West Virginia Department of Agriculture
Kent A. Leonhardt, Commissioner
Joseph L. Hatton, Deputy Commissioner

Dear Personal Care Products Council:

Thank you for submitting your comments to the West Virginia Department of Agriculture regarding 61CSR30. The Department has reviewed your comments and have considered how these changes would impact the current regulations of hemp products.

The comments you have submitted to the WVDA highlight the importance of the certificate of analysis (COA) for hemp products. The WVDA is determined to ensure that hemp products are safe for consumers throughout West Virginia, while also creating the testing requirements that are feasible for manufactures. Your comments suggest that the WVDA should clarify their position on "guaranteed cannabinoids" and create COA requirements that are not as strenuous on the manufacturing process.

The WVDA would like to make appropriate changes to the current regulations that can help address these concerns. Moving forward, we will take these comments into consideration while updating current regulations for hemp products.

Sincerely,

Stoney Helmick
Hemp Product Program Specialist
WV Dept. of Agriculture
1900 Kanawha Blvd. E.
Charleston, WV 25305
304-546-9273
shelmick@wvda.us

Personal Care Products Council
Committed to Safety, Quality & Innovation

July 27, 2021

Via Electronic Submission
Stoney Helmick
WV Department of Agriculture
1900 Kanawha Boulevard
East Charleston, WV 25305
Email: shelmick@wvda.us

Re: Title 61, Series 30, Comments on West Virginia Department of Agriculture's Proposed Rule on Hemp Products

The Personal Care Products Council ("PCPC")[1] is pleased to submit the following comments on the West Virginia Department of Agriculture's (the "Department") Proposed Rulemaking related to hemp products (the "Proposed Rule") that was publicly released on June 28, 2021.[2] Our member companies are involved in the distribution and sale of over-the-counter ("OTC") drug products, cosmetics, toiletries, fragrances, and ingredients in West Virginia, and therefore have a strong interest in the scope and applicability of this Proposed Rule.

The Proposed Rule addresses in detail the importance of sensible test methods for hemp products in an effort to make sure West Virginia consumers can make informed purchasing decisions. While PCPC supports the Department's role to provide guidance on the responsibilities of manufacturers to provide hemp products in the state, the extent of the certificate of analysis ("COA") requirements go beyond what is needed to facilitate compliance and product safety, and could inadvertently hurt good actors.

Our Position

PCPC supports the Department's program to ensure consumer safety and integrity of hemp products distributed and sold in West Virginia through proper testing and labeling standards. Specifically, we support the recent Proposed Rule changes that removed the requirement for hemp product testing to be done by a third-party laboratory. We also support the new language confirming that testing of a hemp product, even products containing the cannabinoids cannabidiol ("CBD") and tetrahydrocannabinol ("THC"), does not need to include testing for solvents,

[1] Based in Washington, D.C., the Council is the leading national trade association representing the $250 billion global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600-member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. As the makers of a diverse range of products that millions of consumers rely on every day, from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance, member companies are global leaders committed to product safety, quality, and innovation.

[2] *See* §61-30-1, *et seq.*, West Virginia Department of Agriculture's Proposed Rule on Hemp Products (Jun. 28, 2021), *available at* http://apps.sos.wv.gov/adlaw/csr/ruleview.aspx?document=17513&KeyWord=.

pesticides, heavy metals, and impurities. These revisions to the Proposed Rule provide much needed flexibility to manufacturers while still ensuring the highest standards of protection for consumer's safety. But as discussed below, we do have some concerns on how the new language in the Proposed Rule could affect manufacturers' ability to provide top-quality hemp products in West Virginia.

A. COA Requirement for Products Without Cannabinoids

As stated in the Proposed Rule, all hemp products registered with the Department must include a "certificate of analysis from a laboratory for the lot of each product."[3] While we agree that COAs provide important disclosures to consumers for products containing THC or CBD, our concern is that the Proposed Rule makes this a requirement for products with hemp derivatives that do not contain such cannabinoids.

While we understand that the Proposed Rule also takes into consideration products specifically containing CBD or THC by adding additional testing requirements,[4] our concern is that it does not consider hemp products *without* such cannabinoids. As written, "hemp product" is defined broadly to include products derived from hemp seeds[5] and hemp seed oil[6]. But according to the U.S. Food and Drug Administration ("FDA"), hemp seed and hemp-seed-derived ingredients do not naturally contain THC or CBD.[7] The hemp seed-derived ingredients contain only trace amounts of THC and CBD, which the seeds may pick up during harvesting and processing when they are in contact with other parts of the plant. Consumption of these hemp seed-derived ingredients is not capable of making consumers "high". [8]

Although hemp products made with hemp seeds and hemp seed oil are included in the Proposed Rule's definition of hemp products, given that these products do not naturally contain THC, they should be exempted from the COA requirement. As such, we believe the COA requirement should only apply to the raw hemp materials and not the final hemp product.

B. Alternative Guarantee for Hemp Products Containing Cannabinoids

As an alternative to a COA, the Proposed Rule states that hemp product can include a "guarantee" of a cannabinoid product derived from hemp.[9] Unfortunately, the Proposed Rule does not provide any additional guidance on this guarantee, making the COA the only option certifying a product's cannabinoid levels. Based on the language, a company is permitted to make a declaration upon the finished hemp product's COA based upon the raw material trace specification in the Proposed

[3] §61-30-4(4.2.f.).
[4] §61-30-2(6.1.).
[5] §61-30-2(2.14.a.).
[6] §61-30-2(2.14.i.).
[7] *See* FDA, FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), Questions and Answers, Question 12 (dated Jan. 22, 2021) *available at* https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#cosmetics.
[8] *Id.*
[9] §61-30-2(6.2.).

Rule. We believe that the Department should provide additional clarification on what the "guarantee" would entail, including how such a guarantee would be permitted without an analytical check present in a COA.

Thank you for the opportunity to submit comments on this important Proposed Rule, and we look forward to continued engagement on this important issue.

Best regards,

Lauren Shapiro
Staff Counsel
Personal Care Products Council

West Virginia Department of Agriculture
Kent A. Leonhardt, Commissioner
Joseph L. Hatton, Deputy Commissioner

Dear Jonathan Miller:

Thank you for submitting your comments to the West Virginia Department of Agriculture regarding 61CSR30. The Department has reviewed your comments and have considered how these changes would impact the current regulation of hemp products.

The comments you have submitted to the WVDA highlight the need to evaluate hemp seed products and hemp seed derivatives moving forward. We also appreciate your comments on the animal supplement products that contain hemp or CBD. The WVDA is evaluating how to further develop our regulations to allow for safe hemp-based animal products/supplements.

The WVDA is determined to ensure that hemp products are safe for consumers throughout West Virginia, while also creating the testing requirements that are feasible for manufactures. We appreciate your concern with the contaminants, heavy metals, and water activity testing. The WVDA will take each of these into consideration as we move forward with regulations.

Labeling requirements that have been established by the WVDA for hemp products are also subject to change as we move forward. The WVDA is happy to consider your comments regarding packaging dates and THC-free claims.

We would like to thank you again for your submission, and each of these comments will be reviewed thoroughly as we move towards making changes.

Sincerely,
Stoney Helmick
Hemp Product Program Specialist
WV Dept. of Agriculture
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Jonathan S. Miller
Member
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July 28, 2021

Stoney Helmick
West Virginia Department of Agriculture
1900 Kanawha Boulevard
East Charleston, WV 23505
Via Email: shelmick@wvda.us

Re: Proposed Amendments to West Virginia Hemp Products Rule, 61 CSR 30

Dear Mr. Helmick:

I serve as General Counsel for the U.S. Hemp Roundtable (the "Roundtable"). The Roundtable appreciates the opportunity to submit comments to the Department of Agriculture on the proposed amendments to West Virginia's Hemp Products Rule, 61 CSR 30 ("the Rule"). The Roundtable is the industry's leading national business advocacy organization that represents over 80 firms from across the country – at each link of the hemp supply and sales chain – and includes the ex officio membership of the industry's major grassroots organizations.

The Roundtable applauds the Department of Agriculture ("the Department") for initiating the proposed amendments, several of which would better align the Rule's labeling and testing requirements with existing federal and state requirements applicable to hemp-derived cannabinoid products. While some amendments are reasonable and would make the Rule more workable for the industry, we offer the following recommendations to further improve upon the language and ensure it reflects sound science, as well as best practices that we believe are working well for the vast majority of the industry.

(1) Remove hemp seed derivatives and hemp fiber products from the scope of the rule.

First and foremost, products that are solely composed of hemp seed derivatives and hemp fiber should be removed from the scope of the rule. These products have been federally legal (and legal in many states) even prior to the legalization of hemp under the 2018 Farm Bill,[1] due

[1] Prior to the passage of the 2018 Farm Bill, 21 U.S.C. 802 (16) - the Federal Controlled Substances Act – excluded the following from the definition of "marihuana": the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

to the fact that they contain only trace amounts of THC and other cannabinoids. The U.S. Food and Drug Administration ("FDA") has also recognized that hemp seed-derived ingredients are Generally Recognized as Safe for use in food.[2] Moreover, West Virginia is the only state in the country that regulates hemp seed and fiber products in substantially the same manner as hemp-derived cannabinoid products, when it is clear these products do not pose the same regulatory considerations.

For these reasons, we strongly urge the Department to amend Section 2.14(n) and exclude hemp seed derivatives, hemp fiber/fiber products, and hemp seed pressed or other processed into oil from the definition of "hemp product" or "hemp commodity," or otherwise exempt these products from the Rule's registration and Certificate of Analysis, labeling, and testing requirements.

(2) **Revise Section 7.5 to allow flexibility with labeling hemp-based animal supplements.**

Currently, the proposed amendments would require hemp products meant for animal consumption to be labeled and comply with the West Virginia Commercial Feed Law. However, certain labeling requirements imposed on animal feed, such as a Guaranteed Analysis, are not typically used in animal health products, also referred to as animal supplements, which are similar to dietary supplements for humans. For example, in recognition that animal supplements are distinct and not intended to be marketed as animal feed, the National Animal Supplement Council ("NASC")[3] – a well-respected organization that is committed to the quality and integrity of animal supplements – has developed labeling guidelines for these products that recognize this distinction, and do not require a Guaranteed Analysis. Although these guidelines are only available to NASC members, we encourage the Department to work with NASC to align its requirements with NASC's guidelines. In the meantime, we request the Rule specify that only products sold as animal feed or pet food must comply with the state's Commercial Feed Law, while animal health products/animal supplements must comply with the Rule's general labeling requirements, where such requirements are applicable. As with its other proposed amendments to the Rule, the Roundtable's proposed amendments to Section 7.5 are set forth below in red font:

7.5. Hemp products intended for animal consumption and intended to be sold as animal feed or pet food shall be labeled and comply with ~~all other applicable federal laws and regulations.~~ the West Virginia Commercial Feed Law, West Virginia Code §19-14-1 *et seq*. Hemp products intended to be sold as animal supplements must comply the requirements under §61-30-7, where applicable.

[2] FDA Constituent Update, *FDA Responds to Three GRAS Notices for Hemp Seed-Derived Ingredients for Use in Human Food* (Dec. 20, 2018), available at: https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food.

[3] National Animal Supplement Council, http://www.nasc.ee/.

(3) Revise Section 7.12(a) to allow labels to include the manufacturer, packer, or distributor contact information.

Consistent with the FDA's requirements for food, dietary supplement, and cosmetic labels, and several state requirements,[4] the Rule's labeling requirements should be revised to allow either the name and contact information for the manufacturer, *or* the packer or distributor of the product. In many cases, the identity of the manufacturer is considered propriety for brand owners that use contract manufacturers and providing the contact information of the packer or distributor provides sufficient means for the Department to obtain any necessary information about the manufacturing of the product.

7.12.a. Manufacturer's, packer's, or distributor's name and contact information;

(4) Delete language prohibiting THC-free and non-THC claims if THC levels are above detectable levels set by the Department.

Section 7.14 prohibits label claims that a product is THC-free or non-THC if it "contains levels of THC above detectable levels as determined by the Department." There is no state in the country that imposes this type of requirement on THC-free/non-THC free claims. So long as companies are able to substantiate such claims with reliable testing that demonstrates the product contains non-detectable levels of THC, we see no reason why the Department should impose its own state-specific definition for what is considered a "detectable level" of THC. Further, the Rule already includes a definition for "THC-free" or "non-THC" under Section 2.24, as meaning a "hemp product that contains less than a detectable or quantifiable amount per serving of tetrahydrocannabinol," and therefore it is unnecessary for the Department to impose even stricter requirements on use of these claims.

(5) Revise the contaminant limits under Section 9 to align with existing state requirements and industry best practices.

We appreciate the Department's inclusion of contaminant limits that in several respects are similar to those imposed by other states, including those proposed by the State of New York.[5] However, as explained below, there are a few limits that either appear to be incorrect or are not reflective of industry best practices, and where we have provided suggested revisions that we urge the Department to consider.

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[4] *See*, e.g., 902 KAR 45:190. Hemp-derived cannabinoid products; packaging and labeling requirements, Section 3(2)(d), available at: https://apps.legislature.ky.gov/law/kar/902/045/190.pdf; New York Cannabinoid Hemp Program Proposed Regulations, Section 1005.9(a)(6), available at: https://regs.health.ny.gov/sites/default/files/proposed-regulations/Cannabinoid%20Hemp_0.pdf.

[5] New York Cannabinoid Hemp Program Proposed Regulations, Section 1005.10, available at: https://regs.health.ny.gov/sites/default/files/proposed-regulations/Cannabinoid%20Hemp_0.pdf

- The Pesticide Limits for Oxamyl and Paclobutrazol for "All Other Products" may have been switched. We believe these should appear as follows, which aligns with New York's proposed limits for these pesticides:

Oxamyl	~~200~~100	~~200~~100
Paclobutrazol	~~100~~200	~~100~~200

- The Toxic Metal Limits for Lead (inhalable/smokable, and all other products) and Mercury (all other products) should be revised, as compliance with the currently proposed limits will be difficult for manufacturers to achieve. Notably, for lead ingestion the No Significant Risk Level for Cancer under California's rigorous Proposition 65 is 15 mcg per *day*[6] and the American Herbal Products Association's ("AHPA") highly respected guidance for Heavy Metals allows for 6 mcg per *day*.[7] To align with New York's and other state requirements, the limits should be increased as follows:

Lead	~~0.2~~ 0.5	~~0.5~~1.0
Mercury	0.1	~~1~~1.5

- Concerning the proposed Microbiological Limits, these limits should include the sample amount, which is critical for testing accuracy and must also be balanced with cost factors. For example, a 1-gram sample is sufficient for Shiga toxin-producing *Escherichia coli* (STEC E. coli) and other pathogenic *E. coli*, as well as *Salmonella*. While some manufacturers use a 10-gram sample, this larger sample size can have a significant economic impact on small businesses that produce dietary supplements.

  We also request the Department eliminate the requirements for listeria testing, as well as *Shigella*, *Clostridium botulinum* and related neurotoxins, *Staphylococcus aureus* and related toxins, and Coliforms. A number of states, including California, Florida, and New York, do not impose these limits on hemp products.

  Further, this type of testing does not reflect industry best practices. For example, according to FDA reports, listeria outbreaks in the U.S. have been link to raw, unpasteurized milks and cheeses, ice cream, raw or processed vegetables, raw or processed fruits, raw or undercooked poultry, sausages, hot dogs, deli meats, and raw

[6] California Office of Environmental Health Hazard Assessment, Lead and Lead Compounds, https://oehha.ca.gov/proposition-65/chemicals/lead-and-lead-compounds. Although the Maximum Allowable Dose Level for Reproductive Toxicity is 0.5 mcg/day, the Proposed Regulations already provide for label warnings for pregnant and nursing women.

[7] American Herbal Products Association Guidance Policy, Heavy Metals (Jul. 2012), http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Heavy_Metals_Guidance.pdf.

or smoked fish and other seafood.[8] In addition, listeria cannot survive heating and requires high water activity to replicate. The FDA's Guidance for Industry concerning Hazard Analysis and Risk-Based Preventive Controls for Human Food and multiple other sources state the kill step temperature for listeria is above 86° F following one (1) hour of heat time.[9] The common hemp decarboxylation heating temperature is 270° F and is generally performed for three (3) hours based on commercial quantity average. Therefore, those using decarboxylation in their processes are appropriately managing the risk of microbiological contaminants such as listeria.

Compliance with 21 CFR 117 (current Good Manufacturing Practices for dietary supplement ingredients and food) requires manufacturers to complete a Hazard Analysis and Risk-Based Preventative Control Plan. This analysis reveals to the manufacturer whether tests, such as listeria, must be included within the Preventative Control Plan for the type of process and product being manufactured. For example, listeria testing is unusual for hemp extract food products and dietary supplements and is not typically recommended for dietary supplements. Further, neither USP nor AHPA require or recommend listeria testing for these types of products. Additionally, listeria testing in particular requires the method dictated in the FDA's Bacteriological Analytical Manual,[10] which requires a 25-gram sample and is cost prohibitive for most hemp extract product manufacturers.

Finally, we recommend that limits for aerobic bacteria and total yeast and mold be included in this list.

9.5.d.1 Shiga toxin-producing *Escherichia coli* (STEC E. coli) and other pathogenic *E. coli*, none present detected in 1 gram.
~~9.5.d.2. *Listeria monocytogenes*, none present.~~
9.5.d.3. *Salmonella* and *Shigella*, none present detected in 1 gram.
9.5.d.4. ~~*Clostridium botulinum* and related neurotoxins, none present~~ Total plate count for aerobic bacteria, $<10^4$ CFUs/gram.
9.5.d.5. ~~*Staphylococcus aureus* and related toxins, none present~~ Total yeast and mold, $<10^3$ CFUs/gram.
~~9.5.d.6. Coliforms greater than 10 colony forming units per gram.~~

- For Mycotoxin Limits, "A" should be added to "Ochratoxin" as follows:

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[8] FDA, Listeria (Listeriosis), https://www.fda.gov/food/foodborne-pathogens/listeria-listeriosis.

[9] FDA, Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food (Jan. 2018), https://www.fda.gov/media/108852/download at Appendix 3, Page 5, Table 3-B "Time and Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Food Products."

[10] FDA, Bacteriological Analytical Manual (BAM) (current as of Dec. 4, 2020), https://www.fda.gov/food/laboratory-methods-food/bam-chapter-10-detection-listeria-monocytogenes-foods-and-environmental-samples-and-enumeration.

Ochratoxin A – 20 mcg/g.

- The Water Activity Limit for Edible Products and Foreign Material Limits should be deleted. We are not aware of any other state that currently imposes such limits on hemp products. In addition, the limits do not align with industry best practices, including AHPA's Limits of Foreign Matter in Herbal Ingredients,[1] an industry guidance that outlines maximum quantitative limits on foreign matter in various herbal raw materials. For example, the guidance recommends plant parts of the same herbal raw material species, other than those named in specifications, should not exceed 5% (by weight), and all other foreign matter should not exceed 2% (by weight).

* * *

Thank you for your consideration of our comments. We would be happy to meet with the Department to further discuss the proposed amendments to the Rule prior to adoption or answer any questions about our comments. You may contact me or my colleague in our Charleston office, Joe Ward.

Sincerely,
Jonathan Miller

General Counsel
U.S. Hemp Roundtable

[1] AHPA, Guidance on Limits of Foreign Matter in Herbal Ingredients (Oct. 2017), available at: https://www.ahpa.org/Portals/0/PDFs/Policies/GuidanceDocuments/Guidance_Foreign_Matter_Limits.pdf.

West Virginia Department of Agriculture
Kent A. Leonhardt, Commissioner
Joseph L. Hatton, Deputy Commissioner

Dear Jennifer Mason:

Thank you for submitting your comments to the West Virginia Department of Agriculture regarding 61CSR30. The Department has reviewed your comments and have considered how these changes would impact the current regulations.

You have requested that the WVDA add an exemption to section 6.4 of the rule for products with "non-detectable" amounts of THC or CBD. The hemp products you wish to include in this exemption would no longer require a certificate of analysis (COA) for each final product if the only hemp ingredient contained fall under the 6.4 exemption you have offered. We at the WVDA have discussed the positive impacts this could have on current product registration. The WVDA wishes to ensure that all products are safe for consumers and make the registration process reasonably efficient for manufactures.

You have also offered your opinions on how the labeling requirements for the list of all ingredients should be updated for cosmetic products. The WVDA will take this comment into consideration, as we wish for our hemp product labeling requirements to be uniform with current manufacturing guidelines.

We would like to thank you for submitting these comments, and they will be considered when moving forward with the hemp product regulations.

Sincerely,

Stoney Helmick
Hemp Product Program Specialist
WV Dept. of Agriculture
1900 Kanawha Blvd. E.
Charleston, WV 25305

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shelnick@wvda.us

Martin, Jodee

From: Helmick, Stoney
Sent: Wednesday, July 28, 2021 12:04 PM
To: Greenlief, Jennifer; Martin, Jodee
Subject: FW: Comment on WVDA Emergency Rule Related to Hemp

Jennifer Mason's comments.

From: Mason, Jennifer <Jennifer.Mason@DINSMORE.COM>
Sent: Tuesday, July 27, 2021 10:16 AM

To: Helmick, Stoney <shelmick@wvda.us>
Subject: RE: Comment on WVDA Emergency Rule Related to Hemp

[NOTICE: This email came from a sender outside of the WVDA organization. Please be careful when opening attachments and/or clicking links in this email.]
My apology .. small changes below to the comment.

Stoney,

Per your instruction, following is the comment that my client has with respect to the new emergency rules. If you have any questions, we are happy to discuss the same.

COMMENTS:

1. Section 6.4 of the regulations appears to include products derived from Hemp Seed. These products have such a low THC/CBD content that FDA has given GRAS (Generally Recognized as Safe) status to Hemp Seed and products derived therefrom. Therefore, in order to be consistent with FDA regulations, as much as possible, WVDA could add an exception to 6.4 of the new regulations that would exclude products with non-detectable (see number 4 below as to a definition of the same) THC and/or CBD. A point of clarity related to use of the language "non-detectable" – this would imply an extremely low level given modern analytical techniques. It would be preferable that clear language establishes a stated threshold below which the COA would not be required on the finished products on a per batch basis – the requested quantity being 10 ppm THC and/or CBD.

2. Definition –a definition of "non-detectable" should be added. We would suggest that "non-detectable be defined as an amount of THC/CBD that is less than 10 ppm in the raw extract.

3. Finally, for products that fall under the revised 6.4, that is those with "non-detectable" THC and/or CBD, the reason for testing at the final product for high THC and/or CBD stage is eliminated. The products will contain far less than 10 ppm because the original product testing at the raw material stage will evidence that the extract, for example, contains less than 10 ppm. Therefore, it is suggested that WVDA add a section wherein, for products that contain a raw product extract with no more than 10 ppm on product intake, WVDA would only require a COA at the stage of product material intake (that is the COA for the extract), when it arrives and before it is combined with other ingredients. This would remove the requirement

for a COA of each final product which for manufacturing companies could result in thousands of COAs that are not normally part of a GMP (Good Manufacturing Practice).

4. Section 7.12.d requires a "list of all ingredients in descending order by weight or volume". This is inconsistent with cosmetic labelling requirements of the FDA. WVDA should add "if applicable" at end of Section 7.12.d.

Dinsmore

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delete it from your system without copying it, and notify the sender by reply e-mail, so that our address record can be corrected.

West Virginia Department of Agriculture
Kent A. Leonhardt, Commissioner
Joseph L. Hatton, Deputy Commissioner

Dear Asa Waldstein:

Thank you for submitting your comments to the West Virginia Department of Agriculture regarding 61CSR30. The Department has reviewed your comments and have considered how these changes would impact the current regulations of hemp products.

You have requested that the WVDA reconsider current label requirements for allowing the word "organic" in the supplement fact panel of hemp products, and the requirement for allergens to be applied to ingestible products. The WVDA would like to create labeling requirements that are in line with federal guidelines, and that create safe products for the consumer(s). These comments are appreciated and will be considered moving forward.

You have also made comments regarding how our residual solvent limits compare to a standard residual solvent test. The WVDA has reviewed residual solvent limits from other states currently testing cannabis/hemp products and has decided that these thresholds are uniform with current regulations around the country.

You have expressed concerns with the WVDA's microbiological contaminant limits. We would like to thank you for sharing your thoughts on how we can create a more efficient standard for these contaminants in the products we are registering.

Finally, you have requested information regarding a class III violation with misbranding and/or improper labeling of product. The WVDA does routine random inspections of products that are currently in circulation. These violations are negligent violations that apply to products we have

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telephone: 304-558-3550 • fax: 304-558-2203

found during inspection(s), and we are happy to work with everyone in order to ensure these products do not fall under this category during registration.

The WVDA appreciates that you have taken the time to highlight your concerns. We would like to thank you for your comments, and each will be taken into consideration as we move forward in updating hemp product regulations.

Sincerely,

Stoney Helmick
Hemp Product Program Specialist
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WEST VIRGINIA SECRETARY OF STATE
MAC WARNER
ADMINISTRATIVE LAW DIVISION

eFILED
6/28/2021 4:43:06 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: 07/28/2021 12:00 PM

COMMENTS MAY BE MAILED OR EMAILED TO:

NAME: Stoney Helmick

ADDRESS: WV Dept. of Agriculture

1900 Kanawha Boulevard, East Charleston WV 25305

EMAIL: shelmick@wvda.us

PLEASE INDICATE IF THIS FILING INCLUDES:

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

(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:

Sets registration and regulation of hemp products in West Virginia

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

definitions and changes to registration

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

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

n/a

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

n/a

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

n/a

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2021 Increase/Decrease (use "-")	2022 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):

At this time we do not have an accurate estimate

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 30, 2020~~

1.4. Effective Date. -- ~~July 1, 2020~~

1.5. Sunset Date. -- This rule shall terminate and have no further force or effect ~~July 1, 2025~~ ten years from its 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~~2017 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~~ direct to the end-point consumer.

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. "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 product.

~~2.8.~~ 2.9. "Grower" means a person, joint venture, ~~or~~ cooperative, or any entity that produces hemp.

~~2.9.~~ 2.10. "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, 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.~~ 2.17. "Licensee" means an ~~individual~~ person or business entity possessing a license issued by the Department to grow, handle, cultivate, or process hemp.

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

~~2.21.~~ 2.20. "Primary label" means the part of the label ~~most likely~~ to be prominently 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.~~ 2.21. "Processing" means converting agricultural commodity into marketable form.

~~2.24.~~ 2.22. "Registrant" means a person or entity ~~an individual or business~~ that has registered hemp products 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.~~ 2.23. "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.

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

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 ~~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~~ Registration of hemp products or extracts.

4.1. ~~The manufacturer of all hemp~~ 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 hemp product registrations ~~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 registrant ~~applicant~~;

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

4.2.c. The name of the product;

4.2.d. ~~The name and address of the~~ 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. Beginning January 1, 2022, registration shall be due by January 1 of each year.

~~4.4~~4.5. 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.~~

4.5.a. Beginning January 1, 2022, in lieu of the $200.00 registration fee stated 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.b. Hemp products that are registered under subdivision 4.5.a of this rule must include a copy of the registrant's West Virginia processing/cultivation license.

4.5.c. Hemp products that are registered under subdivision 4.5.a of this rule 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.

~~4.4.b.~~4.5.d. 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.~~4.5.e. The annual fee for hemp product registrations shall be capped at $1,000 per registrant ~~manufacturer~~ for products that are manufactured and sold in West Virginia.

4.5.f. Beginning January 1, 2022, in lieu of the $1,000 registration cap fee stated in subdivision 4.5.e of this rule, a registration cap fee of $500.00 per registrant shall be paid for hemp products that are grown, harvested, and manufactured in West Virginia, and registered with the WV Grown Program.

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

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

~~4.4.d.~~4.5.g. 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 ~~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.~~4.5.h. 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.

~~4.4.g.~~4.5.i. Hemp products that are of the same chemical composition but of different net quantities qualify as one product.

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

4.5.k. The Commissioner has the ability to waive fees.

~~4.5.~~4.6. The Department may deny or delay registrations and renewals that are incomplete or erroneous.

~~4.6.~~4.7. A new registration is required for any of the following:

~~4.6.a.~~4.7.a. Changes in the chemical composition or formula of the hemp product; or

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

~~4.6.c.~~4.7.b. Changes to health-related label claims for active ingredients.

~~4.7.~~4.8. The person or entity registering the product is responsible for the completeness and accuracy of all information submitted.

~~4.8. A retailer or distributor may register a product in lieu of the manufacturer if the product is not registered.~~

4.9. As a condition of registration, all registrants ~~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. Registrations shall be due on January 1 annually.

~~5.5.~~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 2.9 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.

5.6.d. The Commissioner has the ability to wave registration fees.

~~5.6.~~5.7. The Department may deny or delay registrations for incomplete applications.

~~5.7.~~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.

~~5.8.~~5.9. A distributor of hemp products that does not itself engage in retail sales is not required to register under this section.

§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 hemp products ~~containing CBD or THC hemp~~ 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 or guarantee of a cannabinoid product derived from hemp.~~:~~

~~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.

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

§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 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 ~~all other applicable federal laws and regulations.~~ 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.

7.9.d. The label cannot include the use of the word "organic" unless referencing certified organic products that have ~~the product has~~ 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) ~~CBD or THC~~, the label must properly identify them.~~; and~~

~~7.11.c. The net weight or volume of the contents of the package, in both metric and US customary units must be displayed.~~

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

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

~~7.12.b. Manufacturing or packaging date;~~

~~7.12.c.~~7.12.b. Batch or lot number;

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

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

~~7.12.f.~~7.12.e. Allergens if applicable;

~~7.12.g.~~7.12.f. Artificial food coloring, if applicable;

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

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

~~7.12.j.~~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 ~~THC or CBD~~ (if applicable) shall provide the total amount of the claimed cannabinoid content per package for all manufactured products; and

7.13.b. ~~THC or CBD~~ Cannabinoid (if applicable) content per serving for all hemp products ~~edibles and concentrates,~~ with designated serving sizes.

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

~~7.14~~ 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~~subsection 7.13 and subdivision 7.12.j 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, 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
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
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 (ug/g)	Action Level for All Other Products (ug/g)
Cadmium	0.2	0.5
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 ~~product manufacturers~~ 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.; ~~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 one ~~five~~ 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 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.~~10.3.b. The seller or product manufacturer will be required to pay a penalty of $250.00; and

~~10.3.d.~~10.3.c. ~~If the seller or product manufacturer does not register with the Department in the allotted time, the~~ 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 ~~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.~~ 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 ~~dosage~~ serving size and frequency of use 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:

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 ~~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 one ~~5~~ 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~~, and a specific time and place for a hearing~~.

11.3.c.2. The suspension of permit order shall state the ~~effective~~ time that ~~of~~ the suspension will be effective and give the reason for ~~it~~ the suspension, ~~and a specific time and a place for a hearing, except in~~ 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 one ~~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, and 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 of permit order shall state the time that the suspension will be effective, and 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~~ 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 ~~of~~ for the ~~suspension and specify a time and a place for a hearing to be held in the matter~~ embargo.

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~~ a 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.