ The manufacturer shall be assessed a $\frac{200.00}{5400.00}$ penalty for the Class II violation.

<u>11.4.a.3.</u> 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.

<u>11.4.b.</u> <u>13.4.b.</u> 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 <u>10 business</u> days after the Second Notice has been sent. An additional <u>\$200.00</u>, <u>\$800.00</u> penalty will be assessed for the second Class II violation of a product.

11.4.c. 13.4.c. If a third Class II violation has not been resolved within a specified time frame, the will issue an immediate "Suspension of Permit".

<u>11.4.c.1.</u> 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.

<u>11.4.c.2.</u> 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. 13.5. Class I (Flagrant) Violations.

11.5.a. 13.5.a. Upon the first Class I violation being committed by a manufacturer:

<u>11.5.a.1.</u> 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.

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

11.5.a.3. <u>13.5.a.3.</u> The manufacturer of a product with a Class I violation shall be assessed a penalty of \$250.00. <u>\$1,000.00</u>

<u>13.5.b.</u> Any person knowingly processing, manufacturing, distributing, or selling hemp derived or kratom products that is contaminated with a toxic or illegal substance is guilty of a felony and shall be fined or imprisoned, as defined in chapter 19 article 12, E and F, as determined by the commissioner.

11.5.b. <u>13.5.c.</u> The embargo notice will establish the date effective and give the reason for the <u>embargo</u>.

<u>11.6.</u> <u>13.6.</u> 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.

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

<u>13.8.</u> Law enforcement or any agents other than the commissioner shall work in consultation with the Department prior to and post investigations of any retail establishment or manufacturer.

§61-30-12. §61-30-14. Embargos.

12.1. 14.1. Embargo orders.

12.1.a. <u>14.1.a.</u> When the Commissioner has reasonable cause to believe any lot of hemp <u>or</u> <u>kratom</u> 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. <u>14.1.b.</u> When the embargo is issued, the Commissioner shall affix a tag or other marking to the hemp <u>or kratom</u> product, warning that such product is under embargo and shall notify the custodian of the right to request a hearing.

12.1.c. 14.1.c. The Commissioner shall release the hemp <u>or kratom</u> product so embargoed when said product has been brought into compliance with this article and its rules.

12.1.d. <u>14.1.d.</u> 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.

<u>12.1.e.</u> 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. 14.2. Condemnation and Confiscation

<u>12.2.a.</u> <u>14.2.a.</u> Any hemp <u>or kratom</u> product not in compliance with the provisions of this rule <u>shall_may_be</u> subject to condemnation, <u>and</u> confiscation, <u>and destruction</u>. <u>on complaint of the</u> <u>Commissioner to the circuit court of the county in which the product in question is located</u>. 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.

<u>14.2.b.</u> Any party aggrieved by the penalties set forth in this rule shall respond to the Department within 14 calendar days of the infraction. Upon request, the party shall be afforded the opportunity for a hearing before the commissioner under the rules promulgated by the commissioner.

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.