

# Administrative Procedures – Final Proposed Rule Filing

## Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the “Rule on Rulemaking” adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms requiring a signature shall be original signatures of the appropriate adopting authority or authorized person, and all filings are to be submitted at the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of these forms will be used to generate a notice of rulemaking in the portal of “Proposed Rule Postings” online, and the newspapers of record if the rule is marked for publication. Publication of notices will be charged back to the promulgating agency.

**PLEASE REMOVE ANY COVERSHEET OR FORM NOT REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!**

**Certification Statement:** As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

### Vermont Hemp Rules

 \_\_\_\_\_, on 3/13/20  
(signature) (date)

Printed Name and Title:  
Anson B. Tebbetts, Secretary, Vermont Agency of Agriculture, Food and Markets

RECEIVED BY: \_\_\_\_\_

- Coversheet
- Adopting Page
- Economic Impact Analysis
- Environmental Impact Analysis
- Strategy for Maximizing Public Input
- Scientific Information Statement (if applicable)
- Incorporated by Reference Statement (if applicable)
- Clean text of the rule (Amended text without annotation)
- Annotated text (Clearly marking changes from previous rule)
- ICAR Minutes
- Copy of Comments
- Responsiveness Summary

Received  
3/13/20  
page 1

Final Proposed Coversheet

1. TITLE OF RULE FILING:

**Vermont Hemp Rules**

2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE

19P-045

3. ADOPTING AGENCY:

Vermont Agency of Agriculture, Food and Markets

4. PRIMARY CONTACT PERSON:

*(A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).*

Name: Cary Giguere

Agency: VAAFM

Mailing Address: 116 State Street, Montpelier, VT 05620-2901

Telephone: 802 828 - 6531 Fax: 802 828 - 2361

E-Mail: cary.giguere@vermont.gov

Web URL *(WHERE THE RULE WILL BE POSTED)*:

<https://agriculture.vermont.gov/public-health-agricultural-resource-management-division/hemp-program/hemp-program-rule>

5. SECONDARY CONTACT PERSON:

*(A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).*

Name: Stephanie Smith

Agency: VAAFM

Mailing Address: 116 State Street, Montpelier, VT 05620-2901

Telephone: 802 661 - 8051 Fax: 802 828 - 2361

E-Mail: stephanie.smith@vermont.gov

6. RECORDS EXEMPTION INCLUDED WITHIN RULE:

*(DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE EXEMPTING IT FROM INSPECTION AND COPYING?)* Yes

IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

6 V.S.A. Section 61

PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

Final Proposed Coversheet

As part of the Agency's Hemp Program it will collect information from registrants regarding their operations through questionnaires, surveys, physical samples, and laboratory analyses. Data collection, research and analysis will further Agency agricultural development activities in support of the hemp industry in Vermont. Any information collected by the Agency will be available in aggregate only.

**7. LEGAL AUTHORITY / ENABLING LEGISLATION:**

*(THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).*

6 V.S.A. Secs. 561, 564, 566, 570 and 179

**8. EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:**

The above cited statutes give the Agency the authority to regulate the registration of individuals participating in the Agency's hemp program including hemp growers, hemp processors, and laboratories, and to establish rules regarding the research into the cultivation and marketing of hemp in accordance with authorization provided by section 7606 of the federal Agricultural Act of 2014, Pub. L. No. 113-79 and with Section 10113 of the Agriculture Improvement Act of 2018, Pub. L. No. 115-334.

**9. THE FILING HAS CHANGED SINCE THE FILING OF THE PROPOSED RULE.**

**10. THE AGENCY HAS INCLUDED WITH THIS FILING A LETTER EXPLAINING IN DETAIL WHAT CHANGES WERE MADE, CITING CHAPTER AND SECTION WHERE APPLICABLE.**

**11. SUBSTANTIAL ARGUMENTS AND CONSIDERATIONS WERE NOT RAISED FOR OR AGAINST THE ORIGINAL PROPOSAL.**

**12. THE AGENCY HAS INCLUDED COPIES OF ALL WRITTEN SUBMISSIONS AND SYNOPSES OF ORAL COMMENTS RECEIVED.**

**13. THE AGENCY HAS INCLUDED A LETTER EXPLAINING IN DETAIL THE REASONS FOR THE AGENCY'S DECISION TO REJECT OR ADOPT THEM.**

**14. CONCISE SUMMARY (150 WORDS OR LESS):**

This rule establishes

**Final Proposed Coversheet**

- registration requirements for cultivators, processors of hemp and hemp infused products and laboratories
- requirements for testing for contaminants and potency
- requirements of record keeping, and labeling of products for consumer protection and quality control
- that the Agency will collect information from registrants for research purposes and that the information may be protected under 6 V.S.A. Section 61
- a Vermont brand

**15. EXPLANATION OF WHY THE RULE IS NECESSARY:**

These rules are necessary to establish a program with standards, expectations, and enforcement as outlined by the Vermont Legislature, and to allow individuals to grow and process hemp in Vermont while protecting consumers and the Vermont brand.

**16. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY:**

These rules set out necessary definitions, a registration process, testing and record keeping requirements, performance standards for labeling, inspection and enforcement requirements.

**17. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:**

Individuals and companies that grow and process hemp, certified laboratories, consumers, law enforcement, State of Vermont, bank and insurance industries, USDA Agricultural Marketing Service and Farm Service Agency, University of Vermont Extension Service, technical service providers.

**18. BRIEF SUMMARY OF ECONOMIC IMPACT (150 WORDS OR LESS):**

These rules may impact small scale growers and processors producing small batches of products containing cannabinoids derived from hemp crops. The necessary record keeping, testing and labeling requirements could be considered onerous or costly. The potential costs of compliance testing can run between \$50 and \$600 per hemp harvest lot and process lot. However, the industry and consumers will benefit from rules that set standards and expectations, resulting in

Final Proposed Coversheet

Vermont products that are compliant with delta-9-THC potency requirements and free from contaminants.

19. A HEARING WAS HELD.

20. HEARING INFORMATION

(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION.

Date: 6/27/2019

Time: 01:00 PM

Street Address: 1 Conant Square, Brandon, VT

Zip Code: 05733

Date: 6/28/2019

Time: 01:00 PM

Street Address: Emory Hebard Office Building, 100 Main Street  
Newport, VT

Zip Code: 05855

Date:

Time: AM

Street Address:

Zip Code:

Date:

Time: AM

Street Address:

Zip Code:

21. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):

7/5/19

KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

hemp program

agriculture

hemp processor

cannabinoid

Final Proposed Coversheet  
hemp grower

Legislative Committee on Administrative Rules

Robin Chesnut-Tangerman, Chairperson  
Legislative Committee on Administrative Rules  
c/o Charlene Dindo  
[charlene@leg.state.vt.us](mailto:charlene@leg.state.vt.us)

3/13/2020

Re: Vermont Hemp Program Rules, details on changes since proposed filing

The following outlines changes to the proposed Vermont Hemp Rules.

**Section 1** – Authority and Purpose.

1.1 – Revised for conciseness.

1.2 – Revised to quote Vermont law, 6 V.S.A. §564 (a).

1.3 – Clarity that the Agency expects to operate under the pilot program authorized under the 2014 Farm Bill, which will expire on October 31, 2020, and while the United States Department of Agriculture continues to consider the standards and requirements of its interim final rule that may affect Vermont's decision to submit a State plan to be the primary governing authority over hemp cultivation in the State.

**Section 2** – Applicability: changes for clarity.

**Section 3** – Definitions: renumbering, and revisions for clarity and conciseness, generally. Additional changes described below.

3.1 – Acceptable Potency Level- distinguishing the authority under which the Agency has adopted its definition based on its interpretation of the 2014 Farm Bill, and adding a policy definition and caveat.

3.3 – Added Biomass for clarity.

3.9 – Removed Concentrate for clarity.

3.15 – Clarified that cultivation area includes greenhouses, and indoor facilities.

3.20 – Food was clarified to be more specific and to apply to human consumption

3.27 – Hemp was clarified to refer to the 0.3% delta-9-THC concentration level and the definition was clarified to state it must be grown in accordance with required agricultural practices.

3.34 – Added Negligence for clarity.

3.44 – Removed Retting because it is not used elsewhere in rule.

3.47-3.51 – Removal of all Types of cannabis identified using the ratio of CBD:THC. This method is not permitted under federal law.

**Section 4** – Program Registration Requirements: renumbering, and revisions for clarity and conciseness, generally.

4.1 (c) – Established ineligibility at Secretary’s discretion after evaluation of conduct of registrant.

4.3 – Felony convictions language removed because the State plans to initially operate under its pilot program.

4.5 – Setting a standard for operation within the limitation of the specific registration issued by the Agency.

**Section 5** – Growing, Transferring and Selling, Recordkeeping, and Reporting Requirements for Growers: renumbering, and revisions for clarity and conciseness, generally.

5.3 – Removed based on comments.

5.5 (a)(iii) – Added maintaining records of where a grower gets seeds or plant stock.

5.5 (a)(iv) – Removed testing via genetic tests or a determination of hemp by cannabis type. This method is not permitted under federal law.

**Section 6** – Processing, Transferring and Selling, Recordkeeping, and Reporting Requirements for Processors: renumbering, and revisions for clarity and conciseness, generally.

6.2 – Clarity on approved extraction methods as requested in comments.

**Sections 7 & 8 and Table 1** – Testing Requirements for Growers and Processors: renumbering, and revisions for clarity and conciseness, generally.

Based on comments received, industry stakeholders wanted to know when they should test for potency and contaminants and at what point. The Agency established when testing should be completed based on point in the growing or processing cycle and the sample type to provide greater certainty to the regulated industry.

**Section 9** – Reporting and Disposal, Destruction, or Mitigation Requirements: renumbering, and revisions for clarity and conciseness, generally.

**Section 10** – Requirements for Handling Hemp Crops, Hemp Products and Hemp-Infused Products: renumbering, and revisions for clarity and conciseness, generally.

10.1 – Removed handling of crops based on a determination of hemp by cannabis Type. This determination method is not permitted under federal law.

**Section 11** – Requirements for Labeling Hemp Products and Hemp-Infused Products: renumbering, and revisions for clarity and conciseness, generally.

11.4 (c) – Removed requirement to list ingredients in descending order of predominance, based on comments received by the Agency.

11.4 (d) – Added a standardized method of reporting cannabinoid concentration.

11.5 – Removed to not restrict the Agency’s ability to enforce based on an investigation.

**Section 12** – Vermont Hemp Products and Hemp-Infused Products; renumbering, and revisions for clarity and conciseness, generally.

12.2 – Removed grading system as it didn't capture all hemp products and hemp-infused products. Focuses on cannabidiol content did not capture quality in the opinion of industry comments.

**Section 13** – Inspection, Research, and Record Reviews: renumbering, and revisions for clarity and conciseness, generally.

13.2 – Added clarity to the scope of inspection.

13.4 – Added to capture the ability for the Agency to use samples taken to perform research into genetics or taxonomic determinations.

**Section 14** – Enforcement: renumbering, and revisions for clarity, conciseness to better explain potential actions, and to not restrict the Agency's ability to enforce based on an investigation.

14.1 (c) (i)-(iii) – Removed as this is outlined in Vermont law and was not necessary to include in the rule.

**Section 15** – Exemptions: renumbering, and revisions for clarity and conciseness, generally.

**Section 16** – Added a severability clause.

**Section 17** – Amended effective date

# Administrative Procedures – Adopting Page

## Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible, the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

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### 1. TITLE OF RULE FILING:

**Vermont Hemp Rules**

### 2. ADOPTING AGENCY:

Vermont Agency of Agriculture, Food and Markets

### 3. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

- **AMENDMENT** - Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment as long as the rule is replaced with other text.
- **NEW RULE** - A rule that did not previously exist even under a different name.
- **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

This filing is **A NEW RULE**

### 4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE*):

## INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES (ICAR) MINUTES

**Meeting Date/Location:** May 13, 2019, Pavilion Building, 5<sup>th</sup> floor conference room, 109 State Street, Montpelier, VT 05609

**Members Present:** Chair Brad Ferland, Dirk Anderson, Ashley Berliner, Diane Bothfeld, John Kessler, Matt Langham, and Steve Knudson

**Members Absent:** Clare O'Shaughnessy and Jennifer Mojo,

**Minutes By:** Melissa Mazza-Paquette

- 2:01 p.m. meeting called to order, welcome and introductions.
- Review and approval of minutes from the April 8, 2019 meeting.
- No additions/deletions to agenda. Agenda approved as drafted.
  - Note: During the hearing, proposed rule #10 was presented after proposed rule #5 and all others were presented after.
- No public comments made.
- Presentation of Proposed Rules on pages 2-11 to follow.
  1. Vermont Hemp Rules, Agency of Agriculture, Food and Markets, page 2
  2. Refugee Medical Assistance, Agency of Human Services, page 3
  3. Vermont Residential Building Energy Standards (RBES), Public Service Department, page 4
  4. Vermont Commercial Building Energy Standards (CBES), Department of Public Service, page 5
  5. 2019 Vermont Materials Management Plan: Reducing Solid Waste and Increasing Recycling and Composting, Agency of Natural Resources, page 6
  6. Prescribed Drugs, Agency of Human Services, page 7
    - a. Note: Due to the change in #10, this proposed rule was moved to #7 during the hearing.
  7. Pharmaceuticals, Medical Supplies and Equipment - General Information, Agency of Human Services, page 8
    - a. Note: Due to the change in #10, this proposed rule was moved to #8 during the hearing.
  8. Gender Affirmation Surgery for the Treatment of Gender Dysphoria, Agency of Human Services, page 9
    - a. Note: Due to the change in #10, this proposed rule was moved to #9 during the hearing.
  9. VPharm Prescribed Drugs, Agency of Human Services, page 10
    - a. Note: Due to the change in #10, this proposed rule was moved to #10 during the hearing.
  10. Vermont Wetland Rules, Agency of Natural Resources, page 11
    - a. Note: Rule was moved up to #6 during the hearing.
- Next scheduled meeting is Monday, June 10, 2019 at 2:00 p.m.
- 3:50 p.m. meeting adjourned.

**Proposed Rule: Vermont Hemp Rules, Agency of Agriculture, Food and Markets  
Presented by Gary Giguere**

Motion made to accept the rule by Dirk Anderson, seconded by John Kessler, and passed unanimously except for Diane Bothfeld who abstained, with the following recommendations:

1. Proposed Rule Coversheet, page 4, #11: Include landowners if applicable.
2. Proposed Rule Coversheet, page 4, #12: Include in the Economic Impact Analysis.
3. Proposed Rule Coversheet, page 4, #13 and #14: Include hearing information or TBD.
4. Economic Impact Analysis, pages 1-2, #3: Spell out the acronyms and include them after in parentheses. Consider using a different word for 'route' in the last sentence of the second to last paragraph. Clarify last paragraph (i.e. it states 'These rules' in the first sentence and 'It' in the second). Spell out VAAFMM and include it in parentheses after.
5. Economic Impact Analysis, page 3, #7: Include the positive financial impacts.
6. Environmental Impact Analysis, page 1, #3: Change 'These rule' to the appropriate term.
7. Public Input, page 1, #4: Add 'least' between 'The Agency will hold at' and 'three public meetings...'. Correct misspelled word 'pubic'.
8. Public Input, page 2, #5: Correct misspelled word 'lobbiests'.
9. Text: Clarify the 0.3 percent threshold and 1 percent thresholds.
10. Text: Correct the section reference of the Farm Bill.
11. Text, page 1, Section 2: Change 'wants' to something else, such as 'intends' or 'plans'.
12. Text, pages 1-2, Section 3.5: Add spaces after commas.
13. Text, pages 8-9, Sections 7.6 and 9.3: Section 9.3 does not include disposal guidance.
14. Text: Confusing guidance between federal and state laws – clarification required when inconsistencies between the two exist, such as acceptable THC levels and disposal requirements vs mitigation plans.

# Administrative Procedures – Economic Impact Analysis

## **Instructions:**

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

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### 1. TITLE OF RULE FILING:

**Vermont Hemp Rules**

### 2. ADOPTING AGENCY:

Vermont Agency of Agriculture, Food and Markets

### 3. CATEGORY OF AFFECTED PARTIES:

*LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:*

Individuals and companies that grow and process hemp, certified laboratories, consumers, law enforcement, State of Vermont, bank and insurance industries, USDA AMS and FSA, University of Vermont Extension Service, technical service providers.

The ability to grow hemp in Vermont is due to the creation of a federally compliant Hemp Program at the

## Economic Impact Analysis

Agency. The program allows farmers to diversify into a new crop and supports the development of new industries and products within the state that use this versatile crop.

These rules will provide clarity to Vermont's hemp industry with clear standards and expectations, benefiting consumers and the Vermont brand. These rules may impact small scale growers and processors due to testing, record keeping and labeling requirements. The cost of third-party potency and contaminant testing ranges from \$50- \$1,200 (depending on the type and frequency of tests determined by a risk based analysis) by harvest lot or process lot. Testing requirements will vary depending on end product being produced, and route human exposure.

These rules facilitate exchange of information between law enforcement and growers and processors. It establishes clear lines of jurisdictional for VAAFM so as to not interfere with other agency jurisdiction.

#### 4. IMPACT ON SCHOOLS:

*INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:*

Schools are not affected by these rules.

#### 5. ALTERNATIVES: *CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.*

See answer with question 4 above.

#### 6. IMPACT ON SMALL BUSINESSES:

*INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):*

These rules will provide clarity to Vermont's hemp industry with clear standards and expectations, benefiting consumers and the Vermont brand. These rules may impact small scale growers and processors due to testing, record keeping and labeling requirements. The cost of third party potency and contaminant testing ranges from \$50- \$1,200 (depending on the type and

## Economic Impact Analysis

frequency of tests determined by a risk based analysis) by harvest lot or process lot. Testing requirements will vary depending on end product being produced, and route human exposure.

### 7. **SMALL BUSINESS COMPLIANCE:** *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

There are business models that a hemp grower or processor could employ that would allow them to grow or process and meet the requirements of testing in compliance with these rules, including developing relationships with processors with certified laboratories, or participating in a cooperative wherein necessary testing can be part of a contract. Labeling is required for consumer protection and is unavoidable. These rules build standards for a Vermont brand that could add to the value of products that meet these standards.

### 8. **COMPARISON:**

*COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:*

The Hemp Program provides opportunity for the Vermont hemp industry and these rules support the industry and address consumer protection. A separate rule for small businesses is not possible.

### 9. **SUFFICIENCY:** *EXPLAIN THE SUFFICIENCY OF THIS ECONOMIC IMPACT ANALYSIS.*

This rule stands up a program in Vermont that permits businesses in the state to participate in this new market opportunity. Vermont has the opportunity to be a leader on producing a quality product. These rules support Vermont's hemp industry, to comply with federal requirements, and to implement legislative intent.

# Administrative Procedures – Environmental Impact Analysis

## **Instructions:**

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

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### 1. TITLE OF RULE FILING:

**Vermont Hemp Rules**

### 2. ADOPTING AGENCY:

Vermont Agency of Agriculture, Food and Markets

### 3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*

These rule will not increase or decrease the impact on transportation, building infrastructure, land use and development, or waste generation. Hemp is considered an agricultural commodity that can be grown and processed in Vermont with registration.

### 4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*

Discharge and elimination of pollution, the flow of water in the state, water quality, etc. are not addressed in this rule.

### 5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*

## Environmental Impact Analysis

The rule does not address forestry. While it does not address agronomics associated with hemp production, it will address research into the cultivation and marketing of hemp and hemp infused products. This research may improve outcomes of hemp producers in the state.

6. **RECREATION:** *EXPLAIN HOW THE RULE IMPACT RECREATION IN THE STATE:*

No impact.

7. **CLIMATE:** *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*

No impact.

8. **OTHER:** *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*

No impact.

9. **SUFFICIENCY:** *EXPLAIN THE SUFFICIENCY OF THIS ENVIRONMENTAL IMPACT ANALYSIS.*

This is a new rule that addresses registration, record keeping, consumer protection, and creation of a Vermont brand. It does not include any regulations that address environmental protection.

## Administrative Procedures – Public Input

### Instructions:

In completing the public input statement, an agency describes the strategy prescribed by ICAR to maximize public input, what it did do, or will do to comply with that plan to maximize the involvement of the public in the development of the rule.

This form must accompany each filing made during the rulemaking process:

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1. TITLE OF RULE FILING:

**Vermont Hemp Rules**

2. ADOPTING AGENCY:

Vermont Agency of Agriculture, Food and Markets

3. PLEASE DESCRIBE THE STRATEGY PRESCRIBED BY ICAR TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE:

The proposed rule focus group, external stakeholder comments, solicited input from state government, and shared goals of the rule at multiple workshops, conferences, and meetings with the industry and growers through out the state since September of 2018, and other informal outreach opportunities.

4. PLEASE LIST THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

The Agency will hold at three public meetings post filing to maximize public involvement. These meetings will be held in Rutland or Addison County, Windham County and the Northeast Kingdom.

5. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

Andrea Stander, Rural Vermont; Carl Christianson, Northeast Processing; Dan Chang, Kria Botanicals; Rye Matthews Northeast Hemp Commodities; Jahala Dudley, Continuum; Netaka White; Brendan Beer and Amy Skelton, Kitchen Cabinet Medicinals; Herrick Fox, Meristem; Scot Waring, Elucidation; Chris Bailey, Victory Hemp Foods;

**Public Input**

Tom Hirschfield, Champlain Valley Dispensary; Mike Crowley, CBD-Vermont; Jessilyn Dolan; John Rodgers; Eli Harrington, Heady Vermont; John DiGiuseppe, Lily Hill, Vermont State Attorney's Office, Vermont Division of Fire Safety; Heather Darby, UVM, Ext.; Trace; industry lobbyists and others.

Regarding Vermont Hemp Rules:

1. 3.17 Distillate Definition: Currently the state defines distillate as having cannabinoid percentages greater than 95% for any single cannabinoid. This has NEVER been seen by Northeast Processing in our 10 months of analytical work. Typically we suggest a distillate is just a state of purification and concentration of a particular segment of a mixture. We have seen distillates range from as low as 65% CBD to as high as 90%. Never more than that. I think it is foolish to put a specific percentage on this. A proper definition would read:
  - a. Distillate: means a class of hemp extract where a particular segment of the extract has been selectively concentrated via the methodology of distillation.
2. 3.28 Hemp Concentrate: This definition needs to acknowledge that the "hemp concentrate" is a process intermediate that tends to be out of compliance in regard to THC concentration. It is natural to have all cannabinoids concentrate when being extracted, and this definition should clearly illustrate this point. Future sections of the hemp rules rely on the definition of "Hemp Concentrate" for clearly establishing the marketplace for processors to get material to product producers, and without this clarity, it creates a grey area.
3. 5.2: Should clearly state in this rule that "Transportation" of products to and from a licensed processor is covered.
4. 6.1: This should stipulate that "Hemp Concentrates" are also covered in this section in regards to wholesale, not for retail, outlets. In this language it makes it seem that a processor can only have compliant "products" for sale or transfer. The reality is that the process intermediates are often out of compliance, but are still viable for wholesale to other processors that want to formulate these materials into compliance.
5. 6.7: This needs to clarify that a manufacturer out of state is a viable outlet for material to be sold to. The definition of "Processor" stipulates a VT registration, but this is not a reasonable requirement for out of state companies to have to achieve. Without the clarification, it reads as though we would be unable to sell to out of state companies, thereby restricting interstate commerce.
6. 7.1-7.3: We believe that 7.2 and 7.3 should match the language in 7.1, stipulating that a grower "must" test. Replace the "may" in both 7.2 and 7.3.
7. 8.3: This needs to clarify that process lots can be held in concentrated form in a state that is out of compliance. The way it is written, is that process intermediates and concentrated oils would be out of compliance with "Agency Standards".
8. 10.2: This needs to stipulate that "Process Intermediates" can be sold via wholesale outlets. The section is biased toward retail sale, and undermines the ability for a processor to provide a concentrated oil to a company that needs that concentrated form in order to effectively formulate their consumer products. If a processor must adhere to retail rules, they would be unable to effectively provide brands with oil with which to formulate. This would necessitate vertical integration and undermine businesses from filling a specific niche like extraction and processing, a very underserved aspect of this

industry. The lack of clarity here will drive processors out of business, as they will be unable to sell concentrated oil on a wholesale market.

- a. If a protection against bad actors is necessary, it would be best to provide a stipulation that concentrated oils should maintain at least a 15:1 CBD:THC ratio. Ensuring that the material is derived from compliant hemp, and maintains that standard ratio.

9. 11.4(c): This is outrageous. The vast majority of testing labs do not even have the ability to reliably measure to 0.05%. To require ingredient lists at this level will not be possible and will diminish any value from a label that then has numerous ingredients. We test for 20 cannabinoids and 20 terpenes and that list keeps growing. I think this should stipulate that ingredients must be labelled, but clearly state that constituent parts do not have to be labelled based solely on percentage.
10. 12.2: Percentage has nothing to do with quality. Setting artificial values like this will only diminish the market for VT product. As a processor, we saw the majority of VT hemp that we tested last year score a "Grade C". If we had to label this material as such, and saw diminished market value, it would be the states fault, and we would seek compensation for setting a negative perception of the VT market.
11. 14.1 (a)(c)(d)(e): Exceptions for processors need to be clearly stated. Material that is out of compliance is a natural process intermediate, and the regulations should state that exception of processors for possessing this material.



Northeast Organic Farming Association  
of Vermont

*Growing local farms, healthy food, and strong  
communities in Vermont since 1971.*



July 5th, 2019

Anson Tebbetts  
Secretary  
Vermont Agency of Agriculture, Food, and Markets  
116 State Street  
Montpelier, VT 05620

*Submitted electronically*

**Re: NOFA-VT Comments on the Proposed Hemp Rule**

Dear Secretary Tebbetts,

The Northeast Organic Farming Association of Vermont (NOFA-VT) is one of the oldest organic farming organizations in the country with over 1,000 members – farmers, gardeners and consumers – working to promote an economically viable and ecologically sound food system. Vermont Organic Farmers LLC (VOF) is a USDA accredited organic certification agency owned by NOFA-VT representing over 700 certified organic farmers and processors. VOF has been certifying producers since 1985 and has been accredited by the USDA since 2002.

NOFA-VT has been engaging with the hemp industry in Vermont primarily through our USDA-accredited organic certification agency, VOF. Since hemp was fully legalized by the 2018 Farm Bill, VOF has seen explosive growth in the number of hemp grower and processor applicants. To date, we have over 65 hemp grower applicants who account for over 800 acres of organic hemp production in addition to a few hemp processor applicants. We have also been impressed by the self-reported estimated gross sales anticipated by Vermont organic hemp producers, so far adding up to several million dollars. Clearly, there is an expectation that hemp produced and sold with the Vermont organic brand will command a premium in the market. It is for this reason that we are happy to see the Agency submitting such robust and sensible regulations to maintain a high-quality hemp market under the Vermont brand.

NOFA-VT submits the following comments on the final draft of the Proposed Hemp Rule. We appreciate the time and effort the Agency has put into developing these rules and we appreciate that NOFA-VT has been included as a stakeholder in this process.

Sincerely,

Brian Shevrin  
Organic Certification Specialist

PO Box 697 ♦ 14 Pleasant Street ♦ Richmond, VT 05477  
NOFA 802-434-4122 ♦ VOF 802-434-3821 ♦ Fax 802-434-4154 ♦ [www.nofavt.org](http://www.nofavt.org)

## General Comments

NOFA-VT applauds the Agency's clear effort to create a high integrity and sensibly regulated hemp industry in Vermont. Specifically, we appreciate the detailed level of traceability and record keeping required of hemp growers and processors in Vermont as these practices align well with organic certification.

## Detailed Comments by Section

**4.3:** NOFA-VT recognizes the complexities of compliance with federal law, however, we must recognize that this section perpetuates the disadvantages placed on those who have been previously incarcerated. The hemp industry is fully legal and separate from controlled substances and imposing an additional 10 year waiting period on those who have served their time is unjust. We support the comment submitted regarding this subsection by Rural Vermont and urge the Agency to remove this requirement so that all Vermonters have the opportunity for economic viability through agriculture.

**5.4(b):** NOFA-VT strongly supports this section and the practice of alerting consumers to pesticide inputs used to grow the crops they consume. NOFA-VT recommends that this section be amended to include that a hemp grower's organic certificate may be a substitute for the list required herein.

**5.6 through 5.9:** NOFA-VT applauds the list of records required for a hemp grower to maintain, as it aligns well with the requirements for organic certification.

**6.2:** Although NOFA-VT appreciates the concept of regulating hemp extraction methods, we feel that the current wording of this subsection has the potential to limit innovation and does not offer a clear template for approval of additional methods. VOF has, to date, approved forms of carbon dioxide, lipid, and ethanol extraction for use in organic hemp extract production. However, we expect that hemp producers will continue to innovate and seek new methods for hemp extraction which we have not yet reviewed, such as the use of heat and pressure known as a rosin press or applications of hemp in beer brewing. NOFA-VT suggests changing the structure of this subpart so it allows all natural extraction methods which are not specifically prohibited therein and lists prohibited extraction methods. This structure would mirror the National Organic Program's list of approved and prohibited substances, in which all naturals are approved unless specifically prohibited and synthetics prohibited unless specifically allowed. Definitions of "natural/non-synthetic" and "synthetic" can be found in 7CFR205.2.

NOFA-VT suggests that extraction methods utilizing hydrocarbons, including butane and propane extractions, be listed as prohibited methods. We feel that these changes will allow for innovation while avoiding the use of dangerous and unhealthy methods of extraction.

**6.3:** We strongly support the prohibition of synthetic cannabinoid use in the production of hemp or hemp-infused products in Vermont.

**6.5:** NOFA-VT supports the mandatory use of lot numbers as these are required for use by certified organic operations.

**6.8 through 6.9:** NOFA-VT applauds the list of records required for a hemp processor to maintain, as it aligns well with the requirements for organic certification.

**6.10:** We are confused by implied allowance within this subsection for a hemp-infused product to offer no label guarantee of a specific quantity of CBD (or other cannabinoid content). This seems to directly contradict section 11.4(e). NOFA-VT urges the Agency to strike section 6.10 and require all hemp-infused products to be labeled according to section 11.

**7.3:** NOFA-VT believes it is the responsibility of the Agency to set the standards for testing parameters for quality and safety of hemp products produced in Vermont. Additionally, we are concerned with the amount of administrative burden which would ensue from the level of review necessary should all growers be allowed to submit their own parameters for testing.

**8.2:** See comments above for section 7.3

**10.2:** We humbly note the typo at the end of this subsection in which "accept" is used instead of the correct homophone "except".

**11:** NOFA-VT urges the Agency to use this opportunity to set a standardized unit for label claims of cannabinoid content. An example of a currently used standard for your consideration is milligrams of cannabinoids per milliliter (or per gram for a non-liquid product). We believe a standardized unit for label claims will increase the ability of consumers to make informed purchases.

**11.4:** We applaud the labeling requirements included in this subsection as they align well with the labeling requirements for certified organic products.

**11.4 (e):** As previously noted, we strongly support the requirement for all hemp-infused products to make a label claim of cannabinoid content, preferably with a standardized unit.

**14.1(c):** NOFA-VT is concerned that this allowance, while provided with positive intention, provides an incentive to claim negligence and produce high-THC cannabis with no penalty. NOFA-VT worries that this could have negative consequences for our USDA accredited organic certification program if a certified organic crop, which must be federally legal, turns out to be high-THC cannabis. Additionally, when this practice occurs it reflects poorly on the reputation of the State's hemp program.

Hemp Public Comment Submission Details													
Serial	SO	Time	Dr.R.	Username	Name	Organization	Street Address	City	State	Postal Code	Email	Subject	Comments
3	817	31-May-19	0		Susan Nebert		377 Burr Road	Fair Haven	Vermont	5743	slyb@comcast.net	ag/culture	Can hemp producers limit 1000 gallons per day from stream? What about pervasive smell of hemp in the marketplace? California communities in one about hemp smell? We hope to see the following changes:  More detail and standardization should be included in the rule regarding the testing of pesticides, heavy metals, and other contaminants rather than allowing the producers to set their own parameters. Requiring a standardized unit for CBD label claims would reduce consumer misinformation in the marketplace. Extraction methods for cannabinoids should be generally allowed unless prohibited. Instead of the rule listing only three allowed methods. Support the NOP-A definition. Also, address specifically exempt non-commercial growers from the rules. Unless it is used in a backyard grower with a handful of hemp plants for personal use (homegrown) would be subject to the rules.
4	866	25-Jun-19	0		David Strohman	Spring Hill Farm	20 Chubb Hill Rd	Canterbury	VT	05407-8602	strosman@springhillfarm.com	Hemp	This is an extremely LIMITING statement, especially for an industry that has not yet discovered/determined all the possible methods of extracting or cleaning cannabinoids from hemp. This statement should be rewritten to NOT specifically mention extraction methods unless it is written less restrictively.  In previous years we have purchased hemp crops directly from the field. This means we, we then dry the crop at our facility. When calculating the value of the dry mass, we exclude the weight of any stem, chaff, or seed. This means that the crop must be dried and then ground, an additional step that takes time. We are a small business and do not grow the entire crop at once, but rather leave many plants still on the stalks until they are ready to be ground for extraction. Therefore, our dry weight calculation does not come until we have ground the entire crop. This can often take up to 2 months. We would encourage an allowance or clause in this statement that would allow for accounting of WET crop purchases.  Hello, I'm concerned that hemp is being grown "organically" on fields that do not come close to the strict certification standards our hay crop is subject to. In territories we have seen hemp grown in fields that were conventional com last season or in store chain apple orchards where the trees a few feet away are being sprayed with chemicals proposed by NOPA.  More detail and standardization should be included in the rule regarding the testing of pesticides, heavy metals, and other contaminants rather than allowing the producers to set their own parameters. Requiring a standardized unit for CBD label claims would reduce consumer misinformation in the marketplace. Extraction methods for cannabinoids should be generally allowed unless prohibited. Instead of the rule listing only three allowed methods. Support the Vermont Agency of Agriculture, Food, and Markets proposed rules but also hope to see the following changes:  More detail and standardization should be included in the rule regarding the testing of pesticides, heavy metals, and other contaminants rather than allowing the producers to set their own parameters. Requiring a standardized unit for CBD label claims would reduce consumer misinformation in the marketplace. Extraction methods for cannabinoids should be generally allowed unless prohibited. Instead of the rule listing only three allowed methods. We support the proposed rules as written but also hope to see the following changes:  More detail and standardization should be included in the rule regarding the testing of pesticides, heavy metals, and other contaminants rather than allowing the producers to set their own parameters. Requiring a standardized unit for CBD label claims would reduce consumer misinformation in the marketplace. Extraction methods for cannabinoids should be generally allowed unless prohibited. Instead of the rule listing only three allowed methods.
5	907	26-Jun-19	0		The Sullivan		340 Hoag Road	Johnson	VT	5658	lms@vspraker.com		6.2. A processor shall only use lipid, ethanol, or carbon dioxide (CO2) based extraction methods, or other extraction method
6	909	25-Jun-19	0		Chris Thomas	GOOD BODY PRODUCTS	1728 River Rd	Guildford	Vermont	5501	chrt@goodbodyproducts.com		6.8.b.iii. Amount of hemp on a dry weight basis in pounds (metric) and
7	911	26-Jun-19	0		Chris Thomas	GOOD BODY PRODUCTS	1728 River Rd	Guildford	Vermont	5501	chrt@goodbodyproducts.com		Organic Certification
8	915	26-Jun-19	0		Anonymous		Main Street	Shoreham	VT	5770		One	More detail and standardization should be included in the rule regarding the testing of pesticides, heavy metals, and other contaminants rather than allowing the producers to set their own parameters. Requiring a standardized unit for CBD label claims would reduce consumer misinformation in the marketplace. Extraction methods for cannabinoids should be generally allowed unless prohibited. Instead of the rule listing only three allowed methods. Support the Vermont Agency of Agriculture, Food, and Markets proposed rules but also hope to see the following changes:  More detail and standardization should be included in the rule regarding the testing of pesticides, heavy metals, and other contaminants rather than allowing the producers to set their own parameters. Requiring a standardized unit for CBD label claims would reduce consumer misinformation in the marketplace. Extraction methods for cannabinoids should be generally allowed unless prohibited. Instead of the rule listing only three allowed methods.
9	917	26-Jun-19	0		cornet complete		31 WILLOW CIRCLE	White River Junction	Vermont	5601	cornet@cornetcomplete.com		Hemp Industry Regulation
10	918	26-Jun-19	0		Ursula Sullog		38 North Ave	Burlington	VT	5401	lives.sullog@gmail.com		We support the proposed rules as written but also hope to see the following changes:  More detail and standardization should be included in the rule regarding the testing of pesticides, heavy metals, and other contaminants rather than allowing the producers to set their own parameters. Requiring a standardized unit for CBD label claims would reduce consumer misinformation in the marketplace. Extraction methods for cannabinoids should be generally allowed unless prohibited. Instead of the rule listing only three allowed methods.
11	921	26-Jun-19	0		John Westad	Stone Leaf Tobacco Co	111 Maple Street 466 Packery Gaines Rd	Middlebury	Vermont	5753	westad@stoneleaf.com		6.7. 6.8. 7.9. and 11.
12	923	26-Jun-19	0		Mary/Janet/Maria Theresa Stehrmacher	Franklin Farm	779 E Hill Rd	Guildford	VT	5501	franklinfarm1986@gmail.com		Hemp
14	927	26-Jun-19	0		Meloy Hand		94 S. Main St	Jeffersonville	Vermont	5444	meloyhand@gmail.com		Don't know
15	929	27-Jun-19	0		Robert Sabatini	cliffan	90 north st	Montpelier	VT	5602	rsabatini56@gmail.com		Final proposed rules
16	931	27-Jun-19	0		Matthew Steink	Petricher Farm	503 Uxalin Hill	HUNTINGTON	VT	5462	petricherfarm@gmail.com		Contaminant testing, unit standardization, and extraction

17	943	27-Jan-19	0	Robert Schlosser	Sandwood Farm	1665 Town Hill Rd.	Walcott	Vermont	5680	sara@sandwoodfarm.com	final hemp	<p>*More detail and standardization should be included in the rule regarding the testing of pesticides, heavy metals, and other contaminants rather than allowing the producers to set their own parameters.</p> <p>*Requiring a standardized unit for CBD label claims would reduce consumer misinformation in the marketplace.</p> <p>*Extraction methods for cannabinoids should be generally allowed unless prohibited. Instead of the rule listing only three allowed methods.</p>
18	949	28-Jun-19	0	Jessilyn Dolan	Vermont Cannabis Nurses Association	6 Roy Dr	Underhill	Vermont	5489	Greenurzevt@gmail.com	3.3; 3.14; 3.21; 3.51; 3.52; 6.2; 6.6; 7.3; 8.2; 11.4b; 11.4g; 12.2; 14; 16	<p>3.21-full spectrum-need to specify what extraction methods are full spectrum, as some methods fractionate and then reformulate by combining, as well as methods that do not capture the chlorophyll, etc.... example: CO2 does usually removes chlorophyll....</p> <p>3.51-type IV is now CBG dominant</p> <p>3.52-whole plant-again needs to extrapolate on extraction methods as not all methods get both water and lipid soluble.</p> <p>As a nurse, I think full spectrum and whole plant are very important to define correctly as many companies are mislabeling for marketing purposes, not for patient transparency and efficacy.</p> <p>6.2 BHO extraction should be listed as illegal. As nurses, we are seeing more concerns come up every day with this extraction method and if NOFA is pushing for this to be allowed, NOFA's legitimacy and understanding of safety for consumers should be questioned heavily.</p> <p>6.6 I would love to see a state program where the THC/THCA needing to be disposed of is donated to patients.</p> <p>7.3/8.2-we need strict guidelines for testing, not proposed individually</p> <p>11.4b-can we call it what it is, cannabis sativa?</p> <p>11.4g-manufacturing date is silly, just expiration and lot number makes sense. how about a one year from manufacture expiration date unless they can show proof that shelf life is stable beyond one year? I am concerned that products sitting on shelves for over a year are not reliable and we need more consumer protection.</p> <p>12.2 I think is not the best way at all to determine a quality product unless you grade the FINAL product, not the flower. AND ONLY organic or clean green certified end products should EVER get a AA...make that a separate distinction....</p> <p>Vermont has a unique ability to lead the Northeast hemp movement and we need to push and encourage organic, clean, healthy medicine, consumers, and our precious soil and land! NO product should ever be AA if they are not stewards of the land and advocates for true clean medicine and consumer health!</p> <p>As a nurse, I would want to see that A or AA is the best out there and that HAS to mean organic! No way around it!</p> <p>To be labeled made in VT, it should have to be grown, processed, bottled, everything in state!!</p> <p>section 14....why is Champlain Valley Dispensary absolved from this?</p> <p>section 15....what happens to people mislabeling products knowingly and who do we report them to for consumer safety?</p> <p>Again, as a nurse, this is a HUGE and happening way too much!!</p>
19	951	28-Jun-19	0	Jessilyn Dolan	Vermont Cannabis Nurses Association	6 Roy Dr	Underhill	Vermont	5489	Greenurzevt@gmail.com	3.3; 3.14; 3.21; 3.51; 3.52; 6.2; 6.6; 7.3; 8.2; 11.4b; 11.4g; 12.2; 14; 16	<p>3.21-full spectrum-need to specify what extraction methods are full spectrum, as some methods fractionate and then reformulate by combining, as well as methods that do not capture the chlorophyll, etc.... example: CO2 does usually removes chlorophyll....</p> <p>3.51-type IV is now CBG dominant</p> <p>3.52-whole plant-again needs to extrapolate on extraction methods as not all methods get both water and lipid soluble.</p> <p>As a nurse, I think full spectrum and whole plant are very important to define correctly as many companies are mislabeling for marketing purposes, not for patient transparency and efficacy.</p> <p>6.2 BHO extraction should be listed as illegal. As nurses, we are seeing more concerns come up every day with this extraction method and if NOFA is pushing for this to be allowed, NOFA's legitimacy and understanding of safety for consumers should be questioned heavily.</p> <p>6.6 I would love to see a state program where the THC/THCA needing to be disposed of is donated to patients.</p> <p>7.3/8.2-we need strict guidelines for testing, not proposed individually</p> <p>11.4b-can we call it what it is, cannabis sativa?</p> <p>11.4g-manufacturing date is silly, just expiration and lot number makes sense. how about a one year from manufacture expiration date unless they can show proof that shelf life is stable beyond one year? I am concerned that products sitting on shelves for over a year are not reliable and we need more consumer protection.</p> <p>12.2 I think is not the best way at all to determine a quality product unless you grade the FINAL product, not the flower. AND ONLY organic or clean green certified end products should EVER get a AA...make that a separate distinction....</p> <p>Vermont has a unique ability to lead the Northeast hemp movement and we need to push and encourage organic, clean, healthy medicine, consumers, and our precious soil and land! NO product should ever be AA if they are not stewards of the land and advocates for true clean medicine and consumer health!</p> <p>As a nurse, I would want to see that A or AA is the best out there and that HAS to mean organic! No way around it!</p> <p>To be labeled made in VT, it should have to be grown, processed, bottled, everything in state!!</p> <p>section 14....why is Champlain Valley Dispensary absolved from this?</p> <p>section 16....what happens to people mislabeling products knowingly and who do we report them to for consumer safety?</p> <p>Again, as a nurse, this is a HUGE and happening way too much!!</p>

20	967	3-Jul-19	0	Shayne Kyra	Vermont Cannabis Trade Association	70 South Winslow Ave #284	Burlington	Vermont	5601 info@vcta.org	3.1, 6.6, 6.7, 6.8(b), 7.3, 10.2, 11.1, 5, 12, 34	<p>The proposed rules define acceptable potency level as a hemp crop that has a delta-9 THC concentration of 0.3 percent or less and a total theoretical tetrahydrocannabinol concentration of one percent or less. Vermont statute allows for a delta-9 tetrahydrocannabinol concentration of 0.3 percent or less on a dry weight basis, which is consistent with the 2018 Farm Bill which further requires the testing to occur post-decarboxylation. There is no reference to total theoretical THC concentration in Vermont law. We suggest removing the phrase related to the theoretical THC concentration and including the definition of hemp in accordance with the 2018 Farm Bill.</p> <p>6.6 Processing The rule states that a Processor that extracts THC or THC-A from a hemp crop must submit for approval by the Agency a disposal plan that ensures the THC and THC-A is disposed of in a manner that renders the THC and THC-A unusable and that accounts by process lot number all THC or THC-A removed. This is contrary to Vermont statute. If THC over 0.3% is found, the grower can enter into an agreement with a dispensary for the separation of the THC, sell the hemp crop to a dispensary, or arrange for the Secretary to destroy or order the destruction of the hemp crop.</p> <p>6.7 Processing Under the rules, a processor may transfer or sell hemp concentrate for the purpose of reformulation into hemp products or hemp-infused products only to the Grower if the grower is a processor or to another Processor.  We would suggest clarifying whether this section refers to hemp that is over 0.3% THC, or any hemp concentrate.</p> <p>6.8(b) Records of hemp crops Growers can ship hemp crops out-of-state if they have the requisite paperwork. Processors can receive hemp crops from out-of-state with the requisite paperwork. However, there is nothing that allows processors to ship processed hemp out-of-state. Processors should be allowed to ship hemp, and receive hemp from, out of state with the same requirements as hemp crops.</p> <p>Section 7.3 Testing parameters This provision allows a grower to "propose testing parameters for pesticides, heavy metals, mycotoxins, and bacterial and fungal contaminants that are based on a risk analysis and use for approval by the Agency". How is the risk level determined by either the Grower or the Agency? The rules require testing for "contaminant levels are below action limits outlined by the Agency for pesticides, heavy metals, mycotoxins, and bacterial and fungal contaminants", but these limits are not defined in the proposed rules.</p>
21	969	3-Jul-19	0	Sarah Bangs	FoodScience Corporation	929 Harvest Lane	Williston	Vermont	5695 sbangs@foodsciencercorp.com	See comments	<p>3.8 What qualifications must a lab meet in order to be certified? There are a variety of methods being used to test products and results can vary widely. Article 6 does not provide enough detail.</p> <p>4.1(d) If we are manufacturing in one location, but packaging in another, do both sites need to be registered? What about locations for storing product?</p> <p>6.9(a) We are not receiving crops, which is the determining factor in 6.8, which this rule mentions. Our vendors may or may not be able to provide these document requirements due to variations in their own state regulations and the challenge of being multiple steps removed from the grower.</p> <p>6.9(b) We have many SOPs in place for formulation, manufacturing, testing, and cleaning steps. Is this requiring us to create a SOP specific to the production of hemp products that takes into account elements of the program? Please clarify.</p> <p>8.2. We have testing parameters set up based on industry standards. Will we need to propose these parameters to the Agency even if they are part of our receiving process and subject to other requirements? Is this a requirement and what will the agency be approving for?</p> <p>9.3(c) We purchase product that is already far removed from the agricultural process and should have already gone through these testing procedures, but may or may not have been tested at a VT agency certified laboratory. If we can provide a COA for the material, will that suffice? Or, will we have to send it out to a VT agency certified lab to verify? We will have to do some testing on bulk product regardless.</p> <p>8.4. Are these referring to the same contaminant levels that we may propose and have approved per section 8.2?</p> <p>9.2 What methods of disposal are approved by the agency for process lots?</p> <p>Section 10 "Requirements for Handling Hemp Crops, Hemp Products and Hemp-Infused Products" According to the definition, "handle" only refers to hemp crops and specifically states, "'Handle' does not mean possession of hemp products or hemp-infused products." Please clarify.</p> <p>10.3. Would this potentially include bulk raw materials (for us this means a hemp concentrate) or only products for retail sale?</p> <p>11.1. Please clarify that you are requiring a COA for hemp-specific label guarantees, not all product guarantees.</p> <p>11.2 Would it be possible to add a clause that would allow for federal regulations to supersede any VT Hemp rules Vermont Hemp Program Rules?</p> <p>11.4(a) FDA adverse event requirements along with 21 CFR 101.5 clearly outline our industry's labeling requirements. We have the option to provide phone number, city, state, and zip code. This does not align with the requirements in 11.4(a) Additionally, it is important for our private label business to be able to list the distributor information as opposed to the manufacturer information because the distributor is considered the marketer of the product. Would we have to provide both distributed by and manufactured by information on a privately labeled hemp product?</p> <p>11.4(c) Foods and dietary supplements have strict labeling guidelines outlined in 21 CFR 101.9. The Nutrition Facts Panel and Supplement Facts Panel show the "active ingredients," and the remaining ingredients are listed as "other ingredients." 11.4(c) does not align with FDA labeling requirements for food and dietary supplements. Would we have to include an additional list of ingredients in descending order of predominance by weight in addition to our Supplement Facts Panel, or could we omit the list, having already provided all ingredients in the FDA required format?</p>



27	989	5-Jul-19	D	Neraka White	TalkAboutHemp.com	poB 76	east middlebury	VT	5740	neraka.white@gmail.com	5.3	<p>I understand the Agency's desire to address the issue of male pollen inadvertently affecting a neighbor's crop of female flowers. However, I believe this provision creates an arbitrary legal bias in favor of flower production, placing the burden of responsibility (and culpability) on the "producer of seed". This rule is discriminatory, ineffective and problematic for Vermont's hemp community.</p> <p>1. The rule as presented is simply unreasonable, and for what good? Cannabis physiology is what it is. No one has any control over the path pollen takes, and this rule offers no solution. 2. It is wrong to put a farmer in the position of having to notify, and most likely alarm neighbors that she/he may have no prior relationship with and might live miles away. It's not hard to imagine all kinds of unintended negative consequences coming from this exchange of information.</p> <p>I respectfully request that this provision (Sec 5.3) be struck from the rules.</p> <p>I offer these suggestions for your consideration:</p> <p>1. Leave this issue (of pollination) alone for now, give it time and let's see how it plays out. If legitimate complaints arise of economic damage from unintended pollination, the Agency will have the opportunity to take public comment and consider what, if any, effective measures or policies can be deployed.</p> <p>2. If the Agency feels strongly that a provision aimed at addressing unintentional pollination must be included in the current rule, then please consider the following: "A grower of hemp crops produced outdoors for flowers may request from the Agency the number (amount) of registered Growers of seed within a 5 mile radius of the flower Grower's cultivation areas."</p> <p>- It is not appropriate, or necessary to provide the seed growers' contact information.</p>
28	991	5-Jul-19	O	Neraka White	TalkAboutHemp.com	poB 76	east middlebury	VT	5740	neraka.white@gmail.com	12	<p>All of Section 12</p> <p>I understand the Agency's interest in establishing a hemp quality or grading system, comparable to the system we have for maple syrup. (and many hemp industry players agree that a grading system is one way to enhance the Vermont brand of quality hemp products in national and global markets.</p> <p>However, I feel strongly that the grading system proposed in Sec. 12.2 is inadequate, and premature. I respectfully request the Agency remove this section from the rule. Work with Vermont's hemp growers and processors and continue to explore a more equitable and clearly defined grading system.</p> <p>1. For starters, this standard does nothing for Vermont hemp growers and producers working with seed, starts, clones, food or fiber. These businesses have as much right to access a Vermont Hemp brand grading system as CBD growers and producers.</p> <p>2. Cannabinoid concentration is only one of several "objective" criteria that could imply "quality". This should not be the only measure.</p> <p>3. Sec 12.3 (b) In this case, I believe the proposed standard is being applied BEFORE the Agency has outlined "practices and conditions with the potential to reduce risks for contaminants in locations including and not limited to cultivation areas, and storage, drying, and processing facilities;</p> <p>4. Sec 12.3 (c) "...contaminant action levels as applicable..." Has the Secretary outlined the applicable hemp-specific contaminant action levels?</p>
29	993	5-Jul-19	O	Virginia Bowley		450 Sanders Circle	Montpelier	VT	5602	vbowleyvt@gmail.com	Vermont Hemp Rules general	<p>I am concerned about oversight of this industry. I am worried about many things: that Vermont farmers will be led by Big Marijuana into leaving their land and then being penalized for non-compliance; about pollution, water and electricity; about feeding this to animals; about out-of-state entities with no connection to Vermont taking over the "industry" as Tobacco did for decades, with disastrous public health results. I do not believe that the systems are in place for testing product, or for regulating it effectively. As we have seen in Colorado, Washington and Oregon, the black market has not gone away but has strengthened, and the anticipated windfall has not materialized. Enforcement and health costs are much higher than the revenue, and are borne by us all, not by the industry.</p>
30	997	5-Jul-19	B	Scott M Waring	etucddation	4 Kellogg Road, Unit D	Essex	VT	5446	scot@etucddationsct.com	3	<p>Regarding section 3: the definition "BIOMASS" should be clarified to coincide with this industry standard as raw plant material, regardless of CBD content. Material with less than 8% CBD should be called "trim" or "light", but biomass is already in use.</p>
31	999	5-Jul-19	D	Scott M Waring	etucddation	4 Kellogg Road, Unit D	Essex	VT	5452	scot@etucddationsct.com	4.3	<p>This is unfair on principle. Felons are not restricted in farming any other crop.</p>
32	1001	5-Jul-19	D	Scott M Waring	etucddation LLC	4 Kellogg Road, Unit D	Essex	VT	5452	scot@etucddationsct.com	5.3	<p>It is an unwise to promote a policy where a "grower of hemp crops produced outdoors for seed must notify all growers of biomass and flower within a radius of 5 miles of their cultivation area". This is a sensitive issue. For the AAFM to insist seed and fiber hemp growers take responsibility for self-identifying to CBD flower growers, the agency is 1.) avoiding responsibility in regulating this aspect of the program and 2.) ignoring to the certain conflict this requirement will cause. Simply notifying CBD growers that someone nearby is growing a seed crop does nothing to protect the CBD crop from pollination, but it does put seed and fiber farmers at risk of being scouted out and targeted.</p>
33	1003	5-Jul-19	D	Scott M Waring	etucddation LLC	4 Kellogg Road, Unit D	Essex	VT	5452	scot@etucddationsct.com	12	<p>Aside from CBD concentration, all grades of hemp - especially the higher tiers - should be certified contaminant-free too. Hemp with 18% CBD but tainted with Coliform bacteria or pesticide residues should NOT be considered Grade AA hemp. Tainted material will do MORE to damage the Vermont Hemp brand than CBD levels.</p>
34	1005	5-Jul-19	O	Dean Whitlock	Individual	545 Tucker Hill Road	Theford Center	VT	5075	boetman@deanwhitlock.com	Section 3.1 and all sections that would allow a THC concentration greater than 0.3%	<p>Allowing hemp to have a THC concentration greater than 0.3%, even on a theoretical level, is not in compliance with Federal law. More important, it removes an important protection to public health. I spent several summers during my college years in farming country in Nebraska where hemp had been grown during WWII to produce rope for the Navy. In 1967-69, when I was there, the verge between every field and road was filled with hemp plants growing up to 12 feet high. Many high school and college students (including me) harvested it. It was not very potent but enough to produce a high, and tested sufficiently high when I was arrested to warrant a charge of felony possession. (Luckily for me, possession of less than 2 pounds was made a misdemeanor by the time my case went to trial.) Hemp, and cannabis in general, has a very maleable genome, which is why there are so many different cultivars. In the wild, even hemp can change its potency in just a couple of generations. In a farmed field, dropped seed will grow in company with the next year's sown seed and produce accidental cultivars. When concentrated, any THC level can be higher than expected. All testing must be thorough (wide spot checking is not sufficient), timely (when harvested, not at any time before), and vetted by frequent random inspection and testing by the state. Any violations should be accompanied by fines and/or permit revocation, increasing with each violation to permanent revocation of the permit. Unlike tomatoes, corn, maple syrup, and other Vermont agricultural products, improperly produced hemp, particularly that for human and animal consumption, can cause serious mental and physical health harms, including intoxication behind the wheel of a vehicle. You simply cannot treat this crop like any other plant.</p>



Jessilyn Dolan, Vermont Cannabis Nurses Association, 6/28/19

6 Roy Drive, Underhill, VT 05489

3.3-has all cannabinoids but THC removed

3.14-need to also define chemovar

3.21-full spectrum-need to specify what extraction methods are full spectrum, as some methods fractionate and then reformulate by combining, as well as methods that do not capture the chlorophyll, etc.... example: CO2 does usually removes chlorophyll....

3.51-type IV is now CBG dominant

3.52-whole plant-again needs to extrapolate on extraction methods as not all methods get both water and lipid soluble.

As a nurse, I think full spectrum and whole plant are very important to define correctly as many companies are mislabeling for marketing purposes, not for patient transparency and efficacy.

6.2 BHO extraction should be listed as illegal. As nurses, we are seeing more concerns come up every day with this extraction method and if NOFA is pushing for this to be allowed, NOFA's legitimacy and understanding of safety for consumers should be questioned heavily.

6.6 I would love to see a state program where the THC/THCA needing to be disposed of is donated to patients.

7.3/8.2-we need strict guidelines for testing, not proposed individually

11.4b-can we call it what it is, cannabis sativa l?

11.4g-manufacturing date is silly, just expiration and lot number makes sense. how about a one year from manufacture expiration date unless they can show proof that shelf life is stable beyond one year? I am concerned that products sitting on shelves for over a year are not reliable and we need more consumer protection.

12.2 I think is not the best way at all to determine a quality product unless you grade the FINAL product, not the flower. AND ONLY organic or clean green certified end products should EVER get a AA...make that a separate distinction....

Vermont has a unique ability to lead the Northeast hemp movement and we need to push and encourage organic, clean, healthy medicine, consumers, and our precious soil and land!

NO product should ever be AA if they are not stewards of the land and advocates for true clean medicine and consumer health!

As a nurse, I would want to see that A or AA is the best out there and that HAS to mean organic! No way around it!

**To be labeled made in VT, it should have to be grown, processed, bottled, everything in state!!**

**section 14....why is Champlain Valley Dispensary absolved from this?**

**section 16....what happens to people mislabeling products knowingly and who do we report them to for consumer safety?**

**Again, as a nurse, this is a HUGE and happening way too much!!**

Shayne Lynn, Vermont Cannabis Trade Association

70 South Winooski Ave #284, Burlington, VT 05401

7/3/19

### Section 3.1 Definition of acceptable potency level

The proposed rules define acceptable potency level as a hemp crop that has a delta-9 THC concentration of 0.3 percent or less and a total theoretical tetrahydrocannabinol concentration of one percent or less. Vermont statute allows for a delta-9 tetrahydrocannabinol concentration of 0.3 percent or less on a dry weight basis, which is consistent with the 2018 Farm bill which further requires the testing to occur post-decarboxylation. There is no reference to total theoretical THC concentration in Vermont law. We suggest removing the phrase related to the theoretical THC concentration and including the definition of hemp in accordance with the 2018 Farm Bill.

### 6.6 Processing

The rule states that a Processor that extracts THC or THC-A from a hemp crop must submit for approval by the Agency a disposal plan that ensures the THC and THC-A is disposed of in a manner that renders the THC and THC-A unusable and that accounts by process lot number all THC or THC-A removed. This is contrary to Vermont statute. If THC over 0.3% is found, the grower can enter into an agreement with a dispensary for the separation of the THC, sell the hemp crop to a dispensary, or arrange for the Secretary to destroy or order the destruction of the hemp crop.

### 6.7. Processing

Under the rules, a processor may transfer or sell hemp concentrate for the purpose of reformulation into hemp products or hemp-infused products only to the Grower if the grower is a processor or to another Processor.

We would suggest clarifying whether this section refers to hemp that is over 0.3% THC, or any hemp concentrate.

### 6.8(b) Records of hemp crops

Growers can ship hemp crops out-of-state if they have the requisite paperwork. Processors can receive hemp crops from out-of-state with the requisite paperwork. However, there is nothing that allows processors to ship processed hemp out-of-state. Processors should be allowed to ship hemp, and receive hemp from, out of state with the same requirements as hemp crops.

### Section 7.3 Testing parameters

This provision allows a grower to "propose testing parameters for pesticides, heavy metals, mycotoxins, and bacterial and fungal contaminants that are based on a risk analysis and use for approval by the Agency". How is the risk level determined by either the Grower or the Agency?

The rules require testing for "contaminant levels are below action limits outlined by the Agency for pesticides, heavy metals, mycotoxins, and bacterial and fungal contaminants", but these limits are not defined in the proposed rules.

#### Section 10.2 Handling hemp

Registrants shall not formulate, handle, wholesale or retail a hemp product or hemp-infused product that contains a delta-9 tetrahydrocannabinol concentration greater than 0.3 percent on a dry weight basis except as provided in Section 6.7. However, Section 6.7 does not reference THC concentration over 0.3 percent. This should be further clarified.

#### Section 11 Labeling

We recommend including on the label the total amount of THC in all products.

We also recommend including in the future on the label the total amount of CBG, CBN, and THCV.

We are concerned that this section is not effective on passage. We believe that, for public safety purposes, labeling should not be delayed for another year.

#### Section 11.5 Labeling

The rule states that all label guarantees regarding potency must be accurate and within +/-10% per serving size listed on the label. The +/-10% accuracy of the per serving size dosage will make it impossible to formulate anything less than 5-10mg, due to both manufacturing constraints as well as testing accuracy. We suggest that this should be increased to +/-20%.

#### Section 12 Grading

The grading system and application of more desirable grades based solely on the cannabidiol content in the hemp does not account for the numerous and complex characteristics of the plant, which have a significant bearing on the health and quality of a particular crop. Further, applying the higher grades to hemp based solely on the cannabidiol content will encourage growers to cultivate their hemp based solely on this metric to achieve the highest-grade material, minimizing the importance of these alternate quality characteristics. While a grading system such as this may function when grading a product such as maple syrup, it is inadequate for the grading of hemp.

### **Section 14 Enforcement**

**Section 14 allows for the selling of THC to a dispensary, but only in the case of negligent violation of chapter 34 of the Rules. This is contrary to the statute, which allows for the sale of THC to a dispensary in the event the THC of over 0.3% is found in a hemp plant, regardless of negligence. There is no other reference to sales to a dispensary in the Rules.**

**FoodScience Corporation**

**3.8** What qualifications must a lab meet in order to be certified? There are a variety of methods being used to test products and results can vary widely. Article 6 does not provide enough detail.

**4.1(d)** If we are manufacturing in one location, but packaging in another, do both sites need to be registered? What about locations for storing product?

**6.9(a)** We are not receiving crops, which is the determining factor in 6.8, which this rule mentions. Our vendors may or may not be able to provide these document requirements due to variations in their own state regulations and the challenge of being multiple steps removed from the grower.

**6.9(b)** We have many SOP's in place for formulation, manufacturing, testing, and cleaning steps. Is this requiring us to create an SOP specific to the production of hemp products that takes into account elements of the program? Please clarify.

**8.2.** We have testing parameters set up based on industry standards. Will we need to propose these parameters to the Agency even if they are part of our receiving process and subject to other requirements? Is this a requirement and what will the agency be approving for?

**8.3(c)** We purchase product that is already far removed from the agricultural process and should have already gone through these testing procedures, but may or may not have been tested at a VT agency certified laboratory. If we can provide a COA for the material, will that suffice? Or, will we have to send it out to a VT agency certified lab to verify? We will have to do some testing on bulk product regardless.

**8.4.** Are these referring to the same contaminant levels that we may propose and have approved per section 8.2?

**9.2** What methods of disposal are approved by the agency for process lots?

**Section 10 "Requirements for Handling Hemp Crops, Hemp Products and Hemp-Infused Products"**  
According to the definition, 'handle' only refers to hemp crops and specifically states, "'Handle' does not mean possession of hemp products or hemp-infused products." Please clarify.

**10.3.** Would this potentially include bulk raw materials (for us this means a hemp concentrate) or only products for retail sale?

**11.1.** Please clarify that you are requiring a COA for hemp-specific label guarantees, not all product guarantees.

**11.2** Would it be possible to add a clause that would allow for federal regulations to supersede any VT Hemp rules Vermont Hemp Program Rules?

**11.4(a)** FDA adverse event requirements along with 21 CFR 101.5 clearly outline our industry's labeling requirements. We have the option to provide phone number, city, state, and zip code. This does not align with the requirements in 11.4(a) Additionally, it is important for our private label business to be able to list the distributor information as opposed to the manufacturer information because the distributor is considered the marketer of the product. Would we have to provide both distributed by and manufactured by information on a privately labeled hemp product?

11.4(c) Foods and dietary supplements have strict labeling guidelines outlined in 21 CFR 101.9. The Nutrition Facts Panel and Supplement Facts Panel show the "active ingredients," and the remaining ingredients are listed as "other ingredients." 11.4(c) does not align with FDA labeling requirements for food and dietary supplements. Would we have to include an additional list of ingredients in descending order of predominance by weight in addition to our Supplement Facts Panel, or could we omit the list, having already provided all ingredients in the FDA required format?

11.4(g) FoodScience Corporation already has an extensive lot numbering system under 21 CFR 111. Our lot numbers are sequentially assigned automatically by our ERP system. This rule would require an additional process lot code to trace as well as require additional space on product/label to include this secondary process lot code. Additionally, what if we manufacture, package, and store the product at three different registered locations? Or package for another registered processor?

12.3(d) Typo: "Vermont Hemp Program's labeling requirements in Section 10." I believe the labeling requirements are in Section 11.

Additional comment: A large part of our business includes the manufacturing, packaging, and labeling of product for customers all over the world. We call this private label or copacking and customer involvement in the process varies greatly. What are the requirements under these rules for our customers? Would only their labels have to comply or would they have to follow all rules including record keeping, etc.? We would need this to be addressed in order to comply with the program.

Mollie Wills, Rural Vermont Comments on VAAFM Proposed Hemp Rules

46 East State Street, Montpelier, VT 05602

7/3/19

**COMMENT ON REGISTRATION FEE STRUCTURE:**

Rural Vermont understands that the Registration Fee structure for Hemp is not part of the proposed rules however, we feel it is important to register our concern that the \$25 registration fee required of someone who wants to simply grow Hemp for personal use is unfair. It is particularly inconsistent given that there is no registration fee for someone growing marijuana for personal use. We recognize that this would require a legislative amendment but feel it would be an important improvement.

**COMMENTS ON HEMP RULES:**

**SECTION 1:**

1.1 – Secretary must adopt rules establishing how the Agency will conduct research within this program.

Rural Vermont strongly recommends that VAAFM provide more details in the rules that responds to the preceding statement. We believe it will be very helpful for producers and processors to have a clear understanding of how the VAAFM will be conducting research, what the goals of that research will be and how the results of the research will be made public. In particular, it would be helpful to know how the information and data the proposed rules require being collected will be used. Perhaps a "preamble" to the Rules would be the way to accomplish this.

**SECTION 4:**

4.1 (b) - A person whose application is rejected as incomplete may reapply for registration at any time.

What happens to the registration fee if registration is rejected and the registrant chooses not to reapply?

4.1 (e) - Any information provided to the Agency as part of a person's application may be publicly disclosed and may be provided to law enforcement agencies without notice to the applicant

We understand the tortured history of Hemp but no other agricultural product is subjected to such requirements. We believe it is very unreasonable to have information provided through the registration process be made publicly available and especially without notice to the registrants in advance. We strongly recommend that if this information is going to be made available a.) It is made available only upon request and b.) that fact be prominently included in the Hemp Registration form.

4.3 - A person convicted of a felony relating to a controlled substance under state or federal law before, on, or after December 20, 2019 shall be ineligible to register with the Hemp Program during the 10-year period following the date of the conviction unless the person has lawfully registered with the Hemp Program prior to this date.

Rural Vermont objects to this provision in the Rules. We understand this section is included because it corresponds to a specific provision in the 2018 Farm Bill, (Title X, Sec.10113, pg. 432) but it's an unjust and outdated provision and one that Vermont does not support. We respectfully request this provision be removed from Vermont's Hemp Program Rules. Furthermore, we believe that if USDA rejects the VT Hemp Program Plan for not including language that excludes convicted drug felons from participating in VT's hemp program, that we stand our ground on the principle that those who have already "done their time" have every right to participate in the growth of a legal industry involving an agricultural commodity. Furthermore, "ex post facto" laws (those that impose new punishment for past offenses) are specifically forbidden by the United States Constitution in Article 1, Section 9, Clause 3 (with respect to federal laws) and Article 1, Section 10 (with respect to state laws). It is time to return Hemp to its former status as a valuable agricultural crop and treat it like any other crop.

#### SECTION 5:

5.1 - A Grower is responsible for demonstrating compliance with the acceptable potency level for hemp crops offered for sale or transferred to a Processor or the public.

Rural Vermont believes this rule needs more clarity. For example: What responsibility does the grower bear if they are growing from clones that were certified as meeting the acceptable potency level? We believe it would be helpful to provide some guidance regarding at what point in the growing process the hemp crop should be tested for potency.

5.3 - A Grower of hemp crops produced outdoors for seed must notify all Growers of biomass and flower within a radius of 5 miles of their cultivation areas. The Agency will provide names and contact information to the Grower based on previous year Registrants.

Rural Vermont is also concerned about potential conflicts between growers of hemp and neighboring growers of medicinal/recreational cannabis.

5.4 (b) - Offer a list of any pesticides used in the cultivation of the hemp crops, clones, or plants.

Rural Vermont is wondering whether this disclosure applies to all the items on the list that is provided by VAAFM of ACTIVE INGREDIENTS ALLOWED FOR INDUSTRIAL HEMP CULTIVATION.

We are particularly concerned about the inclusion of "Azamax" (active ingredient Azadirachtin). Last year the state of Oregon identified this product as "misbranded" and adulterated with pesticide residues. Please see this Pesticide Advisory:

<https://www.oregon.gov/ODA/programs/Pesticides/Documents/2018Advisories/AzaMax.pdf>

5.6 (b) iii - A Grower shall maintain records of all transfers of hemp crops to a Processor or out-of-state recipient. The records shall be kept by harvest lot number and shall include: an estimate of the amount of hemp transferred on a dry weight basis in pounds.

Rural Vermont is concerned that this requirement will be very difficult to do accurately and we wonder about the value. Is it to ensure checks and balances with processor's reporting? The product is being weighed and reported by the processor and it seems like that is the information that should be collected, not a vague guess from the grower when they've already reported on acreage in production, particularly if off-base estimate would result in VAAFM action. It seems to us that if the grower records the number of plants transferred that would be a more useful metric to track – especially for the VAAFM's research goals.

#### SECTION 6:

6.2 - A Processor shall only use lipid, ethanol, or carbon dioxide (CO2) botanical extraction methods, or other extraction methods for which the Processor has received written approval from the Agency.

Rural Vermont is wondering what other methods the Agency is considering for approval. Will these "other methods" be reported/published?

6.4 - A Processor may process hemp crops only at registered processing sites. A Processor must report in writing to the Agency a closure of a processing site within business 10 days of its closure.

Rural Vermont respectfully suggests that the requirement for reporting on a processing site closure be within 30 days.

#### SECTION 7:

7.1 A Grower must test hemp crops for compliance with these rules.

Rural Vermont wishes to raise the same concern we noted in our comment on Sec. 5.1. We believe this rule needs more clarity. For example: What responsibility does the grower bear if they are growing from clones that were certified as meeting the acceptable potency level? We believe it would be helpful to

provide some guidance or BMPs regarding at what point in the growing process the hemp crop should be tested for potency.

**7.3 - A Grower may propose testing parameters for pesticides, heavy metals, mycotoxins, and bacterial and fungal contaminants that are based on a risk analysis and use for approval by the Agency.**

Rural Vermont appreciates that this provision allows for innovation coming from the Hemp industry but we believe the VAAFM needs to specify how such approval of testing parameters will occur and how they will be published.

#### **SECTION 8:**

**8.2 - A Processor may propose testing parameters for pesticides, heavy metals, mycotoxins, and bacterial and fungal contaminants that are based on a risk analysis, the stage of the manufacturing process, and delivery method (inhalant, ingestion, or absorption) for approval by the Agency.**

As in our comment on Sec. 7.3, Rural Vermont appreciates that this provision allows for innovation coming from the Hemp industry but we believe the VAAFM needs to specify how such approval of testing parameters will occur and how they will be published.

#### **SECTION 10:**

**10.3 (b) Within 30 days of receiving the request for a confirmed crop or product, the Agency will generate a confirmation that may accompany the shipment of the hemp crop, hemp product, or hemp-infused product.**

Rural Vermont would like to express concern that having to wait 30 days for a confirmation may not be practical for many hemp businesses. Especially during this early stage of the industry and given the variations in state laws, it seems likely that hemp businesses may find it prudent to seek such confirmation to protect their shipments and their employees. We respectfully suggest that 10 days would be more practical.

#### **SECTION 12:**

**12.4 The Registrant must apply for certification of meeting all the requirements of Vermont's Hemp brand annually to the Agency, using forms provided by the Agency.**

Rural Vermont understands that this portion of the Rules does not go into effect until 7/1/20 but we feel that more information about any cost or time frame that will be involved with such certification needs to be disclosed in these rules now so growers and processors can incorporate it into their business plans.

**SECTION 13:**

**13.3 - The Agency may inspect any retail location offering hemp products or hemp-infused products. This inspection may include the taking of samples of such products.**

Rural Vermont feels it is important that these Rules disclose under what authority VAAFM will be conducting inspections of retail establishments that offer hemp products, given that under the provisions of Sec. 2.2 registration is not required of retailers.

**From:** Smith, Stephanie A  
**To:** Smith, Stephanie  
**Subject:** FW: Hemp Regulations Update/Feedback  
**Date:** Monday, July 8, 2019 8:42:26 AM

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I'm guessing this was for you? I hope you enjoyed the holiday weekend!

Stephanie A. Smith, MUPP  
Hazard Mitigation Planner  
Vermont Emergency Management  
Desk: (802) 241-5362  
Cell: (802) 989-6793  
[Stephanie.A.Smith@vermont.gov](mailto:Stephanie.A.Smith@vermont.gov)

**From:** Joel Bedard <jtb@thevthempco.com>  
**Sent:** Friday, July 5, 2019 6:47 AM  
**To:** Tebbetts, Anson <Anson.Tebbetts@vermont.gov>; Eastman, Alyson <Alyson.Eastman@vermont.gov>; John Rodgers <jroddgers@leg.state.vt.us>; Carolyn Partridge <CPARTRIDGE@leg.state.vt.us>  
**Cc:** Campbell, Erica (Sanders) <erica\_campbell@sanders.senate.gov>; McLaren, Ryan <Ryan.McLaren@mail.house.gov>; Berry, Tom (Leahy) <tom\_berry@leahy.senate.gov>; Polyte, Megan <Megan.Polyte@vermont.gov>; CPearson@leg.state.vt.us; Trevor Squirrell <TSquirrell@leg.state.vt.us>; George Till <GTill@leg.state.vt.us>; Giguere, Cary <Cary.Giguere@vermont.gov>; Smith, Stephanie A <Stephanie.A.Smith@vermont.gov>  
**Subject:** Hemp Regulations Update/Feedback

After spending years working on this subject matter in Vermont, I am somewhat remiss at having been relegated to providing my comments and feedback via an online portal. Ergo, I am sending a copy via email as well.

1--The 2018 Federal Farm Bill does not come into effect until the USDA releases its formal 'Rules and Regulations', which are not scheduled for release until August, 2019 at the earliest. This alone concerns me, as the Vermont Agency of Agriculture Food and Markets is proposing State measures that may not be in alignment with Federal measures. If the premise of AAFM's actions are to be Federally compliant, and AAFM does not yet know what Federal compliance fully entails, then the proposed regulations will need to be revisited almost immediately. This seems to be a premature action.

2--In 2018, I specifically proposed that non-compliant hemp could potentially be remediated at farmer and State discretion via capable processors. This testimony was given to both Senate and House Committees. I made it clear that this proposal could not be included in any hemp regulation, as it would place AAFM and the State in default of Federal compliance (stripping of/handling THC). This proposed language took from my personal testimony and bastardized

it such that only 'dispensaries' would be able to mitigate non-compliant hemp. I feel somewhat aggravated that I have to keep reminding people that Medical Marijuana dispensaries are *not* Federally legal and are under the purview of the US Department of Justice, not the USDA. Including any dispensary language in Vermont's hemp regulations will place the State in conflict with USDA Rules and Regulations and make it such that every Vermont farmer and cultivator growing hemp is breaking Federal law. It will also make it such that Vermont products will be restricted from interstate commerce. Dispensary language must be removed.

That is but the tip of the iceberg that I have been working on for many years. I appreciate your time and consideration in this matter and look forward to facilitating a successful conclusion to this process.

Best regards,

Joel T Bedard

Netaka White, TakAboutHemp.com

East Middlebury VT 05740

7/5/19

### Section 4.3

I understand this section is included because it corresponds to a specific provision in the 2018 Farm Bill, (Title X, Sec.10113, pg. 432).

However, hemp is now a federally recognized agricultural commodity and there is no rational or legal justification for this provision in the Farm Bill. This is an outdated reminder of Drug Warrior thinking. Vermont should not be complicit by including it in our Hemp Program rule.

Vermont has the opportunity to lead by example and I respectfully request this provision (Section 4.3) be removed from Vermont's Hemp Program Rules.

In addition, I believe that if USDA rejects the VT Hemp Program Plan for not including this provision, that we stand our ground on ethical and legal principle.

Those convicted of a drug crime have already "done their time", and should not be singled out. They should have every right to participate in the growth of a legal industry involving an agricultural commodity.

Furthermore, though I'm not a legal scholar, I believe the Farm Bill provision is unconstitutional. "Ex post facto" laws (those that impose new penalties for past offenses) are specifically forbidden in the US Constitution under Article 1, Section 9, Clause 3 (with respect to federal laws) and Article 1, Section 10, Clause 1 (with respect to state laws).

4."X" – If you register as a Grower, and you qualify under the definition of Personal Cultivation (Sec 3.35) – doesn't that make it unnecessary to also register as a Processor? I recommend adding a clause to Section 4 that states, "A Grower whose sole purpose is for personal use, and meets the definition of Personal Cultivation is not required to register as a Processor"

I understand the Agency's desire to address the issue of male pollen inadvertently affecting a neighbor's crop of female flowers. However, I believe this provision creates an arbitrary legal bias in favor of flower production, placing the burden of responsibility (and culpability) on the "producer of seed". This rule is discriminatory, ineffective and problematic for Vermont's hemp community.

1. The rule as presented is simply unreasonable, and for what good? Cannabis physiology is what it is. No one has any control over the path pollen takes, and this rule offers no solution.
2. It is wrong to put a farmer in the position of having to notify, and most likely alarm neighbors that she/he may have no prior relationship with and might live miles away. It's not hard to imagine all kinds of unintended negative consequences coming from this exchange of information.

I respectfully request that this provision (Sec 5.3) be struck from the rules.

I offer these suggestions for your consideration:

1. Leave this issue (of pollination) alone for now, give it time and let's see how it plays out. If legitimate complaints arise of economic damage from unintended pollination, the Agency will have the opportunity to take public comment and consider what, if any, effective measures or policies can be deployed.

2. If the Agency feels strongly that a provision aimed at addressing unintentional pollination must be included in the current rule, then please consider the following:

"A Grower of hemp crops produced outdoors for flowers may request from the Agency the number (amount) of registered Growers of seed within a 5 mile radius of the flower Grower's cultivation areas."

- It is not appropriate, or necessary to provide the seed growers' contact information.

all of Section 12

I understand the Agency's interest in establishing a hemp quality or grading system, comparable to the system we have for maple syrup. I and many hemp industry players agree that a grading system is one way to enhance the Vermont brand of quality hemp products in national and global markets.

However, I feel strongly that the grading system proposed in Sec. 12.2 is inadequate, and premature. I respectfully request the Agency remove this section from the rule. Work with Vermont's hemp growers and processors and continue to explore a more equitable and clearly defined grading system.

1. For starters, this standard does nothing for Vermont hemp growers and producers working with seed, starts, clones, food or fiber. These businesses have as much right to access a Vermont Hemp brand grading system as CBD growers and producers.

2. Cannabidiol concentration is only one of several "objective" criteria that could imply "quality". This should not be the only measure.

3. (Sec 12.3 (b)) In this case, I believe the proposed standard is being applied BEFORE the Agency has outlined "practices and conditions with the potential to reduce risks for contaminants in locations including and not limited to cultivation areas, and storage, drying, and processing facilities;

4. (Sec 12.3 (c)) "... contaminant action levels as applicable..." Has the Secretary outlined the applicable hemp-specific contaminant action levels?

Catherine Antley

**SECTION 14. ENFORCEMENT:** (c) A corrective action plan for a person who has registered with the Hemp Program and who negligently violates these Rules by producing *Cannabis sativa* L. with a delta-9 tetrahydrocannabinol concentration greater than 0.3 but no greater than one percent on a dry weight basis shall include a requirement that the Registrant:

enter into an agreement with a dispensary registered under 18 V.S.A. chapter 86 for the separation of the delta-9 tetrahydrocannabinol from the hemp crop, return of the hemp crop to the person registered with the Secretary, and retention of the separated delta-9 tetrahydrocannabinol by the dispensary; ii. sell the hemp crop to a dispensary registered under 18 V.S.A. chapter 86; or iii. arrange for the Secretary to destroy or order the destruction of the hemp

**COMMENT:** The foundation of the "hemp" program is the THC level of 0.3 % THC or less. The provisions for enforcement in this rule are insufficient to ensure that this crop will not be grown and sold on the black market, saturating the market with cheap concentrated marijuana. The legislators and the public intended the THC level to be enforced. If this provision is not enforceable the program should be halted until this can be assured. The public and the legislature did not pass the "hemp" law in order for there to be non-enforcement and the law simply create a large source of cheap pot in Vermont. At the public comment session in Brandon, we were told that the THC level could be tested up to a month before harvest. We know that THC levels spike just before harvest. This "rule" would also allow farmers to produce high concentrated THC instead of hemp. Again the 0.3 % THC requirement which is foundational to the hemp program not being a program which supplies a large amount of cheap marijuana to the state. We were also told at the Brandon comment session that 98% of the hemp was for the production of CBD. We know that CBD is a hepatotoxic drug which can interfere with cytochrome p450 and thus change the concentration of other prescribed drugs such as coumadin and immunosuppressants which a patient may be taking. This patient could be at risk for hepatic necrosis or bleeding or stroke. CBD is an FDA tested and approved drug which is available through a prescription by a doctor who will monitor liver function tests. It is illegal to sell such a drug in the US without a prescription or to put it in food. The USDA and FDA have promised to clarify this in the fall. It is premature to create rules and regulations for S58 which must be in compliance with Federal law according to the verbiage in S58 itself when we are still waiting for a ruling on this. At this time CBD is carved out of the 2018 farm bill and under the jurisdiction of the FDA. For all these reasons the "hemp" law and the regulations being created now in Vermont should only deal with cloth, building materials and rope. Furthermore it is beyond the expertise of the Vermont agency of agriculture to produce pharmacy grade drugs which have important CNS side effects which include increasing suicidality and which if the drug composition is not enforced correctly and strictly (ie it contains too much THC) then the drug could trigger addiction relapse or psychosis. Maple syrup, flour, cheese do not contain active and important neurotransmitters and do not cause hepatic necrosis. The requirements needed to produce CBD correctly safely and reliably require oversight on par with that of the FDA. In addition, folks for out of state are leasing land from Vermonters and then not respecting the environmental laws of Vermont. The impaired waterways, the pesticides, heavy metals, phosphorous and run off are all problems which must be remediated. The poor Vermont land owner not the leasee from Colorado or California are required to pay for this. This is not helping our Vermont farmers. The smell and the

pollution are problematic and an environmental impact study must be required for each hemp grow prior to planting. What is the plan to mitigate the smells. The communities must be required to create bonds to compensate the landowners who through no fault of their own are bordering the secret ( non-FOIA discoverable) sites of the hemp farms. Rural and under privileged communities must be compensated for the environmental impact studies and assurance must be written into the rules to be sure that minority areas and poor rural areas are not targeted or exploited by out of state large industry. Lastly we believe that the rules were not given enough time for public comment and respectfully request that this time period be extended. The rules were posted before Phil Scott signed the bill and thus before the public would be looking for rules. Furthermore the rules are fundamentally ambiguous due to the fact the S58 must be in compliance with Federal Law upon which we are still awaiting clarification. For all these reasons and more, the hemp law rules and regulations must be rewritten after appropriate public review and after the final ruling on the 2018 Farm bill and clarification of the status of CBD.

In summary, thank you very much for the opportunity to express some of my views on this far reaching legislation, the intent of which was not to produce THC marijuana , as that bill was being actively debated in another bill in the legislature at the same time that S58 was under review, nor in my view was S58 to produce CBD since at the time S58 was passed the FDA and the USDA was clear that CBD had been carved out of the 2018 farm bill with which S58 states it must be in compliance .

Yours sincerely,

Catherine Antley, MD

ps. Please excuse typographical errors as these comments were drafted under time pressure in an attempt to meet the public comment dead line of 7/5/2019. -ca

July 5, 2019

Secretary of Agriculture Anson Tebbetts  
116 State Street  
Montpelier, Vermont 05602

Secretary of State Jim Condos  
128 State Street  
Montpelier, Vermont 05633-1101

Representative Robin Chesnut-Tangerman  
For the Legislative Committee on Administrative Rules (LCAR)  
115 State Street  
Montpelier, VT 05633-5301

Attorney General T.J. Donovan  
109 State St  
Montpelier, VT 05609

Dear Sirs,

This letter serves as a preamble to my public comments submitted in response to the Secretary of State's posting of May 22, 2019 submitted to his office on May 17, 2019 by the Secretary of Agriculture titled *Vermont Hemp Rules* in response to the rule making requirements of S.0058, *Chapter 34 Hemp*, which was delivered to Governor Phil Scott on May 24, 2019 and signed into law by the Governor on May 30, 2019.

On becoming law, legal authority for the *Hemp Pilot Program* was replaced with the legal authority for the *State Hemp Program* as amended 6 V.S.A. Chapter 34.

I have no financial interest in this matter. Simply I am concerned for the public health and safety, and protecting everyone (including farmers and from downstream damage to the environment) against those who unscrupulously take advantage of others with misinformation and scams.

I write for five reasons:

**1. The rules as proposed for the Vermont Hemp Program under the authority of 6 V.S.A. Chapter 34 by the Secretary fail to comply with the laws of the Federal Government and the State of Vermont.**

Authority: According to 6 V.S.A. Chapter 34 certain requirements of Federal law must be met by any proposed regulations.

- 561.a (1-5) There is no mention of the word drug as inclusive in the findings of the law.
- 561.b Purpose. The intent of this chapter is to establish policy and procedures for growing, processing, testing, and marketing hemp and hemp products in Vermont that comply with federal law so that farmers and other businesses in the Vermont agricultural industry can take advantage of this market opportunity.
- 566.a (4) require labels or label information for hemp products in order to provide consumers with product content or source information or to conform with federal requirements.
- 568.c A crop or product confirmed by the Secretary to meet the definition of hemp under State or federal law may be sold or transferred in interstate commerce to the extent authorized by federal law.

Clearly the Vermont legislators wish for the regulations promulgated by the Vermont Department of Agriculture to comply with federal law.

Acknowledged by statements of the Vermont Department of Agriculture members Ms. Stephanie Smith and Mr. Cary Giguere and confirmed by former FDA Commissioner Gottlieb and current FDA Commissioner Sharpless, the 2018 farm funding bill did not remove the authority of the FDA. It is illegal to violate federal laws concerning drugs. Cannabidiol and tetrahydrocannabinol are drugs. No regulations in violation of the FDA federal drug laws concerning CBD and THC would comply with the intent of 6 V.S.A. Chapter 34 to be in compliance with federal law.

- "The 2018 Farm Bill, however, explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill." <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>
- "To date, the agency has not approved a marketing application for cannabis for the treatment of any disease or condition. FDA has, however, approved one cannabis-derived and three cannabis-related drug products. These approved products are only available with a prescription from a licensed healthcare provider." <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>
- "There are no other FDA-approved drug products that contain CBD. We are aware that some firms are marketing CBD products to treat diseases or for other therapeutic uses, and we have issued several warning letters to such firms. Under the FD&C Act, any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. Drugs must generally either receive premarket approval by FDA through the New Drug Application (NDA) process or conform to a "monograph" for a particular drug category, as established by FDA's Over-the-

Counter (OTC) Drug Review. CBD was not an ingredient considered under the OTC drug review. An unapproved new drug cannot be distributed or sold in interstate commerce.” <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>

- The “FDA has approved Epidiolex, which contains a purified form of the drug substance CBD for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means FDA has concluded that this particular drug product is safe and effective *for its intended use.*” <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>  
This means the benefits for seizures which are untreatable with other drugs outweighs the risks.
- “The agency also has approved Marinol and Syndros for therapeutic uses in the United States, including for the treatment of anorexia associated with weight loss in AIDS patients. Marinol and Syndros include the active ingredient dronabinol, a synthetic delta-9- tetrahydrocannabinol (THC) which is considered the psychoactive component of cannabis. Another FDA-approved drug, Cesamet, contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived.” <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>
- Commissioner Sharpless repeated this position during his opening remarks at the May 2019 Silver Spring, MD open comment. (audio available on the FDA website)

Additionally, the proposed Hemp Program Rules are in conflict with various Vermont pharmacy statutes and rules. There are many. A few examples can be found at Title 26, Chapter 036, Sub Chapter 001, 2022 Definition of drug, manufacturing and manufacturers, practice of pharmacy, wholesale distribution, and others. Title 26, Chapter 036, Sub Chapter 002 and 003.

Conflicts in the proposed regulations exist with Title 18, Chapter 082.

**2. Without the direct supervision of a physician, cannabidiol (CBD) and tetrahydrocannabinol (THC) use is neither safe nor effective.**

Cannabidiol has been studied in evidence-based trials. In September of 2018, the DEA on the recommendation of the FDA placed cannabidiol (commonly known as CBD) in a schedule for controlled substances requiring a practitioner’s prescription. Therefore, cannabidiol is under the control of the federal government as a drug in Controlled Substance Schedule V (five). Evidence-based study for relatively short time periods of 3-5 years has resulted in a list of concerns. These concerns are listed in the package label and medication guide for Epidiolex, brand name legend drug cannabidiol. These concerns can be found in three places [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/210365lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210365lbl.pdf)  
[https://www.epidiolex.com/sites/default/files/EPIDIOLEX\\_Full\\_Prescribing\\_Information.pdf#page=8](https://www.epidiolex.com/sites/default/files/EPIDIOLEX_Full_Prescribing_Information.pdf#page=8)  
[https://www.epidiolex.com/sites/default/files/EPIDIOLEX\\_Full\\_Prescribing\\_Information.pdf](https://www.epidiolex.com/sites/default/files/EPIDIOLEX_Full_Prescribing_Information.pdf)

- “FDA continues to be concerned at the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses although they have not been approved by FDA. Often such products are sold online and are therefore available throughout the country. Selling

unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective.

This deceptive marketing of unproven treatments also raises significant public health concerns, because patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases". <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>

- Unlike drugs approved by FDA, products that have not been subject to FDA review as part of the drug approval process have not been evaluated as to whether they work, what the proper dosage may be if they do work, how they could interact with other drugs, or whether they have dangerous side effects or other safety concerns." <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>

As a pharmacist, when dispensing Epidiolex (cannabidiol), I am required to provide each patient with an advisory patient guide plus counsel on the following concerns:

- Do not use this drug unless monitored by a physician for elevations in liver enzymes, an indication of liver damage. Have pretesting of liver enzymes prior to starting this medication, and throughout use.
- Do not drive or use heavy equipment while using this medication as it is associated with sedation, lethargy and daytime sleepiness.
- Do not stop this medication abruptly without consulting with your physician as stopping can result in an increased incidence of seizures.
- Immediately consult with your health professionals if you experience suicidal thoughts as the use of CBD is associated with an increased risk of suicide. (Cannabidiol is a non-intoxicating, psychoactive drug. What does that mean? It affects the brain.)
- There are reports of hypersensitivity reactions when taking CBD. Report any allergic reactions to your physician and seek immediate medical help if these allergic reactions are severe.
- As a side note, anyone handling cannabis sativa plants should take appropriate safeguards against skin, mucous membrane, and respiratory exposure.
- GI disturbances have been reported by individuals who take CBD including abdominal pain, diarrhea, drooling and others.
- Increased irritability, agitation, aggression and anger are reported side effects of CBD.
- If you are taking CBD, let your surgical team and anesthesiologist know as CBD can interfere with anesthesia.
- Use of CBD is likely to interfere with many other drugs you are taking such as the anticoagulant warfarin.
- Concurrent use of cannabinoids with alcohol has been associated with an increased incidence of accidental death.
- Pregnant and nursing mothers should not take cannabidiol or any other cannabinoid as they have been shown to harm the fetus. Cannabinoid use interferes with the normal development of the brain and other organs.
- Cannabidiol has not been adequately studied as a carcinogen.
- Use of cannabidiol can put you at increased risk for bleeding/stroke and infection.
- Use of cannabidiol can lead to changes in immunosuppressive therapy
- Although not proven in humans, in animal studies and in ongoing investigational study, it is believed use of CBD may increase genetic abnormalities, decrease the ability of red blood cells to carry iron, decrease peripheral nerves, and increase intraocular pressure leading to blindness.

The FDA has authority over THC as an approved drug. Tetrahydrocannabinol (THC), Marinol is a Controlled Substance Schedule III (three). Although not routinely prescribed due to its unsatisfactory profile of adverse effects, THC is available on prescription for use in weight loss associated with anorexia in HIV patients and chemotherapy patients.

**3. The rules as proposed for the Vermont Hemp Program are not in compliance with the requirements of the USDA.**

The USDA has yet to release their hemp program regulations required by the 2018 farm funding bill. Any rules drafted by the Vermont Department of Agriculture in meeting the requirements of the USDA, which have yet to become public, are premature. Due process has not been met for consumers to be fully aware of the impact of the Vermont proposed rules.

**4. The rules as proposed fail to protect the public, including farmers, and the Vermont brand.**

Both THC and CBD are legend drugs for a reason. Both THC and CBD are scheduled controlled substances for a reason. The FDA makes recommendations on more than 100 years of experience in protecting consumers. It makes no sense for these regulations to override that expertise.

I suspect the FDA would tell you, it is not safe to manufacture CBD in one's barn, basement or bathroom, nor is it safe to provide CBD to the public without monitoring those individuals for adverse events, properly labeling the products, protecting the products from improper storage conditions, and other consumer harms. Of particular concern is the high rate of fungus in cannabis crops. For example, *Aspergillus* can be deadly and is very, very difficult to identify in testing of cannabis products.

- "The agency (FDA) has and will continue to monitor the marketplace and take action as needed to protect the public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and that are being marketed for therapeutic uses for which they are not approved. At the same time, FDA recognizes the potential therapeutic opportunities that cannabis or cannabis-derived compounds could offer and acknowledges the significant interest in these possibilities. FDA continues to believe that the drug approval process represents the best way to help ensure that safe and effective new medicines, including any drugs derived from cannabis, are available to patients in need of appropriate medical therapy. The Center for Drug Evaluation and Research (CDER) is committed to supporting the development of new drugs, including cannabis and cannabis-derived drugs, through the investigational new drug (IND) and drug approval process." <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>
- "FDA is not aware of any evidence that would call into question its current conclusions that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been

submitted thus far has not caused us to change our conclusions." <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>

- "Numerous other legal requirements apply to dietary supplement products, including requirements relating to Current Good Manufacturing Practices (CGMPs) and labeling. Information about these requirements, and about FDA requirements across all product areas, can be found on FDA's website." <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>

It is not safe to introduce drugs of known concern, CBD and THC, into the food chain by feeding cannabis sativa (whether from hemp or marijuana) in the form of pellets. Although hemp seeds with scant amounts or no amount of THC and CBD are approved by the FDA for feed. Feed in pellets or otherwise should not be confused with seed. How can the food Vermont brand be protected if cows, hogs and chickens are being fed products containing CBD and THC?

- Under section 301(II) of the FD&C Act [21 U.S.C. § 331(II)], it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. " <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>
- In December 2018, FDA completed its evaluation of three generally recognized as safe (GRAS) notices for the following hemp seed-derived food ingredients: hulled hemp seed, hemp seed protein powder, and hemp seed oil. FDA had no questions regarding the company's conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for the uses described in the notices, provided they comply with all other requirements. <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers>

## 5. The rules of the rules

<https://www.vpr.org/post/vermont-hemp-industry-ready-grow-state-and-feds-look-finalize-regulations>

May 31, 2019

The Vermont Agency of Agriculture just scheduled its first public hearings on the state rules for late June, in Brandon and Newport.

Stephanie Smith, with the Vermont Agency of Agriculture, said the draft rules on hemp cultivation were released earlier this year and the rules are now in the public comment period.

"The agency does want to get the rules in place," Smith said. "We would love to have them in place before harvest season for the purposes of clarity to all the players in the industry, farmers and processors alike."

During the public hearing in Newport, Ms. Smith explained that the draft rules in hand during the meeting were for the Vermont Hemp Pilot Program, and these rules would then be adapted as determined by the Department of Agriculture for submission to the USDA for the Vermont Hemp Program.

It appears that what was posted by the Secretary of State as Hemp Rules in mid-May, were for the then existing Hemp Pilot Program. It appears consumers have yet had an opportunity to respond to the draft rules for the Hemp Program, as this program is now substantially different from what existed in law previously for the Pilot Program. And to complicate matters, the Pilot Program for Hemp appears not to be authorized at this time through legislative action.

Was the public given adequate notice?

Your time on this matter is appreciated.

Sincerely,

Judith Margulies  
Vermont Pharmacist

Contact:

[TemporaryLilac@gmail.com](mailto:TemporaryLilac@gmail.com)

508-699-6013

Attachment: Regulations – Hemp Program Comments (1 page)

## Regulations – Hemp Program Comments

Judith Margulies

July 5, 2019

[temporarylilac@gmail.com](mailto:temporarylilac@gmail.com); 508-699-6013

1. Remove all current proposals and reference to cannabidiol as something that can be extracted from any cannabis sativa plant.
2. Add a statement, CBD and THC are controlled substances under the authority of the FDA. Any extraction, processing, distribution or sale of CBD (cannabidiol) is forbidden unless licensed by the Board of Pharmacy as a pharmacy or by the FDA.
3. All cannabidiol and tetrahydrocannabinol products sold or distributed in Vermont must adhere to the FDA requirements for drugs.
4. Include the following words:

The following hemp-derived products are approved for sale in Vermont

- Hemp seed
- Hemp seed oil
- Hulled hemp
- Hemp seed powder
- Hemp protein
- Clothing
- Building material
- Items made from hemp fiber
- Flower/plant from a Vermont licensed Grower to a Vermont licensed Grower or Processor

### HEMP PRODUCTS NOT APPROVED FOR SALE

The following products are NOT approved for sale in Vermont

- Any food product containing CBD;
- Any product containing CBD derived from hemp that makes therapeutic/medicinal claims;
- Any product that contains hemp as dietary supplement;
- Animal feed that contains any hemp products;<sup>3</sup>
- Unprocessed or raw plant material, including the flower that is meant for end use by a consumer;

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use EPIDIOLEX® safely and effectively. See full prescribing information for EPIDIOLEX.

EPIDIOLEX® (cannabidiol) oral solution, CV  
Initial U.S. Approval: 2018

### INDICATIONS AND USAGE

EPIDIOLEX is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older (1)

### DOSAGE AND ADMINISTRATION

- Obtain serum transaminases (ALT and AST) and total bilirubin levels in all patients prior to starting treatment. (2.1, 5.1)
- EPIDIOLEX is to be administered orally. (2.2)
- The recommended starting dosage is 2.5 mg/kg taken twice daily (5 mg/kg/day). After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day). (2.2)
- Based on individual clinical response and tolerability, EPIDIOLEX can be increased up to a maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day). See Full Prescribing Information for titration. (2.2)
- Dosage adjustment is recommended for patients with moderate or severe hepatic impairment. (2.5, 8.6)

### DOSAGE FORMS AND STRENGTHS

Oral solution: 100 mg/mL (3)

### CONTRAINDICATIONS

Hypersensitivity to cannabidiol or any of the ingredients in EPIDIOLEX (4)

### WARNINGS AND PRECAUTIONS

- Hepatocellular Injury: EPIDIOLEX can cause transaminase elevations. Concomitant use of valproate and higher doses of EPIDIOLEX increase the risk of transaminase elevations. See Full Prescribing Information for serum transaminase and bilirubin monitoring recommendations. (5.1)

- Somnolence and Sedation: Monitor for somnolence and sedation and advise patients not to drive or operate machinery until they have gained sufficient experience on EPIDIOLEX. (5.2)
- Suicidal Behavior and Ideation: Monitor patients for suicidal behavior and thoughts. (5.3)
- Hypersensitivity Reactions: Advise patients to seek immediate medical care. Discontinue and do not restart EPIDIOLEX if hypersensitivity occurs. (5.4)
- Withdrawal of Antiepileptic Drugs: EPIDIOLEX should be gradually withdrawn to minimize the risk of increased seizure frequency and status epilepticus. (5.5)

### ADVERSE REACTIONS

The most common adverse reactions (10% or more for EPIDIOLEX and greater than placebo) are: somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder, and poor quality sleep; and infections. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Greenwich Biosciences at 1-833-424-6724 (1-833-GBIOSCI) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### DRUG INTERACTIONS

- Moderate or strong inhibitors of CYP3A4 or CYP2C19: Consider dose reduction of EPIDIOLEX. (7.1)
- Strong inducer of CYP3A4 or CYP2C19: Consider dose increase of EPIDIOLEX. (7.1)
- Consider a dose reduction of substrates of UGT1A9, UGT2B7, CYP2C8, CYP2C9, and CYP2C19 (e.g., clobazam). (7.2)
- Substrates of CYP1A2 and CYP2B6 may also require dose adjustment. (7.2)

### USE IN SPECIFIC POPULATIONS

Pregnancy: Based on animal data, may cause fetal harm. (8.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide

Revised: 12/2018

## FULL PRESCRIBING INFORMATION: CONTENTS\*

### 1 INDICATIONS AND USAGE

### 2 DOSAGE AND ADMINISTRATION

- 2.1 Assessments Prior to Initiating EPIDIOLEX
- 2.2 Dosage Information
- 2.3 Administration Instructions
- 2.4 Discontinuation of EPIDIOLEX
- 2.5 Patients with Hepatic Impairment

### 3 DOSAGE FORMS AND STRENGTHS

### 4 CONTRAINDICATIONS

### 5 WARNINGS AND PRECAUTIONS

- 5.1 Hepatocellular Injury
- 5.2 Somnolence and Sedation
- 5.3 Suicidal Behavior and Ideation
- 5.4 Hypersensitivity Reactions
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### 6 ADVERSE REACTIONS

- 6.1 Clinical Trials Experience
- 7.2 Effect of EPIDIOLEX on Other Drugs
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### 8 USE IN SPECIFIC POPULATIONS

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### 8.4 Pediatric Use

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### 8.6 Hepatic Impairment

### 9 DRUG ABUSE AND DEPENDENCE

- 9.1 Controlled Substance
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\* Sections or subsections omitted from the full prescribing information are not listed.

## FULL PRESCRIBING INFORMATION

### 1 INDICATIONS AND USAGE

EPIDIOLEX is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients 2 years of age and older.

### 2 DOSAGE AND ADMINISTRATION

#### 2.1 Assessments Prior to Initiating EPIDIOLEX

Because of the risk of hepatocellular injury, obtain serum transaminases (ALT and AST) and total bilirubin levels in all patients prior to starting treatment with EPIDIOLEX [see Warnings and Precautions (5.1)].

#### 2.2 Dosage Information

- EPIDIOLEX is to be administered orally.
- The starting dosage is 2.5 mg/kg twice daily (5 mg/kg/day).
- After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day).
- Patients who are tolerating EPIDIOLEX at 5 mg/kg twice daily and require further reduction of seizures may benefit from a dosage increase up to a maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day), in weekly increments of 2.5 mg/kg twice daily (5 mg/kg/day), as tolerated. For patients in whom a more rapid titration from 10 mg/kg/day to 20 mg/kg/day is warranted, the dosage may be increased no more frequently than every other day. Administration of the 20 mg/kg/day dosage resulted in somewhat greater reductions in seizure rates than the recommended maintenance dosage of 10 mg/kg/day, but with an increase in adverse reactions.

#### 2.3 Administration Instructions

Food may affect EPIDIOLEX levels [see Clinical Pharmacology (12.3)].

A calibrated measuring device (either 5 mL or 1 mL oral syringe) will be provided and is recommended to measure and deliver the prescribed dose accurately [see How Supplied/Storage and Handling (16.1)]. A household teaspoon or tablespoon is not an adequate measuring device.

Discard any unused EPIDIOLEX remaining 12 weeks after first opening the bottle [see How Supplied/Storage and Handling (16.2)].

#### 2.4 Discontinuation of EPIDIOLEX

When discontinuing EPIDIOLEX, the dose should be decreased gradually. As with all antiepileptic drugs, abrupt discontinuation should be avoided when possible, to minimize the risk of increased seizure frequency and status epilepticus [see Warnings and Precautions (5.5)].

#### 2.5 Patients with Hepatic Impairment

Dose adjustment is recommended in patients with moderate (Child-Pugh B) hepatic impairment or severe (Child-Pugh C) hepatic impairment [see Warnings and Precautions (5.1), Use in Specific Populations (8.6); and Clinical Pharmacology (12.3)]. It may be necessary to have slower dose titration in patients with moderate or severe hepatic impairment than in patients without hepatic impairment (see Table 1).

EPIDIOLEX does not require dose adjustment in patients with mild (Child-Pugh A) hepatic impairment.

**Table 1: Dose Adjustments in Patients with Hepatic Impairment**

Hepatic Impairment	Starting Dosage	Maintenance Dosage	Maximum Recommended Dosage
Mild	2.5 mg/kg twice daily (5 mg/kg/day)	5 mg/kg twice daily (10 mg/kg/day)	10 mg/kg twice daily (20 mg/kg/day)
Moderate	1.25 mg/kg twice daily (2.5 mg/kg/day)	2.5 mg/kg twice daily (5 mg/kg/day)	5 mg/kg twice daily (10 mg/kg/day)
Severe	0.5 mg/kg twice daily (1 mg/kg/day)	1 mg/kg twice daily (2 mg/kg/day)	2 mg/kg twice daily (4 mg/kg/day)

### 3 DOSAGE FORMS AND STRENGTHS

Cannabidiol oral solution: 100 mg/mL for oral administration. Each bottle contains 100 mL of a clear, colorless to yellow solution.

### 4 CONTRAINDICATIONS

EPIDIOLEX is contraindicated in patients with a history of hypersensitivity to cannabidiol or any of the ingredients in the product [see Description (11) and Warnings and Precautions (5.4)].

### 5 WARNINGS AND PRECAUTIONS

#### 5.1 Hepatocellular Injury

EPIDIOLEX causes dose-related elevations of liver transaminases (alanine aminotransferase [ALT] and/or aspartate aminotransferase [AST]). In controlled studies for LGS and DS, the incidence of ALT elevations above 3 times the upper limit of normal (ULN) was 13% in EPIDIOLEX-treated patients compared with 1% in patients on placebo. Less than 1% of EPIDIOLEX-treated patients had ALT or AST levels greater than 20 times the ULN. There were cases of transaminase

elevations associated with hospitalization in patients taking EPIDIOLEX. In clinical trials, serum transaminase elevations typically occurred in the first two months of treatment initiation; however, there were some cases observed up to 18 months after initiation of treatment, particularly in patients taking concomitant valproate. Resolution of transaminase elevations occurred with discontinuation of EPIDIOLEX or reduction of EPIDIOLEX and/or concomitant valproate in about two-thirds of the cases. In about one-third of the cases, transaminase elevations resolved during continued treatment with EPIDIOLEX, without dose reduction.

#### Risk Factors for Transaminase Elevation

##### Concomitant Valproate and Clobazam

The majority of ALT elevations occurred in patients taking concomitant valproate [see Drug Interactions (7.3)]. Concomitant use of clobazam also increased the incidence of transaminase elevations, although to a lesser extent than valproate [see Drug Interactions (7.2)]. In EPIDIOLEX-treated patients, the incidence of ALT elevations greater than 3 times the ULN was 30% in patients taking both concomitant valproate and clobazam, 21% in patients taking concomitant valproate (without clobazam), 4% in patients taking concomitant clobazam (without valproate), and 3% in patients taking neither drug. Consider discontinuation or dose adjustment of valproate or clobazam if liver enzyme elevations occur.

#### Dose

Transaminase elevations are dose-related. Overall, ALT elevations greater than 3 times the ULN were reported in 17% of patients taking EPIDIOLEX 20 mg/kg/day compared with 1% in patients taking EPIDIOLEX 10 mg/kg/day.

#### Baseline Transaminase Elevations

Patients with baseline transaminase levels above the ULN had higher rates of transaminase elevations when taking EPIDIOLEX. In controlled trials (Studies 1, 2, and 3) in patients taking EPIDIOLEX 20 mg/kg/day, the frequency of treatment-emergent ALT elevations greater than 3 times the ULN was 30% when ALT was above the ULN at baseline, compared to 12% when ALT was within the normal range at baseline. No patients taking EPIDIOLEX 10 mg/kg/day experienced ALT elevations greater than 3 times the ULN when ALT was above the ULN at baseline, compared with 2% of patients in whom ALT was within the normal range at baseline.

#### Monitoring

In general, transaminase elevations of greater than 3 times the ULN in the presence of elevated bilirubin without an alternative explanation are an important predictor of severe liver injury. Early identification of elevated liver enzymes may decrease the risk of a serious outcome. Patients with elevated baseline transaminase levels above 3 times the ULN, accompanied by elevations in bilirubin above 2 times the ULN, should be evaluated prior to initiation of EPIDIOLEX treatment.

Prior to starting treatment with EPIDIOLEX, obtain serum transaminases (ALT and AST) and total bilirubin levels. Serum transaminases and total bilirubin levels should be obtained at 1 month, 3 months, and 6 months after initiation of treatment with EPIDIOLEX, and periodically thereafter or as clinically indicated. Serum transaminases and total bilirubin levels should also be obtained within 1 month following changes in EPIDIOLEX dosage and addition of or changes in medications that are known to impact the liver. Consider more frequent monitoring of serum transaminases and bilirubin in patients who are taking valproate or who have elevated liver enzymes at baseline.

If a patient develops clinical signs or symptoms suggestive of hepatic dysfunction (e.g., unexplained nausea, vomiting, right upper quadrant abdominal pain, fatigue, anorexia, or jaundice and/or dark urine), promptly measure serum transaminases and total bilirubin and interrupt or discontinue treatment with EPIDIOLEX, as appropriate. Discontinue EPIDIOLEX in any patients with elevations of transaminase levels greater than 3 times the ULN and bilirubin levels greater than 2 times the ULN. Patients with sustained transaminase elevations of greater than 5 times the ULN should also have treatment discontinued. Patients with prolonged elevations of serum transaminases should be evaluated for other possible causes. Consider dosage adjustment of any co-administered medication that is known to affect the liver (e.g., valproate and clobazam).

#### 5.2 Somnolence and Sedation

EPIDIOLEX can cause somnolence and sedation. In controlled studies for LGS and DS, the incidence of somnolence and sedation (including lethargy) was 32% in EPIDIOLEX-treated patients, compared with 11% in patients on placebo and was dose-related (34% of patients taking EPIDIOLEX 20 mg/kg/day, compared with 27% in patients taking EPIDIOLEX 10 mg/kg/day). The rate was higher in patients on concomitant clobazam (46% in EPIDIOLEX-treated patients taking clobazam compared with 16% in EPIDIOLEX-treated patients not on clobazam). In general, these effects were more common early in treatment and may diminish with continued treatment. Other CNS depressants, including alcohol, could potentiate the somnolence and sedation effect of EPIDIOLEX. Prescribers should monitor patients for somnolence and sedation and should advise patients not to

drive or operate machinery until they have gained sufficient experience on EPIDIOLEX to gauge whether it adversely affects their ability to drive or operate machinery.

### 5.3 Suicidal Behavior and Ideation

Antiepileptic drugs (AEDs), including EPIDIOLEX, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with an AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior.

Pooled analyses of 199 placebo-controlled clinical trials (mono- and adjunctive therapy) of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk (adjusted Relative Risk 1.8, 95% CI: 1.2, 2.7) of suicidal thinking or behavior compared to patients randomized to placebo. In these trials, which had a median treatment duration of 12 weeks, the estimated incidence rate of suicidal behavior or ideation among 27863 AED-treated patients was 0.43%, compared to 0.24% among 16029 placebo-treated patients, representing an increase of approximately one case of suicidal thinking or behavior for every 530 patients treated. There were four suicides in drug-treated patients in the trials and none in placebo-treated patients, but the number is too small to allow any conclusion about drug effect on suicide.

The increased risk of suicidal thoughts or behavior with AEDs was observed as early as 1 week after starting drug treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed.

The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5-100 years) in the clinical trials analyzed. Table 2 shows absolute and relative risk by indication for all evaluated AEDs.

**Table 2: Risk of Suicidal Thoughts or Behaviors by Indication for Antiepileptic Drugs in the Pooled Analysis**

Indication	Placebo Patients with Events Per 1000 Patients	Drug Patients with Events Per 1000 Patients	Relative Risk: Incidence of Events in Drug Patients/ Incidence in Placebo Patients	Risk Difference: Additional Drug Patients with Events Per 1000 Patients
Epilepsy	1.0	3.4	3.5	2.4
Psychiatric	5.7	8.5	1.5	2.9
Other	1.0	1.8	1.9	0.9
Total	2.4	4.3	1.8	1.9

The relative risk for suicidal thoughts or behavior was higher in clinical trials in patients with epilepsy than in clinical trials in patients with psychiatric or other conditions, but the absolute risk differences were similar for the epilepsy and psychiatric indications.

Anyone considering prescribing EPIDIOLEX or any other AED must balance the risk of suicidal thoughts or behaviors with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment, consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

### 5.4 Hypersensitivity Reactions

EPIDIOLEX can cause hypersensitivity reactions. One subject in the EPIDIOLEX clinical trials had pruritus, erythema, and angioedema requiring treatment with antihistamines. Patients with known or suspected hypersensitivity to any ingredients of EPIDIOLEX were excluded from the clinical trials. If a patient develops hypersensitivity reactions after treatment with EPIDIOLEX, the drug should be discontinued. EPIDIOLEX is contraindicated in patients with a prior hypersensitivity reaction to cannabidiol or any of the ingredients in the product, which includes sesame seed oil [see Description (1)].

### 5.5 Withdrawal of Antiepileptic Drugs (AEDs)

As with most antiepileptic drugs, EPIDIOLEX should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus [see Dosage and Administration (2.4) and Clinical Studies (14)]. But if withdrawal is needed because of a serious adverse event, rapid discontinuation can be considered.

## 6 ADVERSE REACTIONS

The following important adverse reactions are described elsewhere in labeling:

- Hepatocellular Injury [see Warnings and Precautions (5.1)]
- Somnolence and Sedation [see Warnings and Precautions (5.2)]
- Suicidal Behavior and Ideation [see Warnings and Precautions (5.3)]
- Hypersensitivity Reactions [see Warnings and Precautions (5.4)]
- Withdrawal of Antiepileptic Drugs [see Warnings and Precautions (5.5)]

### 6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In controlled and uncontrolled trials in patients with LGS and DS, 689 patients were treated with EPIDIOLEX, including 533 patients treated for more than 6 months, and 391 patients treated for more than 1 year. In an expanded access program and other compassionate use programs, 161 patients with DS and LGS were treated with EPIDIOLEX, including 109 patients treated for more than 6 months, 91 patients treated for more than 1 year, and 50 patients treated for more than 2 years.

In placebo-controlled trials of patients with LGS or DS (includes Studies 1, 2, 3, and a Phase 2 controlled study in DS), 323 patients received EPIDIOLEX. Adverse reactions are presented below; the duration of treatment in these trials was up to 14 weeks. Approximately 46% of patients were female, 83% were Caucasian, and the mean age was 14 years (range 2 to 48 years). All patients were taking other AEDs.

In controlled trials, the rate of discontinuation as a result of any adverse reaction was 2.7% for patients taking EPIDIOLEX 10 mg/kg/day, 11.8% for patients taking EPIDIOLEX 20 mg/kg/day, and 1.3% for patients on placebo. The most frequent cause of discontinuations was transaminase elevation. Discontinuation for transaminase elevation occurred at an incidence of 1.3% in patients taking EPIDIOLEX 10 mg/kg/day, 5.9% in patients taking EPIDIOLEX 20 mg/kg/day, and 0.4% in patients on placebo. Somnolence, sedation, and lethargy led to discontinuation in 3% of patients taking EPIDIOLEX 20 mg/kg/day compared to 0% of patients taking EPIDIOLEX 10 mg/kg/day or on placebo.

The most common adverse reactions that occurred in EPIDIOLEX-treated patients (incidence at least 10% and greater than placebo) were somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder, and poor quality sleep; and infections.

Table 3 lists the adverse reactions that were reported in ≥3% of EPIDIOLEX-treated patients, and at a rate greater than those on placebo in the placebo-controlled trials in LGS and DS.

**Table 3: Adverse Reactions in Patients Treated with EPIDIOLEX in Controlled Trials**

Adverse Reactions	EPIDIOLEX		Placebo
	10 mg/kg/day	20 mg/kg/day	
	N=75 %	N=238 %	N=227 %
<b>Hepatic Disorders</b>			
Transaminases elevated	8	16	3
<b>Gastrointestinal Disorders</b>			
Decreased appetite	16	22	5
Diarrhea	9	20	9
Weight decreased	3	5	1
Gastroenteritis	0	4	1
Abdominal pain, discomfort	3	3	1
<b>Nervous System Disorders</b>			
Somnolence	23	25	8
Sedation	3	6	1
Lethargy	4	8	2
Fatigue, malaise, asthenia	11	12	4
Insomnia, sleep disorder, poor quality sleep	11	5	4
Irritability, agitation	9	5	2
Aggression, anger	3	5	<1
Drooling, salivary hypersecretion	1	4	<1
Gait disturbance	3	2	<1

(continued)

**Table 3: Adverse Reactions in Patients Treated with EPIDIOLEX in Controlled Trials**

Adverse Reactions	EPIDIOLEX		Placebo
	10 mg/kg/day N=75 %	20 mg/kg/day N=238 %	N=227 %
<b>Infections</b>			
Infection, all	41	40	31
Infection, viral	7	11	6
Pneumonia	8	5	1
Infection, fungal	1	3	0
Infection, other	25	21	24
<b>Other</b>			
Rash	7	13	3
Hypoxia, respiratory failure	3	3	1

Adverse reactions were similar across LGS and DS in pediatric and adult patients.

**Decreased Weight:**

EPIDIOLEX can cause weight loss. In the controlled trials of patients with LGS or DS, based on measured weights, 16% of EPIDIOLEX-treated patients had a decrease in weight of  $\geq 5\%$  from their baseline weight, compared to 8% of patients on placebo. The decrease in weight appeared to be dose-related, with 18% of patients on EPIDIOLEX 20 mg/kg/day experiencing a decrease in weight  $\geq 5\%$ , compared to 9% in patients on EPIDIOLEX 10 mg/kg/day. In some cases, the decreased weight was reported as an adverse event (see Table 3).

**Hematologic Abnormalities:**

EPIDIOLEX can cause decreases in hemoglobin and hematocrit. In controlled trials of patients with LGS or DS, the mean decrease in hemoglobin from baseline to end of treatment was -0.42 g/dL in EPIDIOLEX-treated patients and -0.03 g/dL in patients on placebo. A corresponding decrease in hematocrit was also observed, with a mean change of -1.5% in EPIDIOLEX-treated patients, and -0.4% in patients on placebo. There was no effect on red blood cell indices. Thirty percent (30%) of EPIDIOLEX-treated patients developed a new laboratory-defined anemia during the course of the study (defined as a normal hemoglobin concentration at baseline, with a reported value less than the lower limit of normal at a subsequent time point), versus 13% of patients on placebo.

**Increases in Creatinine:**

EPIDIOLEX can cause elevations in serum creatinine. The mechanism has not been determined. In controlled studies in healthy adults and in patients with LGS and DS, an increase in serum creatinine of approximately 10% was observed within 2 weeks of starting EPIDIOLEX. The increase was reversible in healthy adults. Reversibility was not assessed in studies in LGS and DS.

**7 DRUG INTERACTIONS**

**7.1 Effect of Other Drugs on EPIDIOLEX**

**Moderate or Strong Inhibitors of CYP3A4 or CYP2C19:**

EPIDIOLEX is metabolized by CYP3A4 and CYP2C19. Therefore, coadministration with a moderate or strong inhibitor of CYP3A4 or CYP2C19 will increase cannabidiol plasma concentrations, which may result in a greater risk of adverse reactions [see *Clinical Pharmacology* (12.3)]. Consider a reduction in EPIDIOLEX dosage when coadministered with a moderate or strong inhibitor of CYP3A4 or CYP2C19.

**Strong CYP3A4 or CYP2C19 Inducers:**

Coadministration with a strong CYP3A4 or CYP2C19 inducer will decrease cannabidiol plasma concentrations, which may lower the efficacy of EPIDIOLEX [see *Clinical Pharmacology* (12.3)]. Consider an increase in EPIDIOLEX dosage (based on clinical response and tolerability) when coadministered with a strong CYP3A4 or CYP2C19 inducer.

**7.2 Effect of EPIDIOLEX on Other Drugs**

**UGT1A9, UGT2B7, CYP1A2, CYP2B6, CYP2C8, CYP2C9, and CYP2C19 Substrates:**

In vitro data predict drug-drug interactions with CYP1A2 substrates (e.g., theophylline, caffeine), CYP2B6 substrates (e.g., bupropion, efavirenz), uridine 5' diphospho-glucuronosyltransferase 1A9 (UGT1A9) (e.g., diflunisal, propofol, fenofibrate), and UGT2B7 (e.g., gemfibrozil, lamotrigine, morphine, lorazepam) when coadministered with EPIDIOLEX. Coadministration of EPIDIOLEX is also predicted to cause clinically significant interactions with CYP2C8 and CYP2C9 (e.g., phenytoin) substrates. Because of potential inhibition of enzyme activity, consider a reduction in dosage of substrates of UGT1A9, UGT2B7, CYP2C8, and CYP2C9, as clinically appropriate, if adverse reactions are experienced when administered concomitantly with EPIDIOLEX. Because of potential for both induction and inhibition of enzyme activity, consider adjusting dosage of substrates of CYP1A2 and CYP2B6, as clinically appropriate.

**Sensitive CYP2C19 Substrates:**

In vivo data show that coadministration of EPIDIOLEX increases plasma concentrations of drugs that are metabolized by (i.e., are substrates of) CYP2C19 (e.g., diazepam) and may increase the risk of adverse reactions with these substrates [see *Clinical Pharmacology* (12.3)]. Consider a reduction in dosage of sensitive CYP2C19 substrates, as clinically appropriate, when coadministered with EPIDIOLEX.

**Clobazam:**

Coadministration of EPIDIOLEX produces a 3-fold increase in plasma concentrations of N-desmethyclobazam, the active metabolite of clobazam (a substrate of CYP2C19) [see *Clinical Pharmacology* (12.3)]. This may increase the risk of clobazam-related adverse reactions [see *Warnings and Precautions* (5.1, 5.2)]. Consider a reduction in dosage of clobazam if adverse reactions known to occur with clobazam are experienced when co-administered with EPIDIOLEX.

**7.3 Concomitant Use of EPIDIOLEX and Valproate:**

Concomitant use of EPIDIOLEX and valproate increases the incidence of liver enzyme elevations [see *Warnings and Precautions* (5.1)]. Discontinuation or reduction of EPIDIOLEX and/or concomitant valproate should be considered. Insufficient data are available to assess the risk of concomitant administration of other hepatotoxic drugs and EPIDIOLEX.

**7.4 CNS Depressants and Alcohol:**

Concomitant use of EPIDIOLEX with other CNS depressants may increase the risk of sedation and somnolence [see *Warnings and Precautions* (5.2)].

**8 USE IN SPECIFIC POPULATIONS**

**8.1 Pregnancy**

**Pregnancy Exposure Registry:**

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antiepileptic drugs (AEDs), such as EPIDIOLEX, during pregnancy. Encourage women who are taking EPIDIOLEX during pregnancy to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry by calling the toll free number 1-888-233-2334 or visiting <http://www.aedpregnancyregistry.org>.

**Risk Summary:**

There are no adequate data on the developmental risks associated with the use of EPIDIOLEX in pregnant women. Administration of cannabidiol to pregnant animals produced evidence of developmental toxicity (increased embryofetal mortality in rats and decreased fetal body weights in rabbits; decreased growth, delayed sexual maturation, long-term neurobehavioral changes, and adverse effects on the reproductive system in rat offspring) at maternal plasma exposures similar to (rabbit) or greater than (rat) that in humans at therapeutic doses (see *Animal Data*). In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2–4% and 15–20%, respectively. The background risks of major birth defects and miscarriage for the indicated populations are unknown.

**Data:**

**Animal Data:**

Oral administration of cannabidiol (0, 75, 150, or 250 mg/kg/day) to pregnant rats throughout the period of organogenesis resulted in embryofetal mortality at the highest dose tested. There were no other drug-related maternal or developmental effects. The highest no-effect dose for embryofetal toxicity in rats was associated with maternal plasma cannabidiol exposures (AUC) approximately 16 times that in humans at the recommended human dose (RHD) of 20 mg/kg/day.

Oral administration of cannabidiol (0, 50, 80, or 125 mg/kg/day) to pregnant rabbits throughout organogenesis resulted in decreased fetal body weights and increased fetal structural variations at the highest dose tested, which was also associated with maternal toxicity. Maternal plasma cannabidiol exposures at the no-effect level for embryofetal developmental toxicity in rabbits were less than that in humans at the RHD.

When cannabidiol (75, 150, or 250 mg/kg/day) was orally administered to rats throughout pregnancy and lactation, decreased growth, delayed sexual maturation, neurobehavioral changes (decreased activity), and adverse effects on male reproductive organ development (small testes in adult offspring) and fertility were observed in the offspring at the mid and high dose. These effects occurred in the absence of maternal toxicity. The no-effect dose for pre- and postnatal developmental toxicity in rats was associated with maternal plasma cannabidiol exposures approximately 9 times that in humans at the RHD.

**8.2 Lactation**

**Risk Summary:**

There are no data on the presence of cannabidiol or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EPIDIOLEX and any potential adverse effects on the breastfed infant from EPIDIOLEX or from the underlying maternal condition.

#### 8.4 Pediatric Use

Safety and effectiveness of EPIDIOLEX for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome have been established in patients 2 years of age and older.

Safety and effectiveness of EPIDIOLEX in pediatric patients below 2 years of age have not been established.

#### Juvenile Animal Data

Administration of cannabidiol (subcutaneous doses of 0 or 15 mg/kg on Postnatal Days (PNDs) 4-6 followed by oral administration of 0, 100, 150, or 250 mg/kg on PNDs 7-77) to juvenile rats for 10 weeks resulted in increased body weight, delayed male sexual maturation, neurobehavioral effects (decreased locomotor activity and auditory startle habituation), increased bone mineral density, and liver hepatocyte vacuolation. A no-effect dose was not established. The lowest dose causing developmental toxicity in juvenile rats (15 sc/100 po mg/kg) was associated with cannabidiol exposures approximately 30 times that in humans at the recommended dose of 20 mg/kg/day.

#### 8.5 Geriatric Use

Clinical trials of EPIDIOLEX in the treatment of LGS and DS did not include any patients aged above 55 years to determine whether or not they respond differently from younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy [see Dosage and Administration (2.5), Warnings and Precautions (5.1), and Clinical Pharmacology (12.3)].

#### 8.6 Hepatic Impairment

Because of an increase in exposure to EPIDIOLEX, dosage adjustments are necessary in patients with moderate or severe hepatic impairment [see Dosage and Administration (2.5), Warnings and Precautions (5.1), and Clinical Pharmacology (12.3)]. EPIDIOLEX does not require dosage adjustments in patients with mild hepatic impairment.

### 9 DRUG ABUSE AND DEPENDENCE

#### 9.1 Controlled Substance

EPIDIOLEX is controlled in Schedule V of the Controlled Substances Act.

#### 9.2 Abuse

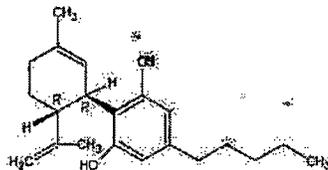
Animal abuse-related studies show that cannabidiol does not produce cannabinoid-like behavioral responses, including generalization to delta-9-tetrahydrocannabinol (THC) in a drug discrimination study. Cannabidiol also does not produce animal self-administration, suggesting it does not produce rewarding effects. In a human abuse potential study, acute administration of cannabidiol to non-dependent adult recreational drug users at therapeutic and supratherapeutic doses of 750, 1500, and 4500 mg in the fasted state (equivalent respectively to 10, 20, and 60 mg/kg in a 75 kg adult) produced responses on positive subjective measures such as Drug Liking and Take Drug Again that were within the acceptable placebo range. In contrast, 10 and 30 mg of dronabinol (synthetic THC) and 2 mg alprazolam produced large increases on positive subjective measures compared to placebo that were statistically significantly greater than those produced by cannabidiol. In other Phase 1 clinical studies conducted with cannabidiol, there were no reports of abuse-related adverse events.

#### 9.3 Dependence

In a human physical dependence study, administration of cannabidiol 1500 mg/day (750 mg twice daily) to adults for 28 days did not produce signs or symptoms of withdrawal over a 6-week assessment period beginning three days after drug discontinuation. This suggests that cannabidiol likely does not produce physical dependence.

### 11 DESCRIPTION

Cannabidiol is a cannabinoid designated chemically as 2-[[1R,6R)-3-Methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol (IUPAC/CAS). Its empirical formula is  $C_{21}H_{30}O_2$  and its molecular weight is 314.46. The chemical structure is:



Cannabidiol, the active ingredient in EPIDIOLEX, is a cannabinoid that naturally occurs in the *Cannabis sativa* L. plant.

Cannabidiol is a white to pale yellow crystalline solid. It is insoluble in water and is soluble in organic solvents.

EPIDIOLEX (cannabidiol) oral solution is a clear, colorless to yellow liquid containing cannabidiol at a concentration of 100 mg/mL. Inactive ingredients include dehydrated alcohol, sesame seed oil, strawberry flavor, and sucralose. EPIDIOLEX contains no ingredient made from a gluten-containing grain (wheat, barley, or rye).

### 12 CLINICAL PHARMACOLOGY

#### 12.1 Mechanism of Action

The precise mechanisms by which EPIDIOLEX exerts its anticonvulsant effect in humans are unknown. Cannabidiol does not appear to exert its anticonvulsant effects through interaction with cannabinoid receptors.

#### 12.2 Pharmacodynamics

There are no relevant data on the pharmacodynamic effects of cannabidiol.

#### 12.3 Pharmacokinetics

Cannabidiol demonstrated an increase in exposure that was less than dose-proportional over the range of 5 to 20 mg/kg/day in patients.

#### Absorption

Cannabidiol has a time to maximum plasma concentration ( $T_{max}$ ) of 2.5 to 5 hours at steady state ( $C_{ss}$ ).

#### Effect of Food

Coadministration of EPIDIOLEX with a high-fat/high-calorie meal increased  $C_{max}$  by 5-fold, AUC by 4-fold, and reduced the total variability, compared with the fasted state in healthy volunteers [see Dosage and Administration (2.2)].

#### Distribution

The apparent volume of distribution in healthy volunteers was 20963 L to 42849 L. Protein binding of the cannabidiol and its metabolites was >94% in vitro.

#### Elimination

The half-life of cannabidiol in plasma was 56 to 61 hours after twice-daily dosing for 7 days in healthy volunteers. The plasma clearance of cannabidiol following a single EPIDIOLEX 1500 mg dose (1.1 times the maximum recommended daily dosage) is 1111 L/h.

#### Metabolism

Cannabidiol is metabolized in the liver and the gut (primarily in the liver) by CYP2C19 and CYP3A4 enzymes, and UGT1A7, UGT1A9, and UGT2B7 isoforms.

After repeat dosing, the active metabolite of cannabidiol, 7-OH-CBD, has a 38% lower AUC than the parent drug. The 7-OH-CBD metabolite is converted to 7-COOH-CBD, which has an approximately 40-fold higher AUC than the parent drug. Based on preclinical models of seizure, the 7-OH-CBD metabolite is active; however, the 7-COOH-CBD metabolite is not active.

#### Excretion

EPIDIOLEX is excreted in feces, with minor renal clearance.

#### Specific Populations

##### Patients with Hepatic Impairment

No effects on the exposures of cannabidiol or metabolite exposures were observed following administration of a single dose of EPIDIOLEX 200 mg in patients with mild (Child-Pugh A) hepatic impairment. Patients with moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment had an approximately 2.5 to 5.2-fold higher AUC, compared with healthy volunteers with normal hepatic function [see Dosage and Administration (2.5), Warnings and Precautions (5.1), Use in Specific Populations (8.6)].

#### Drug Interaction Studies

##### In Vitro Assessment of Drug Interactions

##### Drug Metabolizing Enzymes [see Drug Interactions (7.1, 7.2)]

Cannabidiol is a substrate for cytochrome p450 (CYP) enzymes CYP3A4 and CYP2C19. Cannabidiol has the potential to inhibit CYP2C8, CYP2C9, and CYP2C19 at clinically relevant concentrations. Cannabidiol may induce or inhibit CYP1A2 and CYP2B6 at clinically relevant concentrations. Cannabidiol inhibits uridine 5'-diphospho-glucuronosyltransferase (UGT) enzymes UGT1A9 and UGT2B7, but does not inhibit the UGT1A1, UGT1A3, UGT1A4, UGT1A6, or UGT2B17 isoforms.

##### Transporters

Cannabidiol and the cannabidiol metabolite, 7-OH-CBD, are not anticipated to interact with BCRP, BSEP, MDR1/P-gp, OAT1, OAT3, OCT1, OCT2, MATE1, MATE2-K, OATP1B1, or OATP1B3. The cannabidiol metabolite, 7-COOH-CBD, is not a substrate of BCRP, OATP1B1, OATP1B3, or OCT1. However, 7-COOH-CBD is a substrate for P-gp. 7-COOH-CBD is an inhibitor of transport mediated via BCRP and BSEP at clinically relevant concentrations.

**In Vivo Assessment of Drug Interactions**

**Drug Interaction Studies with AEDs**

**Clobazam and Valproate**

The interaction potential with other AEDs (clobazam and valproate) was evaluated in dedicated clinical studies following coadministration of EPIDIOLEX (750 mg twice daily in healthy volunteers and 20 mg/kg/day in patients). Coadministration with clobazam in healthy volunteers increased the cannabidiol active metabolite 7-OH CBD mean  $C_{max}$  by 73% and AUC by 47%; and increased the clobazam active metabolite, N-desmethyclobazam,  $C_{max}$  and AUC by approximately 3-fold [see Drug Interactions (7.2)]. When EPIDIOLEX was coadministered with valproate, there was no effect on valproate exposure.

**Effect of EPIDIOLEX on Midazolam**

Coadministration of EPIDIOLEX with midazolam (a sensitive CYP3A4 substrate) did not result in changes in plasma concentrations of midazolam compared to midazolam administered alone.

**13 NONCLINICAL TOXICOLOGY**

**13.1 Carcinogenesis and Mutagenesis**

**Carcinogenesis:**

Adequate studies of the carcinogenic potential of cannabidiol have not been conducted.

**Mutagenesis:**

Cannabidiol was negative for genotoxicity in *in vitro* (Ames) and *in vivo* (rat Comet and bone marrow micronucleus) assays.

**Impairment of Fertility**

Oral administration of cannabidiol (0, 75, 150, or 250 mg/kg/day) to male and female rats, prior to and throughout mating and continuing in females during early gestation, produced no adverse effects on fertility. The highest dose tested was associated with plasma exposures approximately 60 times that in humans at the maximum recommended human dose (20 mg/kg/day).

**14 CLINICAL STUDIES**

**14.1 Lennox-Gastaut Syndrome**

The effectiveness of EPIDIOLEX for the treatment of seizures associated with LGS was established in two randomized, double-blind, placebo-controlled trials in patients aged 2 to 55 years.

Study 1 (N=171) compared a dose of EPIDIOLEX 20 mg/kg/day with placebo. Study 2 (N=225) compared a 10 mg/kg/day dose and a 20 mg/kg/day dose of EPIDIOLEX with placebo. In both studies, patients had a diagnosis of LGS and were inadequately controlled on at least one AED, with or without vagal nerve stimulation and/or ketogenic diet. Both trials had a 4-week baseline period, during which patients were required to have a minimum of 8 drop seizures ( $\geq 2$  drop seizures per week). The baseline period was followed by a 2-week titration period and a 12-week maintenance period.

In Study 1, 94% of patients were taking at least 2 concomitant AEDs. The most frequently used concomitant AEDs (>25%) in Study 1 were clobazam (49%), valproate (40%), lamotrigine (37%), levetiracetam (34%), and rufinamide (27%). In Study 2, 94% of patients were taking at least 2 concomitant AEDs. The most frequently used concomitant AEDs (>25%) in Study 2, were clobazam (49%), valproate (38%), levetiracetam (31%), lamotrigine (30%), and rufinamide (29%).

The primary efficacy measure in both studies was the percent change from baseline in the frequency (per 28 days) of drop seizures (atonic, tonic, or tonic-clonic seizures) over the 14-week treatment period. Key secondary endpoints in both studies included analyses of change in total seizure frequency and changes from baseline in the Subject/Caregiver Global Impression of Change (S/CGIC) score at the last visit. For the S/CGIC, the following question was rated on a 7-point scale: "Since [you/your child] started treatment, please assess the status of [your/your child's] overall condition (comparing [your/their] condition now to [your/their] condition before treatment) using the scale below." The 7-point scale was as follows: "Very Much Improved" (1); "Much Improved" (2); "Slightly Improved" (3); "No Change" (4); "Slightly Worse" (5); "Much Worse" (6); "Very Much Worse" (7).

In Studies 1 and 2, the median percent change from baseline (reduction) in the frequency of drop seizures was significantly greater for both dosage groups of EPIDIOLEX than for placebo (Table 4). A reduction in drop seizures was observed within 4 weeks of initiating treatment with EPIDIOLEX, and the effect remained generally consistent over the 14-week treatment period.

**Table 4: Change in Drop Seizure Frequency in Lennox-Gastaut Syndrome during the Treatment Period (Studies 1 and 2)**

Drop Seizure Frequency (per 28 Days)	Placebo	EPIDIOLEX 10 mg/kg/day	EPIDIOLEX 20 mg/kg/day
<b>Study 1</b>	<b>N=85</b>	<b>N/A</b>	<b>N=86</b>
Baseline Period Median	75	N/A	71
Median Percentage Change During Treatment	-22	N/A	-44
p-value compared to placebo			0.01
<b>Study 2</b>	<b>N=76</b>	<b>N=73</b>	<b>N=76</b>
Baseline Period Median	80	87	86
Median Percentage Change During Treatment	-17	-37	-42
p-value compared to placebo		<0.01	<0.01

Figure 1 displays the percentage of patients by category of reduction from baseline in drop seizure frequency per 28 days during the treatment period in Study 1.

**Figure 1: Proportion of Patients by Category of Seizure Response for EPIDIOLEX and Placebo in Patients with Lennox-Gastaut Syndrome (Study 1)**

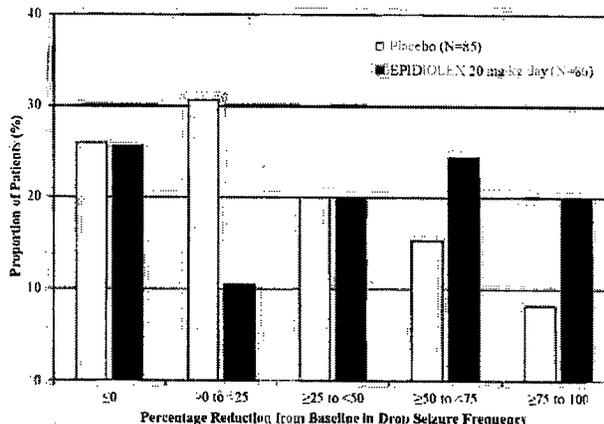
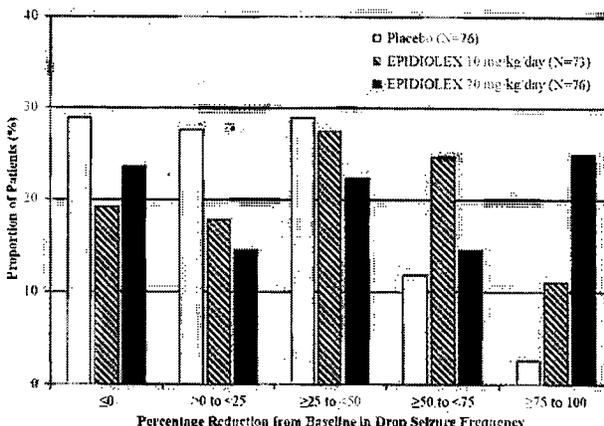


Figure 2 displays the percentage of patients by category of reduction from baseline in drop seizure frequency (per 28 days) during the treatment period in Study 2.

**Figure 2: Proportion of Patients by Category of Seizure Response for EPIDIOLEX and Placebo in Patients with Lennox-Gastaut Syndrome (Study 2)**



In Study 1, 3 of 85 (4%) patients in the EPIDIOLEX 20 mg/kg/day group reported no drop seizures during the maintenance period, compared to 0 patients in the placebo group. In Study 2, 3 of 73 (4%) patients in the EPIDIOLEX 10 mg/kg/day group, 5 of 76 (7%) patients in the EPIDIOLEX 20 mg/kg/day group, and 1 of 76 (1%) patients in the placebo group reported no drop seizures during the maintenance period.

In LGS patients, EPIDIOLEX was associated with significant reductions in total seizure frequency (drop and non-drop seizures) versus placebo. During the treatment period in Study 1, the median percent reduction in total seizure frequency (per 28 days) was 41% in patients taking EPIDIOLEX 20 mg/kg/day compared to 14% in patients taking placebo ( $p < 0.01$ ). In Study 2, the median percent reduction in total seizure frequency (per 28 days) was 36% in the 10 mg/kg/day group, 38% in the 20 mg/kg/day group, and 18% in the placebo group ( $p < 0.01$  for both groups).

A greater improvement on the Subject/Caregiver Global Impression of Change (S/CGIC) was reported in patients treated with EPIDIOLEX compared with placebo in Studies 1 and 2. In Study 1, the mean S/CGIC score at last visit was 3.0 in the 20 mg/kg/day EPIDIOLEX group (corresponding to "slightly improved") compared with 3.7 (most closely associated with "no change") in the placebo group ( $p < 0.01$ ). In Study 2, the mean S/CGIC score at last visit was 3.0 and 3.2 in the 10 mg/kg/day and 20 mg/kg/day EPIDIOLEX groups, respectively ("slightly improved"), compared with 3.6 ("no change") in the placebo group ( $p < 0.01$  and  $p = 0.04$ , respectively).

#### 14.2 Dravet Syndrome

The effectiveness of EPIDIOLEX for the treatment of seizures associated with DS was demonstrated in a single randomized, double-blind, placebo-controlled trial in 120 patients aged 2 to 18 years. Study 3 compared a dose of EPIDIOLEX 20 mg/kg/day with placebo. Patients had a diagnosis of treatment-resistant DS and were inadequately controlled with at least one concomitant AED, with or without vagal nerve stimulation or ketogenic diet. During the 4-week baseline period, patients were required to have at least 4 convulsive seizures while on stable AED therapy. The baseline period was followed by a 2-week titration period and a 12-week maintenance period. The primary efficacy measure was the percent change from baseline in the frequency (per 28 days) of convulsive seizures (all countable atonic, tonic, clonic, and tonic-clonic seizures) over the 14-week treatment period.

In Study 3, 93% of patients were taking at least 2 concomitant AEDs during the trial. The most commonly used concomitant AEDs (>25%) in Study 3 were clobazam (65%), valproate (57%), stiripentol (43%), levetiracetam (28%), and topiramate (26%). The baseline median convulsive seizure frequency was 13 per 28 days for the combined groups.

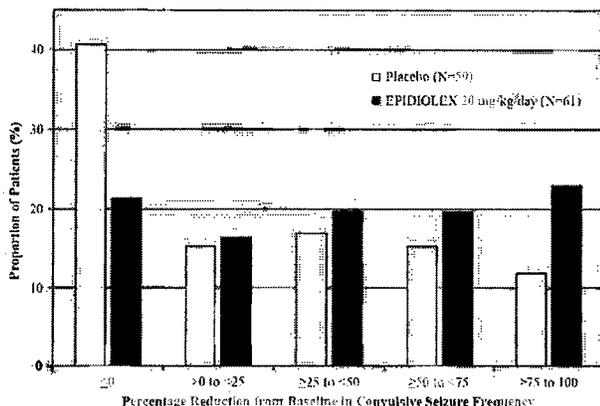
The median percent change from baseline (reduction) in the frequency of convulsive seizures was significantly greater for EPIDIOLEX 20 mg/kg/day than for placebo (see Table 5). A reduction in convulsive seizures was observed within 4 weeks of initiating treatment with EPIDIOLEX and the effect remained generally consistent over the 14-week treatment period.

**Table 5: Change in Convulsive Seizure Frequency in Dravet Syndrome during the Treatment Period (Study 3)**

Total Convulsive Seizure Frequency (per 28 Days)	Placebo	EPIDIOLEX 20 mg/kg/day
Study 3	N=59	N=61
Baseline Period Median	15	12
Median Percentage Change During Treatment	-13	-39
p-value compared to placebo		0.01

Figure 3 displays the percentage of patients by category of reduction from baseline in convulsive seizure frequency (per 28 days) during the treatment period in Study 3.

**Figure 3: Proportion of Patients by Category of Seizure Response for EPIDIOLEX and Placebo in Patients with Dravet Syndrome (Study 3)**



In Study 3, 4 of 60 (6.7%) patients treated with EPIDIOLEX 20 mg/kg/day reported no convulsive seizures during the maintenance period, compared to 0 patients in the placebo group.

#### 16 HOW SUPPLIED/STORAGE AND HANDLING

##### 16.1 How Supplied

EPIDIOLEX is a strawberry flavored clear, colorless to yellow solution supplied in a 105 mL amber glass bottle with a child-resistant closure containing 100 mL of oral solution (NDC 70127-100-01). Each mL contains 100 mg of cannabidiol. EPIDIOLEX is packaged in a carton with two 5 mL calibrated oral dosing syringes and a bottle adapter (NDC 70127-100-10). The pharmacy will provide 1 mL calibrated oral dosing syringes when doses less than 1 mL are required.

##### 16.2 Storage and Handling

Store EPIDIOLEX in an upright position at 20°C to 25°C (68°F to 77°F); excursions are permitted between 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature]. Do not freeze. Keep the cap tightly closed. Use within 12 weeks of first opening the bottle, then discard any remainder.

#### 17 PATIENT COUNSELING INFORMATION

Advise the caregiver or patient to read the FDA-approved patient labeling (Medication Guide and Instructions for Use).

##### Administration Information

Advise patients who are prescribed EPIDIOLEX to use the adapter and oral dosing syringes provided [see Dosage and Administration (2.3) and Instructions for Use].

Instruct patients to discard any unused EPIDIOLEX oral solution after 12 weeks of first opening the bottle [see Dosage and Administration (2.3)].

##### Hepatocellular Injury

Inform patients about the potential for elevations of liver enzymes. Discuss with the patient the importance of measuring hepatic laboratory values and having them evaluated by the healthcare provider before treatment with EPIDIOLEX and periodically during treatment [see Warnings and Precautions (5.1)]. Advise patients of the clinical signs or symptoms suggestive of hepatic dysfunction (e.g., unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine) and to contact a healthcare provider promptly if these signs or symptoms occur.

##### Somnolence and Sedation

Caution patients about operating hazardous machinery, including motor vehicles, until they are reasonably certain that EPIDIOLEX does not affect them adversely (e.g., impair judgment, thinking or motor skills) [see Warnings and Precautions (5.2)].

##### Suicidal Thinking and Behavior

Counsel patients, their caregivers, and their families that antiepileptic drugs, including EPIDIOLEX, may increase the risk of suicidal thoughts and behavior and advise them to be alert for the emergence or worsening of symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts of self-harm. Instruct patients, caregivers, and families to report behaviors of concern immediately to healthcare providers [see Warnings and Precautions (5.3)].

##### Withdrawal of Antiepileptic Drugs (AEDs)

Advise patients not to discontinue use of EPIDIOLEX without consulting with their healthcare provider. EPIDIOLEX should normally be gradually withdrawn to reduce the potential for increased seizure frequency and status epilepticus [see Dosage and Administration (2.4), Warnings and Precautions (5.4)].

##### Pregnancy Registry

Advise patients to notify their healthcare provider if they become pregnant or intend to become pregnant during EPIDIOLEX therapy. Encourage women who are taking EPIDIOLEX to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry if they become pregnant. This registry is collecting information about the safety of antiepileptic drugs during pregnancy [see Use in Specific Populations (8.1)].

##### Drug Testing

Advise patients of the potential for positive cannabis drug screens.

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**MEDICATION GUIDE**  
**EPIDIOLEX® (EH-peh-DYE-oh-lex)**  
(cannabidiol)  
oral solution, CV

Read this Medication Guide before you start taking EPIDIOLEX and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

**What is the most important information I should know about EPIDIOLEX?**

**EPIDIOLEX can cause serious side effects, including:**

1. EPIDIOLEX may cause liver problems. Your healthcare provider may order blood tests to check your liver before you start taking EPIDIOLEX and during treatment. In some cases, EPIDIOLEX treatment may need to be stopped. Call your healthcare provider right away if you develop any of these signs and symptoms of liver problems during treatment with EPIDIOLEX:

- loss of appetite, nausea, vomiting
- fever, feeling unwell, unusual tiredness
- yellowing of the skin or the whites of the eyes (jaundice)
- itching
- unusual darkening of the urine
- right upper stomach area pain or discomfort

2. EPIDIOLEX may cause you to feel sleepy, which may get better over time. Other medicines (e.g., clobazam) or alcohol may increase sleepiness. **Do not** drive, operate heavy machinery, or do other dangerous activities until you know how EPIDIOLEX affects you.

3. Like other antiepileptic drugs, EPIDIOLEX may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

**Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:**

- thoughts about suicide or dying
- attempt to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

**How can I watch for early symptoms of suicidal thoughts and actions?**

- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.

4. Do not stop taking EPIDIOLEX without first talking to your healthcare provider. Stopping a seizure medicine such as EPIDIOLEX suddenly can cause you to have seizures more often or seizures that do not stop (status epilepticus).

Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

**What is EPIDIOLEX?**

- EPIDIOLEX is a prescription medicine that is used to treat seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in people 2 years of age and older.
- EPIDIOLEX is controlled in Schedule V of the Controlled Substances Act. Keep EPIDIOLEX in a safe place to prevent misuse and abuse.
- Selling or giving away EPIDIOLEX is against the law.
- It is not known if EPIDIOLEX is safe and effective in children under 2 years of age.

**Who should not take EPIDIOLEX?**

Do not take EPIDIOLEX if you are allergic to cannabidiol or any of the ingredients in EPIDIOLEX. See the end of this Medication Guide for a complete list of ingredients in EPIDIOLEX.

**Before taking EPIDIOLEX, tell your healthcare provider about all of your medical conditions, including if you:**

- have or have had depression, mood problems or suicidal thoughts or behavior.
- have liver problems.
- have abused or been dependent on prescription medicines, street drugs or alcohol.
- are pregnant or plan to become pregnant. Tell your healthcare provider right away if you become pregnant while taking EPIDIOLEX. You and your healthcare provider will decide if you should take EPIDIOLEX while you are pregnant.
  - If you become pregnant while taking EPIDIOLEX, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic medicines during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if EPIDIOLEX passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking EPIDIOLEX.

**Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, and any cannabis-based products.** EPIDIOLEX may affect the way other medicines work, and other medicines may affect how EPIDIOLEX works. Do not start or stop taking other medicines without talking to your healthcare provider. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**Tell your healthcare provider if you are planning to have a cannabis drug screen** because EPIDIOLEX may affect your test results. Tell the person giving the drug test that you are taking EPIDIOLEX.

**How should I take EPIDIOLEX?**

- Read the **Instructions for Use** at the end of this Medication Guide for information on the right way to use EPIDIOLEX.
- Take EPIDIOLEX exactly as your healthcare provider tells you.
- Your healthcare provider will tell you how much EPIDIOLEX to take and when to take it.
- Measure each dose of EPIDIOLEX using the bottle adapter and 5 mL dosing syringes that come with EPIDIOLEX. If your dose of EPIDIOLEX is less than 1 mL, your pharmacist will provide you with 1 mL syringes to take your medicine.
- Use a dry syringe each time you take EPIDIOLEX. If water is inside the syringe, it could cause the oil-based medicine to look cloudy.

**What should I avoid while taking EPIDIOLEX?**

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how EPIDIOLEX affects you. EPIDIOLEX may cause you to feel sleepy.

**What are the possible side effects of EPIDIOLEX?**

**EPIDIOLEX can cause serious side effects, including:**

- See "What is the most important information I should know about EPIDIOLEX?"

**The most common side effects of EPIDIOLEX include:**

- sleepiness
- decreased appetite
- diarrhea
- increase in liver enzymes
- feeling very tired and weak
- rash
- sleep problems
- infections

These are not all of the possible side effects of EPIDIOLEX. For more information ask your healthcare provider or pharmacist. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also contact Greenwich Biosciences at 1-833-424-6724 (1-833-GBIOSCI).

**How should I store EPIDIOLEX?**

- Store EPIDIOLEX at room temperature between 68°F to 77°F (20°C to 25°C).
  - Always store EPIDIOLEX in an upright position.
  - Do not freeze.
  - Keep the child-resistant cap tightly closed.
  - Use EPIDIOLEX within 12 weeks of first opening the bottle.
- Throw away (dispose of) any unused medicine after 12 weeks.

**Keep EPIDIOLEX and all medicines out of the reach of children.**

**General Information about the safe and effective use of EPIDIOLEX.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use EPIDIOLEX for a condition for which it was not prescribed. Do not give EPIDIOLEX to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about EPIDIOLEX that is written for health professionals.

**What are the ingredients in EPIDIOLEX?**

**Active ingredient:** cannabidiol

**Inactive ingredients:** dehydrated alcohol, sesame seed oil, strawberry flavor, and sucralose

EPIDIOLEX does not contain gluten (wheat, barley or rye).

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For more information, go to [www.EPIDIOLEX.com](http://www.EPIDIOLEX.com) or call 1-833-424-6724 (1-833-GBIOSCI).

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This Medication Guide has been approved by the U.S. Food and Drug Administration  
Issued: 12/2018

**INSTRUCTIONS FOR USE**  
**EPIDIOLEX® (EH-peh-DYE-oh-lex)**  
**(cannabidiol)**  
**oral solution, CV**  
**100 mg/mL**

Be sure that you read, understand and follow these instructions carefully to ensure proper dosing of the oral solution.

**Important:**

- Follow your healthcare provider's instructions for the dose of EPIDIOLEX to take or give.
- Ask your healthcare provider or pharmacist if you are not sure how to prepare, take, or give the prescribed dose of EPIDIOLEX.
- Always use the oral syringe provided with EPIDIOLEX to make sure you measure the right amount of EPIDIOLEX.
- Do not use EPIDIOLEX after the expiration date on the package and each bottle.
- Use EPIDIOLEX within 12 weeks of first opening the bottle.
- After 12 weeks, safely throw away (dispose of) any EPIDIOLEX that has not been used.

**Each package contains:**

Child-resistant cap



Bottle adapter



1 bottle of EPIDIOLEX oral solution (100 mg/mL)

Front

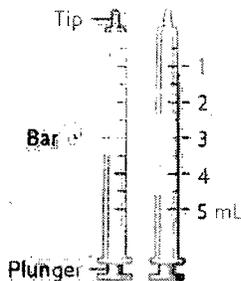
Back



Please note expiration date

2 reusable 5 mL oral syringes:

- 1 syringe to take or give the dose of EPIDIOLEX
- 1 extra syringe (included as a spare if needed)



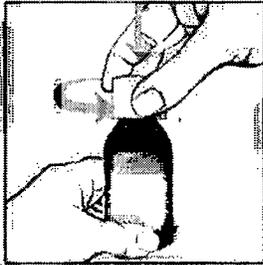
Supplies not included in the package:

- If your dose of EPIDIOLEX is less than 1 mL, your pharmacist will provide you with 1 mL syringes to take your medicine.
- Call your pharmacist right away if your dose of EPIDIOLEX is less than 1 mL and you do not receive 1 mL syringes with your medicine.

**Note:** If you lose or damage an oral syringe, or cannot read the markings, use the spare syringe.

**Prepare The Bottle- to use EPIDIOLEX for the first time**

1. Remove the child-resistant cap by pushing down while turning the cap to the left (counter-clockwise).



2. Push the bottle adapter firmly into the bottle. **Make sure the bottle adapter is fully inserted.** If not fully inserted, small parts such as the bottle adapter may become a choking hazard for children and pets.

**Note:** Do not remove the bottle adapter from the bottle after it is inserted.



**Prepare The Dose**

Your healthcare provider will tell you how much EPIDIOLEX to take or give.

3. Use this table to measure the total dose of EPIDIOLEX to be given.

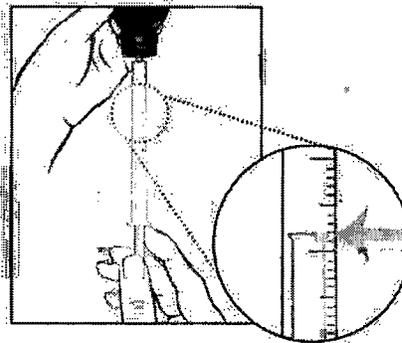
Dose	How to measure
5 mL or less	Use the oral syringe 1 time
More than 5 mL	Use the oral syringe more than 1 time

4. Push the plunger all the way down and insert the tip of the oral syringe fully into the bottle adapter. With the oral syringe in place, turn the bottle upside down.



5. Slowly pull the plunger of the oral syringe to withdraw the dose of EPIDIOLEX needed. See Step 3 for how to measure the total dose of EPIDIOLEX.

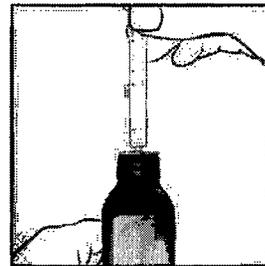
**Line up** the end of the plunger with the marking for your dose of EPIDIOLEX.



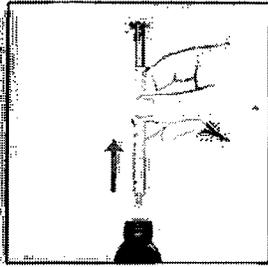
**What to do if you see air bubbles:**

If there are air bubbles in the oral syringe, keep the bottle upside down and push the plunger so that all of the liquid flows back into the bottle. Repeat Step 5 until the air bubbles are gone.

6. When you have measured the correct dose of EPIDIOLEX, leave the oral syringe in the bottle adapter and turn the bottle right side up.

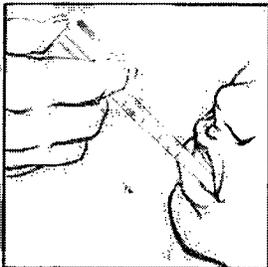


7. Carefully remove the oral syringe from the bottle adapter.



#### Give EPIDIOLEX

8. Place the tip of the oral syringe against the inside of the cheek and gently push the plunger until all the EPIDIOLEX in the syringe is given.



**Do not** forcefully push on the plunger.

**Do not** direct the medicine to the back of the mouth or throat. This may cause choking.

**If the dose of EPIDIOLEX prescribed by the healthcare provider is more than 5 mL, repeat steps 4 through 8 to complete the dose.**

For example:

If your dose of EPIDIOLEX is 8 mL, withdraw 5 mL of medicine into the syringe and give the medicine. Insert the tip of the oral syringe back into the bottle adapter and withdraw 3 mL of medicine. Give the medicine to receive a total dose of 8 mL.

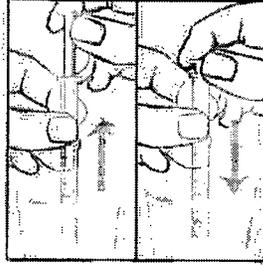
#### Clean Up

9. Screw the child-resistant cap back on the bottle tightly by turning the cap to the right (clockwise).

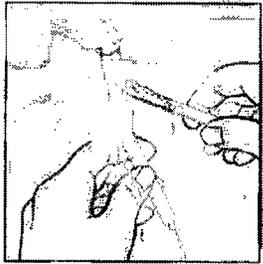


**Do not** remove the bottle adapter. The cap will fit over it.

10. Fill a cup with warm soapy water and clean the oral syringe by drawing water in and out of the syringe using the plunger.

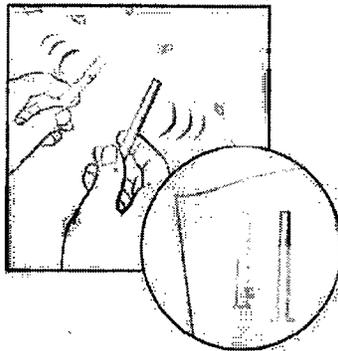


11. Remove the plunger from the barrel of the oral syringe and rinse both parts under tap water.



**Do not** wash the oral syringe in the dishwasher.

12. Shake off any extra water from the plunger and oral syringe barrel, and allow them to air dry until next use.



**Make sure** the oral syringe is completely dry before the next use. If water is inside the syringe, it could cause the oil-based medicine to look cloudy.

**Do not** throw away the oral syringe.

#### How should I store EPIDIOLEX?

- Store EPIDIOLEX at room temperature between 68°F to 77°F (20°C to 25°C).
- Always store EPIDIOLEX in an upright position.
- **Do not** freeze.
- Keep the child-resistant cap tightly closed.
- Use EPIDIOLEX within 12 weeks of first opening the bottle. Dispose of any unused EPIDIOLEX after 12 weeks.
- **Keep EPIDIOLEX and all medicines out of the reach of children.**



December 4, 2019 (revised December 4, 2019)

Proposed Vermont Hemp Rules Responsiveness Summary

The Agency of Agriculture, Food and Markets is referred to as the "Agency"

Responses to General Comments

1. The 2018 Federal Farm Bill and the authority to regulate production of hemp in Vermont – the Effective date of the 2018 Farm Bill was December 20, 2018. USDA continues to work on developing the national plan to regulate and enforce the production of hemp. It will issue guidance to states that will seek primary regulatory authority over the production of hemp within their state. However, the 2018 Farm Bill outlines the content of plans:

*"(i) a practice to maintain relevant information regarding land on which hemp is produced in the State or territory of the Indian tribe, including a legal description of the land, for a period of not less than 3 calendar years;*

*"(ii) a procedure for testing, using post decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp produced in the State or territory of the Indian tribe;*

*"(iii) a procedure for the effective disposal of—*

*"(I) plants, whether growing or not, that are produced in violation of this subtitle; and*

*"(II) products derived from those plants;*

*"(iv) a procedure to comply with the enforcement procedures under subsection (e);*

*"(v) a procedure for conducting annual inspections of, at a minimum, a random sample of hemp producers to verify that hemp is not produced in violation of this subtitle;*

*"(vi) a procedure for submitting the information described in section 297C(d)(2), as applicable, to the Secretary not more than 30 days after the date on which the information is received; and*

*"(vii) a certification that the State or Indian tribe has the resources and personnel to carry out the practices and procedures described in clauses (i) through (vi);*

Once a plan is approved and to ensure a state acts in accordance with an approved plan, the Farm Bill includes audits for compliance and potential action if a state is not executing its plan as approved by USDA. These are the measures envisioned by Congress to govern production of hemp.

While this process moves forward, states with pilot programs, which includes Vermont, can continue to operate under the 2014 Farm Bill, 7 U.S.C. 5940, which remains in effect until one year after the date on which the Secretary establishes a plan under section 297C of the 2018 Farm Bill.

2. The ability of the Agency's to regulate botanical extracts from hemp- The 2018 Farm Bill defines hemp broadly as "the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." The Agency believes that its ability to regulate extracts and cannabinoids comes directly from the 2018 Farm Bill. Act 44 also give the Agency the authority to regulate hemp and hemp-infused products. [6 V.S.A §562(4)]. It will retain all references to cannabidiol and the ability to regulate within its rules.

3. Regulation of THC and Cannabidiol-In the 2018 Farm Bill, Section 12619 Conforming Changes to Controlled Substances Act, the definition of 'marihuana' was amended and no longer includes 'hemp', as defined. The definition of 'tetrahydrocannabinol' was also amended to except tetrahydrocannabinol derived from hemp.
  
4. Regulatory Oversight, generally-
  - a. Water consumption/withdrawals- The Agency does not regulate water withdrawals from Vermont's surface waters. It is within the jurisdiction of the Agency of Natural Resources. More information on how can be found here, <https://dec.vermont.gov/watershed/rivers/streamflow-protection>.
  - b. The Agency administers many other regulations to protect water quality, animal health, farm operators (seed, feed and fertilizer), and the public. These regulations are already in place and cover many agricultural sectors.
  - c. As part of the Hemp Program, the Agency has the authority to establish a Cannabis Quality Control Program, which will include testing for compliance and contaminants. Registrants are responsible to maintain records of compliance by harvest lot, and by process lot. The Agency is also required to conduct random inspections, as outlined in the 2018 Farm Bill, and will respond to complaints, either of which may include review of records, taking samples and testing for compliance.
  - d. The Vermont Hemp Rules do not affect the administration of other laws at the state or federal level. The Hemp Rules do not affect or supersede the administration of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); section 351 of the Public Health Service Act (42 U.S.C. 262); or the authority of the Commissioner of Food and Drugs and the Secretary of Health and Human Services under— the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or section 351 of the Public Health Service Act (42 U.S.C. 262).
  - e. These rules would govern the Agency's actions in association with authority given to it under the 2018 Farm Bill and authority under Title 6 Chapter 34. They will also be the basis of Vermont's state plan.
  
5. Odors from farming hemp. Farming, in general, can exhibit many characteristics that others may find offensive. Unless the operation is a large farm operation, the Agency does not regulate nuisance related concerns such as odors, noise and flies.
  
6. Compliance testing and acceptable potency level-The Agency understands the concerns regarding potency of crops and variability of genetics. In order to marry these concerns and not rely entirely on environmental conditions that could contribute to unpredictability of chemical composition of a plant the Agency, as enabled in Vermont law, will take different approaches to establish whether a crop is hemp. It will set defensible standards to bookend allowable delta-9 tetrahydrocannabinol concentration and by using "other similarly reliable methods"
  - a. a HPLC test result showing delta-9 THC concentration no greater than 0.3% and total theoretical THC no greater than 1%;



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- b. comparing the % concentration between CBD and THC, and if the ratio is 20:1 or greater it would qualify as a Type III hemp crop; and
  - c. genetic testing of crops
  
7. Must individuals that cultivate for personal use register. The 2018 Farm Bill outlines that state plans must include "a practice to maintain relevant information regarding land on which hemp is produced in the State ..., including a legal description of the land...". Vermont law outlines steps for registering individuals that grow for personal use, therefore all growers of hemp must register with the Agency. For these reasons, the rules outline a process for registration which is applicable to individuals that grow for personal use. Despite the fact that these plants may not enter commerce, it is still the responsibility of the Agency to ensure that registrants are compliant with federal and state law. Registration is also an effective communication tool with law enforcement if questions arise regarding the legality of the cultivation of hemp. Registration is also required of research institutions that may not cultivate hemp for the commercial market. The Agency had originally interpreted that the requirement of a state to have "a practice to maintain relevant information regarding land on which hemp is produced in the ..., including a legal description of the land... applied to all persons that "produce" hemp. However, the Agency notes that the 2018 Farm Bill also uses the term "hemp producer". While the 2018 Farm Bill does not define who a "producer" is, the National Organic Program, 7 C.F.R. § 205.2, defines a "producer" as any person engaged in the business of growing or producing food or feed. This may lead the Agency to a different analysis of who should be subject to the state plan. It will research whether it is possible to exempt personal use cultivation from the Agency rules and the state plan.
  
8. Use of the marketing term organic or certified organic. The Agency does not regulate or enforce the use of the term "organic", however other organizations do in Vermont.
  
9. Informing the public about hemp products and hemp-infused product. The Vermont Hemp Rules include labeling requirements that include
  - d. A statement that the product contains ingredients derived from hemp; and
  - e. A statement that a product contains THC, if applicable.
  
10. Pesticides-There are no EPA approved pesticides for use on cannabis, currently. VAAFM does not have an approved list of pesticides, nor a process to approve pesticides on hemp. However, the Agency has developed a list of active ingredients acceptable to use on hemp crops, <https://agriculture.vermont.gov/sites/agriculture/files/documents/PHARM/hemp/Hemp%20products.pdf>. The lens the Agency used to create the list of active ingredients was
  - the active ingredient leaves no residue, and
  - the active ingredient has a tolerance exemption under FFDCa

The pesticide products must

- only contain the active ingredients on the Agency list,
- be labeled for use on food crops,
- be registered in Vermont, which for this list includes two categories of pesticides- either EPA Section 3 pesticides, minimum risk 25b or under a special registration (Section 18 or 24c of FIFRA).

#### Comments on specific sections of the Vermont Hemp Rules

1. Section 1.1- Secretary must adopt rules establishing how the Agency will conduct research within this program. The Agency appreciates recommendations to further explain the type of research it will conduct and will provide some guidelines regarding collecting and reporting information for research, provide goals, process, and report format. The Agency will also preserve its ability to amend its process and goals as the industry changes, to not limit the collection of information that would be most useful for the development of the industry.
2. Section 3- Generally Definitions- The Agency will consider all comments to modify definitions and make the necessary adjustments.
3. Section 4.1 (b)- A person whose application is rejected as incomplete may reapply for registration at any time. The Agency was given the authority to deny registrations, and while this is possible, the Agency will work with applicants to obtain the necessary information to enable the Agency to review and approve the application. However, an unresponsive applicant risks denial of their application. Based on existing practice within the Agency across permitting programs, fees are not refunded to the applicant, and cannot be applied to a future application.
4. Section 4.1 (d)-Registration of processing locations. The location of processing of hemp crops and use of hemp concentrate in end products must be registered with the Agency. Persons that package/repackage/or manufacture white label products using a concentrate that meets the definition of a hemp or hemp-infused product do not need to be registered as Processors.
5. Section 4.1(e) -Public records requests. A change in 6 V.S.A. §564(f) on May 30, 2019 (after the public comment period opened) limits what the Agency may disclose under a public records request. Specifically, "all records produced or acquired by the Agency of Agriculture, Food and Markets related to the location of parcels where hemp will be grown, including coordinates, maps, and parcel identifiers, shall be confidential and shall not be disclosed for inspection and copying under the Public Records Act."

Confidential business information is protected from inspection and copying under 6 V.S.A. § 61 or 1 V.S.A. §317(c)(9). It is also possible that other exemptions in 1 V.S.A. §317(c) may apply to "public records" that come into the Agency's possession as part of the administration of the



Hemp Program. Please know that the Agency will abide by Vermont law when public records requests are made, and to the extent the public record is protected or confidential, the Agency will not disclose. The Agency will also follow the Public Records Act when responding to requests for public records, as required by law and disclose what is otherwise not exempt nor confidential under the law.

1. Section 4.3 - A person convicted of a felony relating to a controlled substance under state or federal law ... is ineligible. The Agency will consider removing this provision from the Vermont Hemp Rules, but this requirement is in 2018 Farm Bill and is referred to in 6 V.S.A. §564 (c) (4), "the Secretary may deny an application for registration or renewal if the applicant... does not, as determined by the Secretary, satisfy the requirements of section 10113 of the Agriculture Improvement Act of 2018, Pub. L. No. 115- 334 for participation in the Program." The Agency will implement what is necessary to attain primary regulatory control over cultivation of hemp in Vermont.
2. New Section 4.7- clarify that it is not necessary to register as a processor if a person registers for personal use. The Agency will consider the following proposed language "A Grower whose sole purpose is for personal use and whose operation meets the definition of Personal Cultivation is not required to register as a processor."
3. Section 5.2- Grower handling limitations. The Agency will include clarification that a Grower can transport hemp crops to a registered processor.
4. Section 5.3 -A Grower of hemp crops produced outdoors for seed must notify all Growers of biomass and flower. The Agency will remove this requirement from the rules.
5. 5.4 (b) - Offer a list of any pesticides used in the cultivation of the hemp crops, clones, or plants. All pesticides must be disclosed upon request, even those on the list offered by the Agency or considered organic. A misbranded pesticide product is an issue for the Agency's pesticide program enforcement team.
6. Section 6 -The qualifications for laboratory certification. The Agency will develop the Cannabis Quality Control Program independently of the Vermont Hemp Rules.
7. Section 6.1 -Addressing compliance with acceptable potency level for hemp and hemp-infused products. This requirement is for hemp and hemp-infused products and does not address "hemp concentrate". Section 6.7 addresses hemp concentrate, and specifically allows the transfer or sale of "hemp concentrate" between Processor Registrants.

8. **Section 6.2 – limitations on extraction methods.** This section explicitly allows certain extraction methods and to permit review and approval of innovation in extraction technology by the Agency. The Agency will add mechanical extraction methods that do not include solvents as an approved method for processing hemp crops. So long as other approved methods are not considered “confidential business information” [under 6 V.S.A. § 61 or 1 V.S.A. §317(c)(9)] the Agency will develop a list of the other approved methods of extraction and make available on its website.
9. **Section 6.7- Transfer of hemp concentrate outside Vermont.** The Agency can’t regulate the transfer of hemp concentrate outside of its borders; it can only regulate what happens within its borders under its rules. This Section outlines that a registered Processor can transfer a hemp concentrate to another registered Processor.
10. **Section 6.8 (a)iii and (b)iii reporting hemp on a dry weight basis-** The Agency wants consistent reporting on a dry weight basis. The Agency could provide a calculation to convert wet harvest to a dry weight basis and clarify the condition of the harvest as part of the metric.
11. **Section 6.10- products without label guarantees of cannabinoid content.** Processors that make hemp-infused products are required to comply with labeling requirements. However, the product is not required to be traceable to a certificate of analysis when there is no label guarantee (i.e. no guarantee as to quantity of CBD per serving). The Agency will not require that all hemp-infused products make a label guarantee of CBD/serving. The Agency will consider a standardization of unit measurement in cannabinoid products when the product makes a label claim as to the amount per serving. When there are no label claims regarding the amount of a cannabinoid, the unit of measurement will not be required.
12. **Section 7.2 -Testing for compliance responsibility.** A Grower must have documentation that demonstrates potency level of the crops the Registrants grows and harvests. The Agency will modify the rule to make clear they must maintain documentation that demonstrates compliance, but testing can be done by certified lab and not the grower registrant.
13. **Section 7.3 and 8.2 -Standardization of testing for contaminants.** The Agency appreciates the desire for clarity on testing for pesticides, heavy metals, mycotoxins, and bacterial and fungal contaminants and for the parameters under which contaminant testing would be necessary. It will work towards outlining parameters either in the rule and/or as part of the Cannabis Quality Control Program.

14. Section 8.3- Clarity on when the demonstration of compliance on products applies. Hemp concentrate is a process intermediate and is not considered a hemp product or hemp-infused products for retail sale and therefore does not need to meet this section of the rule.
15. Section 9.2: Approved methods of disposal or destruction. The rules outline that there is an opportunity for a registrant to propose and the Secretary to approve disposal/destruction methods. No methods are pre-approved.
16. Section 10.2-Clarity concerning hemp concentrate and when it can be sold or transferred. This section addresses only hemp products and hemp-infused products it does not address hemp concentrate/process intermediate. In Vermont hemp concentrate can be sold and transferred only to registered Processors.
17. Section 10.3 – Confirmation by the Secretary. This provision applies to any processor registered with the Agency that would like a confirmation that their hemp crop, hemp product or hemp-infused product is compliant with Vermont law. A confirmation prior to shipping hemp crops, products and infused products is not required. This is a service enabled in Vermont law, and was enacted prior to the passage of the 2018 Farm Bill, SEC. 10114, which specifically addresses interstate commerce and the transportation of hemp and hemp products. Section 10.3 of the Vermont Hemp Rules sets expectations for when the Agency will respond so a registrant may plan appropriately if seeking confirmation.
18. Section 11 and 11(e)- Standardization of cannabinoid content. The Agency may consider a standardized label for hemp products and hemp-infused products. It appreciates the suggestion of milligram per milliliter or per gram. But the Agency will not require manufacturers to make label claims if the product contains cannabinoids but not to a specified amount. We may include a requirement that there be an affirmative statement that there are no label claims.
19. Section 11.1 -Label guarantees for cannabinoid content. The Agency will clarify that label guarantees are for cannabinoid content only, not other guarantees. If a processor wants to include a label guarantee for other cannabinoids (CBN, CBG, THCV, etc.) they may, so long as it is traceable to a CoA. Labeling THC content is necessary if the label makes a guarantee to a specific amount, and all products must be compliant with potency requirements.
20. Sections 11.2 and 11.4- Questions of regulatory jurisdiction. The Vermont Hemp Rules' section governing labeling does not supersede federal laws applicable to those entities operating under



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those federal rules in addition to the Vermont Hemp Rules. The Agency established exemptions from this section for seed or seed oil for consumption and is "Generally Recognized as Safe" by the U.S. Food and Drug Administration (FDA), and for hemp as a fiber product, a building material or as animal bedding and is not part of an order of destruction of a hemp crop in Section 15. The Agency appreciates there are federal requirements for dietary supplements. It will consider exempting dietary supplements from the label requirements in Section 11.4 if they are manufactured in accordance with GMP standards, packaged, labeled, and marketed for sale pursuant to FDA regulations for dietary supplements.

21. Section 11.4(g)- Manufacture date and expiration dates on labels. Labels will only be required to include expiration dates of hemp products and hemp-infused products.
22. Section 11.5 – Accuracy of the per serving size. The Agency will consider the accuracy of serving size to +/- 20% and will use an appropriate analytical variation for THC compliance.
23. Section 12 .2 Hemp Grades. The Agency accepts the comments received by stakeholders regarding the grades of hemp and will strike these subsections from the rule. It will explore alternative options in the future that might address scale of operation (single source hemp products), and includes all types of hemp products including grain, fiber and hemp derived cannabinoid products.
24. Section 14.1(c): Incentive to claim negligence and produce high-THC cannabis with no penalty. The negligent violations section of the Vermont Hemp Rules comes from the 2018 Farm Bill, which also includes the ability to enter a Corrective Action Plan. The Agency attempted to put limitations on when something qualifies as a negligence and when an action goes beyond negligence.
25. Section 12.4- Applying for certification for Vermont's Hemp brand annually to the Agency. The Agency will use the authority in 6 V.S.A., Chapter 21 to establish the Vermont Hemp brand for hemp crops, hemp products or hemp-infused products.

6 V.S.A. §173 provides, "The Secretary may determine or design brands, labels, or trademarks for identifying farm products packed in accordance with official grades and standards so established and may cause to be printed such brands, labels, or trademarks and may distribute the same at a reasonable price. A written application to the Secretary requesting permission to use such brands, labels, or trademarks and a written acceptance thereto by the Secretary or a duly authorized assistant shall be a condition precedent to the use of such brands, labels, or trademarks."

6 V.S.A. §174 provides, "Upon the establishment of such grades or standards and upon the determination of brands, labels, or trademarks, the Secretary shall give them due publicity and distribute information relative to their use."



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The Agency will consider a more flexible implementation date so that it has opportunity to give "due publicity" and to "distribute information relative to [the brand's] use", so that businesses can plan accordingly.

26. Section 13.3 – Inspection of any retail location offering hemp products or hemp-infused products and taking samples. This provision comes directly from 6 V.S.A. §568(b)(2).
  
27. Section 14.1(c)- Use of dispensaries to mitigate a crop. The Agency will outline when corrective action [also referred to as the "Safe Harbor" provision in the 2018 Farm Bill] is appropriate in this section by qualifying what it considers negligent production of crops, who can mitigate or remediate the crop, what can be done with excess THC, and who bears the cost.

Vermont Hemp Rules

**Section 1** Authority and Purpose

1.1 The Secretary of the Agency of Agriculture, Food and Markets (the Agency) adopts the Vermont Hemp Rules pursuant to 6 V.S.A. Chapter 34 and consistent with the Agriculture Improvement Act of 2018, Public L. No. 115-334. The intent of Chapter 34 is to establish policy and procedures for growing hemp in Vermont that comply with federal law so that farmers and other businesses in the Vermont agricultural industry can take advantage of this market opportunity. Chapter 34 provides that the Secretary may to adopt rules to implement Chapter 34 and this program and that the the chapter and the State Hemp Program (Vermont Hemp Program). The Secretary must is required to adopt rules establishing how the Agency will conduct research within this program and rules and establishing requirements for the registration of processors of hemp and hemp-infused products.

1.2 The Agency Secretary establishes the Vermont Hemp Program to (Hemp Program) to conduct research the growth, cultivation and regulate the growing, processing, testing, and marketing of industrial hemp and hemp products in the State.

1.2.1.3 The Agency expects to continue operating Vermont's pilot program pursuant to the 2014 federal Farm Bill for the 2020 growing season. After the General Assembly updated Chapter 34 following enactment of the Agriculture Improvement Act of 2018, Pub. L. No. 115-334, the United States Department of Agriculture (USDA) issued an Interim Final Rule (IFR) in late 2019 that makes important distinctions from the pilot program. USDA informed the Agency that it could continue to operate its pilot program during the 2020 growing season, and the Agency plans to do so. As federal law develops and evolves, the Agency continues to evaluate it, continues to propose pragmatic changes, and will continue to evaluate how hemp may be grown, produced, and regulated in the State of Vermont. Compliance with these Rules does not guarantee compliance with other legal requirements, and each registrant is personally responsible for complying with all applicable state and federal laws.

**Section 2** Applicability

2.1. AnyA person who plans to grow, cultivate, or process grows, processes, or tests hemp or hemp products in Vermontthe State:

- (a) must register annually with the Vermont Hemp Program (the Hemp Program);
- (b) must register all hemp cultivation, drying, and storage areas, and/or processing sites that they plan to use to grow or process hemp with the Hemp Program; and
- (c) must comply with the Vermont Hemp Rules (the Rules).

2.2. A person doesis not needrequired to register with the Hemp Program in order to sell hemp products or hemp-infused products in Vermont.

**Section 3 Definitions**

- 3.1. Acceptable potency level means a hemp crop that has a delta-9 THC tetrahydrocannabinol concentration of 0.3 percent or less on a dry weight basis. This initial requirement accords with the federal 2014 Farm Bill. As an additional policy limitation implemented to protect public safety, the Agency also requires that the total theoretical tetrahydrocannabinol concentration not exceed one percent on a dry weight basis. The acceptable potency level may change as the law develops following the 2020 growing season.
- 3.2. Agency means the Vermont Agency of Agriculture, Food and Markets.
- 3.3. Biomass means harvested hemp including the stalks and leaves and may include flowers/buds and/or seeds.
- 3.3.3.4. Broad spectrum means a concentrate that was extracted from hemp which contains some containing cannabinoids but except THC which has had THC been removed.
- 3.4.3.5. Cannabidiol or CBD is one of the naturally occurring cannabinoids found in the Cannabis sativa L. plant.
- 3.5.3.6. Cannabinoid means any of a group of closely related chemical compounds which include THC (tetrahydrocannabinol), THCA (tetrahydrocannabinolic acid), CBD (cannabidiol), CBDA (cannabidiolic acid), CBN (cannabinol), CBG (cannabigerol), CBC (cannabichromene), CBL (cannabicyclol), CBV (cannabivarin), THCV (tetrahydrocannabivarin), CBDV (cannabidivarin), CBCV (cannabichromevarin), CBGV (cannabigerovarin), CBGM (cannabigerol monomethyl ether), CBE (cannabielsoin), CBT (cannabicitran-), and other active constituents that are naturally occurring in the Cannabis sativa L. plant.
- 3.6.3.7. Cannabinoid content refers to the test-verified levels of specific cannabinoids that are tested to be present in a harvest lot or a process lot.
- 3.7.3.8. Certificate of analysis means a report prepared by a certified laboratory about the laboratory's report describing its analytical testing it performed and the results of the testing.
- 3.8.3.9. Certified laboratory means a laboratory that is certified by the Agency under 6 V.S.A. § 567.
- 3.9. Concentrate means the product containing any chemical compounds removed by extraction, including cannabinoids, isomers, acids, salts and salts of isomers from a hemp crop harvest lot.
- 3.10. Consumable means a hemp product or hemp-infused product that is intended for human consumption.
- 3.11. Consumption means ingesting human ingestion, inhaling, or topically applying to skin or hair.
- 3.12. Contaminant means any pesticide, solvent, heavy metal, mycotoxin, foreign material, and bacterial and/or fungal impurity introduced through cultivation or processing.
- 3.13. Crop means hemp grown under a following proper registration issued by through the Agency.
- 3.14. Cultivar means a plant variety with known characteristics that has been grown and produced by humans.
- 3.15. Cultivation area means one (1) contiguous tract of land, indoor facility or greenhouse used to produce or intended to be used to produce hemp.
- 3.16. Delta-9 tetrahydrocannabinol, also referred to as "THC," is the principal psychoactive cannabinoid found in the Cannabis sativa L. plant.
- 3.17. Distillate means an odorless clear concentrate greater than 75% where a segment of all cannabinoid compounds created by heat separation cannabinoids from an initial extraction are selectively concentrated through heating and cooling, with all impurities removed.

- 3.18. Drying/ or storage area means ~~the~~any area where hemp is dried and/or stored. A Drying/Storage Area ~~drying or storage area~~ may include areas where harvested hemp is confined, housed, or stored, whether within or without structures, and areas to store agricultural inputs or hemp agricultural wastes associated with producing the crop inside or outside of any structure.
- 3.19. Dry weight means the weight of plant material with no greater than 13% moisture content.
- 3.20. Food means:
- (a) ~~articles used for~~of food or, drink for humans, confectionery, or condiment for human consumption, whether simple, mixed, or animals,
  - (b) ~~3.20.~~ chewing gum compound, and all substances and ingred ~~nts~~ used in the preparation thereof.
  - (c) ~~articles used for~~ components or any such article.
- 3.21. Full spectrum means a hemp product or hemp-infused product that is:
- (a) derived from a hemp extraction and concentrate;
  - 3.21.(b) contains cannabinoids, aromatics, essential vitamins and minerals, fatty acids, protein, chlorophyll, flavonoids, and terpenes, and that ~~and has not been reformulated or has not had cannabinoid isolates or distillates added to it.~~
  - (c) ~~has not been reformulated or has not had cannabinoid isolates or distillates added to it.~~ Grow
- 3.22. Grow may be used interchangeably with the word "produce" or "cultivate" and means the:
- (a) planting, cultivating, harvesting, or drying hemp, and/or
  - 3.22.(b) selling, storing or transporting of hemp crops grown by the Grower. "Grow" may be used interchangeably with the word "produce" or "cultivate." hemp.
- 3.23. Grower means a person who is registered with the Agency to grow ~~produce~~ hemp crops.
- 3.24. Handle means ~~the possession of~~ to possess hemp crops for any period of time on premises owned, leased, operated, or controlled by a Registrant registered to grow or process hemp. Handling registrant. "Handle" also includes possession of ~~means to possess~~ hemp crops for any period of time other than during their actual transport from ~~thea~~ a registrant's premises of a Registrant to ~~the another registrant's premises of another Registrant or out-of-state recipient to cultivate or process them.~~ "Handle" does not mean possession of hemp products or hemp-infused products.
- 3.25. Harvest lot means a quantity of hemp grower's harvested by the same Grower in hemp produced during a single growing season that is grown contiguously in a contiguous area containing the same cultivation area ~~cultivar or variety.~~
- 3.26. Harvest lot number means a unique numerical identifier that begins with the last ~~five~~four digits of a ~~Grower's~~ grower's registration number, followed by the year of harvest, and a unique number to identify the harvest lot.
- 3.27. Hemp means the plant Cannabis sativa L. ~~whether growing or not~~ and any part of ~~that~~the plant, including the seeds, and all derivatives, extracts, cannabinoids, ~~isomers,~~ acids, salts, ~~isomers,~~ and salts of isomers, ~~whether growing or not,~~ with the federally defined ~~a~~ delta-9 tetrahydrocannabinol concentration level, or is a type III or IV cannabis plant as defined in Sections 3.50 and 3.51 of these Rules ~~not more than 0.3 percent on a dry weight basis.~~ The cultivation of hemp shall be subject to and comply with the required agricultural practices adopted pursuant to 6 V.S.A. § 4810.
- 3.28. Hemp concentrate means a ~~substance~~ process intermediate obtained by separating cannabinoids from a hemp leaves, flowers, or stalk crop using a mechanical, chemical or other process which consists primarily of cannabinoids. Hemp concentrate is not a hemp product or hemp-infused product as defined by these rules.

- 3.29. Hemp crop means a standing or harvested hemp that complies with crop or biomass. Use of "hemp crop" or "hemp crops" includes both the federal definition of hemp prior singular and plural usages whenever appropriate and shall be read to processing be inclusive of both forms whenever possible.
- 3.30. Hemp product or Hemp-infused product means all products product that have satisfies the federally defined required tetrahydrocannabinol concentration level for hemp, that are derived from, or made by, processing hemp plants and/or plant parts, and that are prepared in a form available for commercial sale. This includes, including cosmetics, personal care products, food intended for animal or human consumption, cloth, cordage, fiber, fuel, paint, paper, particleboard construction materials, plastics, and any product containing one or more hemp-derived cannabinoids, such as cannabidiol.
- 3.31. Ingredient means any substance that is used in the manufacture of a hemp product or a hemp-infused product and that is intended to be present in the finished process lot.
- 3.32. Isolate means a concentrate greater that is more than 95% percent comprised of a single cannabinoid compound created by a chemical process.
- 3.33. Label Guarantee is the declared minimum or maximum amount of individual cannabinoid content in a hemp product or hemp-infused product.
- ~~3.34.~~ Negligence means the failure to exercise the level of care that a reasonably prudent person would exercise in complying with Chapter 34 of Title 6 of Vermont law and these rules.
- ~~3.34-3.35.~~ Person means:
- (a) an individual, sole proprietor, or any form of partnership, corporation, association, unincorporated organization, trust, or other legal or commercial entity, including a joint venture or affiliated ownership, or
  - (b) individuals and entities any individual or entity affiliated with each any other individual or entity for profit, consideration, or any other beneficial interest derived from agricultural management, including lessors and lessees.
- ~~3.35-3.36.~~ Personal cultivation use means cultivating hemp on less than 0.5 acres for personal an individual's own use. No, when no hemp crop, hemp product, or hemp-infused product shall enter into enters commerce from cultivation areas registered for personal use this purpose.
- ~~3.36-3.37.~~ Process means a processor's storing, drying, trimming, handling, compounding, and/or converting a conversion of hemp crop or hemp concentrate crops into hemp products or hemp-infused products that comply with the federal definition of hemp. It also includes. "Process" includes processing hemp from single or multiple growers, and transporting, aggregating, or packaging hemp from a single or multiple growers or processors. "Process" does not include the addition of. "also includes manufacturing hemp products or hemp-infused products from hemp concentrate" to a product at the point of sale.
- ~~3.37-3.38.~~ Processor means a person who is registered with the Agency to process hemp crops. A retail establishment selling hemp products or hemp-infused products is not a processor.
- 3.38. Process lot means:
- (a) any amount of pressed seed oil, fiber, hemp concentrate, hemp product or seed hemp-infused product of the same type, processed at the same time using the same methods and same standard operating procedures; or
  - (b) 3.39. any amount of consumable hemp product or hemp-infused product of the same type processed at the same time using the same ingredients and same standard operating procedures.

- ~~3.39~~ 3.40. Process lot number means a unique numerical identifier that begins with the last five digits of a Processor's registration number, followed by the year of processing, and then followed by a unique number to identify the process lot.
- ~~3.40~~ 3.41. Processing site means a single parcel of land and all infrastructure on that parcel used to process for the processing or intended to be used to process processing of hemp.
- 3.41.3.42. "Produced in Vermont" means only those hemp products or hemp-infused products that are derived from hemp crops exclusively grown and manufactured processed in their entirety within Vermont pursuant to standards established by, and the products are formulated in Vermont in compliance with these Rules.
- ~~3.42~~ Product complaint means a written, electronic, or oral communication received by the Agency in which the person making the communication states a concern related to a hemp crop, a hemp product, or a hemp-infused product.
- 3.43. Registrant means a person registered with the Hemp Program.
- ~~3.44~~ Retting means to soak in water or expose to moisture to facilitate the removal of the fiber from woody tissue through partial retting.
- ~~3.45~~ 3.44. Tetrahydrocannabinolic acid (THCA) is the precursor of delta-9 THC before decarboxylation.
- ~~3.46~~ 3.45. Total theoretical tetrahydrocannabinol or THC content (or total theoretical THC) is the maximum amount of possible delta-9 tetrahydrocannabinol in a hemp crop if total conversion were to occur and will be. The calculated amount is determined by the following calculation as follows:

the sum of the concentration of delta-9 tetrahydrocannabinol and its precursor, tetrahydrocannabinol-A, added to the amount of tetrahydrocannabinolic acid after it is multiplied by 0.8777877 on a dry weight basis and reported to two significant figures. The mathematical equation follows:

$$\begin{aligned} \text{Total theoretical THC} &= ([\text{delta-9 THC}] + ([\text{THC-A}] \times 0.877))([\text{delta-9 THC}] \\ &+ ([\text{THCA}] \times 0.877)) \end{aligned}$$

- ~~3.47~~ Taxonomic determination means a process of classification based on genetic testing of known cannabinoid ratios based on stable cultivars.
- ~~3.48~~ Type I means a cultivar of *Cannabis sativa* L. that is THC dominate.
- ~~3.49~~ Type II means a cultivar of *Cannabis sativa* L. ratio between CBD and THC vary, and where delta-9 THC concentration is greater than 0.3 percent.
- ~~3.50~~ Type III means a cultivar of *Cannabis sativa* L. that is CBD dominate, at least 20:1.
- ~~3.51~~ Type IV means a cultivar of *Cannabis sativa* L. that is neither THC nor CBD dominate.
- ~~3.52~~ 3.46. Whole plant concentrate means an extract that contains both water and lipid soluble plant compounds.

**Section 4** Program Registration Requirements

4.1. To register as a Grower or Processor ~~in~~with the Hemp Program, a person must ~~complete an application on a form provided~~apply by ~~submitting the Agency and submit the Agency's completed application form, all the required documentation, and a registration fee to~~(collectively, the Agency, "application"). The ~~person~~person's application must include in their application a listing and the location ~~including GPS coordinates of all cultivation areas, drying, and or storage areas, and/or processing sites at which they plan~~where the person plans to grow or process hemp. A ~~person and their~~person's cultivation, drying, and storage areas, and/or processing sites are registered with the Hemp Program when the person receives ~~at~~the Agency's written notice of registration ~~from the Agency.~~

- (a) To process an application, the Agency may ~~request additional documents to verify the information provided on~~in the submitted application form and required documentation. ~~The Agency may request additional documentation.~~
- (b) ~~If the~~The application form is not fully completed, ~~if complete unless and until all requested documentation is not~~documents are provided, or if and the registration fee is not submitted at the same time as the application form, ~~the~~received. The Agency may reject the application as ~~any~~incomplete application. A person whose application is rejected as incomplete may reapply for registration at any time.
- (c) A person who materially falsifies any information in ~~the~~an application form and requested documentation ~~is~~shall be ineligible to participate in the Hemp Program. ~~The duration of the ineligibility shall be at the Secretary's discretion after evaluating the applicant's conduct. If the applicant is permitted to reapply, the applicant must exclusively provide accurate information.~~
- (d) To register multiple cultivation areas or processing sites, a person may submit a single application form identifying all cultivation areas and/or processing sites associated with that application and ~~that includes all appropriate registration fee(s).~~
- (e) ~~Any~~Public information provided to the Agency as part of a person's application may be publicly disclosed and ~~all information~~may be provided to law enforcement agencies without notice to the ~~applicant~~person.

~~4.2. Changes~~Any change to registrations ~~registration information must be requested in writing and must obtain written approval from~~approved by the Agency.

~~4.3. A person convicted of a felony relating to a controlled substance under state or federal law before, on, or after December 20, 2019 shall be ineligible to register with the Hemp Program during the 10-year period following the date of the conviction unless the person has lawfully registered with the Hemp Program prior to this date.~~

4.4.4.2. \_\_\_\_\_ it may become effective. Registrations may not be sold or transferred by a Registrant ~~person~~ to any other person.

~~4.5.4.3. \_\_\_\_\_ Registrations expire on December 31 of each year. A new application for registration must be submitted for each~~calendar year of growing or processing.

4.6.4.4. \_\_\_\_\_ A person holding a valid registration at ~~on~~the date of the adoption or amendment of these Rules ~~are adopted or amended~~ will be considered registered for the remainder of the calendar year in which the Rules are adopted or amended.

4.5 A registrant shall exclusively operate within the terms of the specific type of registration issued and shall not exceed the scope of that authorized activity. As examples, a registrant licensed to test

hemp shall not also grow or process it, and a registrant authorized to grow hemp for personal use shall not use it for anything other than personal use.

**Section 5 Growing, Transferring and Selling, Recordkeeping, and Reporting Requirements for Growers**

5.1. A Grower grower is responsible for demonstrating compliance with the acceptable potency level for all hemp crops offered for sale or transferred to a Processor or the public.

5.2. A Grower grower shall only grow hemp crops only in registered cultivation areas and may only handle their hemp crops only in registered drying and storage areas area.

5.3. A Grower of hemp crops produced outdoors for seed must notify all Growers of biomass and flower within a radius of 5 miles of their cultivation areas. The Agency will provide names and contact information to the Grower based on previous year Registrants.

5.3. A Grower may transfer or sell hemp crops, clones, or plants to When a grower transfers or sells hemp crop, clones, or plants, the grower must:

5.4. provide a copy of a consumer for personal cultivation and use and when doing so, the Grower must:

(a) make certificate certificate of analysis available upon request for public inspection the cultivar being transferred or sold; and

(b) offer a list of any pesticides used in the cultivation of thea hemp cropscrop, clones, or plants.

5.5.5.4. A Grower grower must assign each harvest lot a harvest lot number.

5.6.5.5. A Grower For a minimum of three (3) years from harvest date, a grower shall maintain the following records listed in (a) through (c) below. for each harvest lot organized by harvest lot number:

(a) Records of all purchases of hemp seed, starts, and clones. The records, which shall include:

i. the date of purchase;

ii. the cultivar name;

iii. the name and address of the company from which seller and the purchase was made; Agency-issued license number for each seed dealer or nursery dealer;

iv. a certificate of analysis by a certified laboratory endemonstrating the cultivar's compliance with the federally defined tetrahydrocannabinol concentration required acceptable potency level or associated genetic tests that the cultivar is; and

iv. a type III or type IV cannabis plant;

v. the name and addresscopy of the certified laboratory that conducted the analysis; and

v. a notation of map submitted during the registration process that shows the cultivation area where the cultivar was grown.

(b) Records of all hemp crop transfers of hemp crops to a Processor each in-state and/or out-of-state recipient. The records shall be kept by harvest lot number and processor, which shall include:

i. the datesdate(s) of harvest and transfer;

ii. the name and address of the Processoreach processor and theirits registration number or the name; and address of the out-of-state recipient; and

iii. an estimate of the amountdry weight of hemp transferred on a dry weight basismeasured in pounds.

~~(e) Records of testing request forms, documentation of sampling in conformance with Agency sampling protocols, and certificate of analysis for each harvest lot identified.~~

(c) Copies of all sampling and testing records to demonstrate compliance with Vermont Pre-Harvest Sampling Protocols, and the testing required by these Rules including all certificates of analyses performed by certified laboratories.

~~5.7. A Grower shall keep the records required by this section for a minimum of three (3) years from harvest date by harvest lot number.~~

5.8.5.6. A Grower/grower shall make the all records available to the Agency for inspection upon its request.

5.9.5.7. A Grower/grower shall submit annually submit a report to the Agency a report containing the information required by this section by December 1 detailing the total acreage of hemp planted, harvested, and any other information requested by the Agency under Title 6 if applicable, disposed or destructed. This information shall be publicly available upon request to the public provided that pursuant to 6 V.S.A. § 61 it is presented in a form which does not disclose the identity of individual persons, households, or businesses from whom the information was obtained, or whose characteristics, activities, or products the information is about. See 6 V.S.A. § 61.

#### Section 6 Processing, Transferring and Selling, Recordkeeping, and Reporting Requirements for Processors

6.1. A Processor/processor is responsible for demonstrating compliance with the acceptable potency level for hemp products and/or hemp-infused products offered for sale or transfer.

6.2. A Processor/processor shall only use lipid, ethanol, or carbon dioxide (CO2) botanical extraction methods, solvent free mechanical extraction methods, or other extraction methods for which the Processor has received written approval from the Agency- pre-approves in writing. All other methods of botanical extraction, including use of butane, propane, hexane and other hydrocarbons is prohibited.

6.3. A Processor/processor shall not use synthetic cannabinoids in the production of any hemp products/product or hemp-infused products/product.

6.4. A Processor may processor shall only process hemp crops only at registered processing sites.

6.4.6.5. A Processor/processor must report in writing to notify the Agency a closure in writing of any processing site closure within 10 business 10 days of its closure.

6.5.6.6. A Processor/processor, at the time of processing, must assign each process lot a process lot number at the time of processing to each lot of hemp concentrate, hemp product, and/or hemp-infused product extracted or manufactured/formulated by the Processor/processor.

6.6. A Processor that extracts THC or THC-A from a hemp crop must submit for approval by the Agency a disposal plan that ensures the THC and THC-A is disposed of in a manner that renders the THC and THC-A unusable and that accounts by process lot number all THC or THC-A removed.

6.7. A Processor may A processor shall only transfer or sell hemp concentrate for the purpose of reformulation into hemp products or hemp-infused products only to:

- (a) the Grower/grower of the hemp crop if they are the grower is also a Processor/processor, or
- (b) to another Processor/processor.

6.8. A Processor extracting hemp concentrate shall maintain the records listed in (a) through (c) below.

6.8. For a minimum of three (3) years from the date of processing a process lot, a processor shall maintain the following records for each extracted hemp concentrate organized by process lot number:

- (a) Records of all hemp crop(s) received by harvest lot number including:
  - i. The name, address, and registration number of the Grower/grower for any amount of hemp crop transferred to the Processor/processor;
  - ii. Date(s) the each hemp crop was received;
  - iii. Amount of hemp on a dry weight basis measured in pounds as received;
  - ~~iv. Documentation~~ Copies of sampling performed and testing records as required by Agency sampling protocols; and
  - ~~v. All testing request forms~~ Vermont Pre-Harvest Sampling Protocols and certificates of analysis these Rules; and
  - ~~v. Certificates of analyses from certified laboratories~~
- (b) Records of hemp crops that the Processor/processor receives from out-of-state; including:
  - i. The name and address of the out-of-state grower for any amount of hemp crop received;
  - ii. The out-of-state grower registration number in the respective state;
  - ~~iii.~~ Date the hemp crop was received;
  - ~~iv.~~ Amount of hemp on a dry weight basis crop measured in pounds as received; and
  - ~~v.~~ The associated certificate Certificates of analyses analyses for the hemp crop potency.
- (c) Records of certificate of analysis Certificates of analyses from certified laboratories organized by process lot number reported by a certified laboratory, and detailing cannabinoid content for any hemp crop extracted by Processor/concentrate a processor produced.

6.9. A Processor who manufactures For a minimum of three (3) years from the date of processing a process lot, a processor that formulates hemp products or hemp-infused products of the same type from a harvest lot or harvest lots or from a hemp concentrate or hemp concentrates and who uses the same formula and the same standard operating procedures and who offers them for retail sale label guarantee, shall maintain the following records organized by hemp product or hemp-infused product process lot number:

- (a) Copies of records from harvest lots as outlined in Section 6.8 that are used to formulate the each product;
- (b) The standard operating procedure for formulating the each product;
- (c) A certificate of analysis reported by a Certificates of analyses from certified laboratory that demonstrates laboratories demonstrating the cannabinoid content of the each product; and
- (d) A copy of the each product's label, as required in Section 11.

6.10. A Processor/processor of hemp products or hemp-infused products that offer/offers no label guarantee of any specific quantity of CBD/cannabinoids in the product shall be required to maintain records of formulation, including certificates of analyses for the hemp concentrate, used in product formulation, but shall not be required to maintain records of a certificate of analysis on the formulated product.

6.11-6.10. A Processor shall keep all records required under this section certificates of analyses for a minimum of three (3) years every process lot of the finished product.

6.12-6.11. A Processor/processor shall make these records available to the Agency for inspection upon its request.

~~6.13.6.12. A Processor shall submit annually to the Agency a report containing the information required by this section and any other information. When requested by the Agency under Title 6 and in a format described by the Agency during the annual registration process, a processor shall provide the total dry weight (measured in pounds) of the hemp crop handled in the preceding year. This information shall be publicly available upon request to the public provided that pursuant to 6 V.S.A. § 61 it is presented in a form which does not disclose the identity of individual persons, households, or businesses from whom the information was obtained, or whose characteristics, activities, or products the information is about. See 6 V.S.A. § 61.~~

### **Section 7 Testing Requirements for Growers**

~~7.1. A Grower~~ grower must test hemp crops for compliance with these rules.

~~7.2. A Grower may have a grower~~ must test each harvest lot tested for potency level levels to be reported on a dry weight basis, including reporting total theoretical tetrahydrocannabinol concentration.

~~7.3. A grower must test all harvest lots for the following substances:~~

~~(a) target pesticides established in the Cannabis Quality Control program, unless it is a certified organic crop; and~~

~~7.2.(b) heavy metals when the property was previously used for orchard crops or request a taxonomic determination of cultivars a land use other than farming as defined in the Required Agricultural Practices Rule, unless a recent soil test demonstrates that the heavy metals are within a harvest lot the action limits for soils as authorized in the Cannabis Quality Control Program.~~

~~7.3.(c) A Grower may propose testing parameters for pesticides, heavy metals, mycotoxins, and bacterial and fungal other potential contaminants that are based on a risk analysis and use for approval by when the Agency of Natural Resources has approved the property for biosolid application.~~

~~7.4. All hemp crop testing for compliance with required by these rules, potency, and contaminants~~ Rules shall be conducted by a certified laboratory. ~~This requirement excludes soil tests for heavy metals.~~

~~7.5. A harvest lot complies with the acceptable potency level and contaminant action limits under these Rules when a certified laboratory's certificate of analysis from the certified laboratory shows that demonstrates as follows:~~

~~(a) the cultivars that comprise the harvest lot are either type III or type IV cannabis plant; or~~

~~(a) the delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis,~~

~~(b) a total theoretical THC concentration is 0.3 percent or less and the total theoretical THC concentration is 1 that does not exceed one percent or less on a dry weight basis; and~~

~~(c) contaminant levels are below the action limits outlined by the Agency for pesticides, and heavy metals, mycotoxins, and bacterial and fungal contaminants established in the Cannabis Quality Control program.~~

~~7.6. When a harvest lot does not satisfy the acceptable potency level the Grower~~ grower must dispose of or destroy the hemp crop in accordance with Section 14.

~~7.7. The Agency may offer testing services to a Grower. The Agency will charge a fee for this service.~~

7.7. When a harvest lot does not satisfy the heavy metal and/or pesticide action limits established in the Cannabis Quality Control Program the grower must either mitigate or destroy the harvest lot. The harvest lot may not be sold as trim flower to the consumer.

**Section 8 Testing Requirements for Processors**

8.1. A Processor/processor must ensure retail that all hemp products and hemp-infused products offered for sale are compliant/comply with these rules/Rules.

8.2. A Processor may propose testing parameters for processor must have all process lots tested according to Table 1 for potency, water activity, pesticides, heavy metals, mycotoxins, and bacterial and fungal contaminants that are based on a risk analysis, the stage of the manufacturing process, and delivery method (inhalant, ingestion, or absorption) by sample type.

**Table 1, Testing Requirements**

<u>Sample type</u>	<u>potency</u>	<u>moisture or water activity</u>	<u>mycotoxins, bacterial and fungal</u>	<u>heavy metals</u>	<u>pesticides</u>	<u>Residual solvents</u>
<b><u>Plant material</u></b>						
<u>Trim flower</u>	<u>Note 1</u>	<u>Each process lot</u>	<u>Each process lot</u>	<u>Note 1</u>	<u>Note 1</u>	<u>N/A</u>
<b><u>Concentrates</u></b>						
<u>Liquids</u>	<u>Each process lot</u>		<u>Each process lot</u>	<u>Each process lot</u>	<u>Each process lot</u>	<u>Note 3</u>
<u>Solids</u>	<u>Each process lot</u>		<u>Each process lot</u>	<u>Each process lot</u>	<u>Each process lot</u>	<u>Note 3</u>
<b><u>Infused products</u></b>						
<u>Liquid-infused products (tinctures, water based)</u>	<u>Note 4</u>		<u>Note 2</u>	<u>Note 1 or 2</u>	<u>Note 2</u>	<u>N/A</u>
<u>Solid-infused products, edibles, tablets</u>	<u>Note 4</u>		<u>Note 2</u>	<u>Note 1 or 2</u>	<u>Note 2</u>	<u>N/A</u>

8-2. Note 1: Testing completed for harvest lot is sufficient for approval by the Agency showing compliance.

A Note 2: Testing completed for trim flower or hemp concentrate is sufficient for showing compliance.

Note 3: Residual solvents are tested only if solvent-based extraction techniques are used.

Note 4: Please apply Section 8.3 (a) for potency.

8.3. A hemp product or hemp-infused product process lot complies with Agency standards these Rules when the following terms apply:

- (a) a certificate of analysis from the a certified laboratory shows laboratory's certificate of analysis demonstrates that the product's THC concentration product meets the acceptable potency level; or
- (b)(a) the Processor's processor's formulation represents demonstrates compliance with the acceptable potency level, and a certificate of analysis from the
- (c)(b) a certified laboratory shows based on laboratory's certificate of analysis demonstrates compliance with Section 8.2 and evaluation of what contaminant tests are appropriate that contaminant levels are below action limits as outlined by the Secretary for pesticides, heavy metals, mycotoxins, and bacterial and fungal contaminants as established in the Cannabis Quality Control program.

8.4. When a hemp product or hemp-infused product does not satisfy meet the acceptable potency or contaminant levels level and is offered for retail sale/or the required action limits, the product is subject to stop sale and must be disposed of or destroyed in accordance with Section 14.

8.5. The Agency may offer testing services to a Processor. The Agency will charge a fee this service.

## **Section 9 Reporting and Disposal, Destruction, or Mitigation Requirements**

9.1. If a harvest lot is not compliant with exceeds the acceptable potency level or contaminants levels:

9.1. Within 24 hours of the completion of testing of a harvest lot, the required action limits in the Cannabis Quality Control Program, then the following conditions apply:

- (a) The certified laboratory shall send the certificate of analysis containing the result to and the testing request form within 24 hours of completing the harvest lot test to:
  - i. the Agency by certified mail or electronically to [AGR.Hemp@vermont.gov](mailto:AGR.Hemp@vermont.gov) an individual identified by the Agency, and
  - ii. the Registrant registrant who requested the testing.
- (b) Within The registrant, within 48 hours of receipt of receiving the certificate of analysis containing the result from the certified laboratory, the Registrant who requested the testing, shall notify the Agency and provide the following information to the Agency by certified or electronical mail or electronically (to [AGR.Hemp@vermont.gov](mailto:AGR.Hemp@vermont.gov) an Agency-identified individual):
  - i. a copy of the certificate of analysis for the harvest lot;
  - ii. a map copy of the location of map used during the registration process depicting the harvest lot cultivation area; and
  - iii. the Registrant's proposed actions action plan for disposal, destruction, or mitigation.

- (c) Failure to notify the Agency within 48 hours of receipt of a certificate of analysis of a harvest lot exceeding the acceptable potency level or of a harvest lot with a taxonomic determination as a type I or type II cannabis plant as required may result in enforcement under Vermont law.
  - (d) A harvest lot exceeding the acceptable potency level or a harvest lot with a taxonomic determination as a type I or type II cannabis plant shall not be processed into hemp concentrate or used to create formulate hemp products or hemp-infused products. Doing so will Concentrate, products or infused products created from such a harvest lot may result in the disposal or destruction of those concentrates or products.
- 9.2. All methods of The proposed action plan for disposal and destruction of harvest lots or process lots shall be reviewed and approved by the Agency prior to implementation.
- 9.3. The Registrant registrant is responsible for the full cost of disposal or, destruction, and/or mitigation.

## **Section 10** Requirements for Handling Hemp Crops, Hemp Products and Hemp-Infused Products

- 10.1. Registrants shall only handle hemp crops that have an acceptable potency level or that are type III and type IV cultivars, unless part of a disposal or destruction plan required in Sections 9 and 14.
- 10.2. Registrants shall not formulate, handle, wholesale or retail sell a hemp product or hemp-infused product that contains a delta-9 tetrahydrocannabinol concentration greater than 0.3 percent on a dry weight basis except as provided in Section 6.7.
- 10.3.10.2. A Registrant selling or transporting a hemp crop, hemp product, or hemp-infused product out of state may have exceeds the hemp crop, hemp product or hemp-infused product confirmed by the Secretary to meet the definition of hemp under State or federal law. A request for confirmation by the Secretary must include acceptable potency level.
- (a) A copy of the certificate of analysis from a certified laboratory for a hemp crop identified by harvest lot number, or for a hemp or hemp-infused product identified by process lot number; and
  - (b) Within 30 days of receiving the request for a confirmed crop or product, the Agency will generate a confirmation that may accompany the shipment of the hemp crop, hemp product, or hemp-infused product.

## **Section 11** Requirements for Labeling of Hemp Products and Hemp-infused Products

- 11.1. All guaranteed hemp products or hemp-infused products produced in Vermont must be labeled and traceable to a certificate of analysis for all cannabinoid content label guarantees.
- 11.2. Registrants must label consumable hemp products and hemp-infused products in accordance with this section.

- 11.3. All label claims using the term “whole plant,” “isolate,” “full spectrum,” “broad spectrum,” and/or “distillate” shall comply with the definitions applicable definition contained in these rules.
- 11.4. All labels for consumable hemp products or hemp-infused products grown or processed in Vermont must contain the following information:
- (a) The name and principal mailing address of the manufacturer, processor, of the hemp product, or hemp-infused product;
  - (b) A statement that the product contains ingredients that are derived from “hemp.”
  - (c) A list of all ingredients, in descending order of predominance by weight in the product, when the ingredient represents at least 0.05% of the content in the product;
  - (d)(c) An accurate statement of the quantity of the content in weight, measure, or numerical count;
  - (e)(d) The When offering a guarantee, the guaranteed amount of any purported cannabinoids listed cannabinoid contained in the product by serving size, measured in milligrams, milliliters, or grams;
  - (f)(e) A statement that the product contains THC, if applicable; and
  - (g)(f) Manufacturing date, expiration date, and A process lot number.

~~11.5. All label guarantees regarding potency must be an accurate and within +/- 10% per serving size listed on the label.~~

11.5. If a product is sold as a dietary supplement and in compliance with federal Food and Drug Administration manufacturing standards and label requirements, those label requirements supersede this Rule's Section 11.4 (a)-(f) label requirements.

## **Section 12 Vermont Hemp Products and Hemp-Infused Products**

12.1. The Secretary establishes and adopts the Vermont Hemp brand and grades under its authority in 6 V.S.A. Chapter 21.

~~12.2. A hemp crop grown, and sampled and tested in accordance with Agency sampling and testing protocols, and with a certificate of analysis from a certified laboratory shall have the following grades~~

- ~~(a) Grade AA is a hemp crop produced with a cannabidiol concentration greater than 14 percent;~~
- ~~(b) Grade A is a hemp crop produced with a cannabidiol concentration between 14 percent and 12 percent;~~
- ~~(c) Grade B is a hemp crop produced with a cannabidiol concentration between less than 12 percent and 10 percent;~~
- ~~(d) Grade C is a hemp crop produced with a cannabidiol concentration between less than 10 percent and 8 percent; and~~
- ~~(e) A hemp crop produced with a cannabidiol concentration less than 8 percent is considered biomass.~~

12.3.12.2. Vermont Hemp is a hemp crop, hemp product, or hemp-infused product that satisfies the following standards and is certified by the Agency;

- (a) Vermont Hemp is Produced produced in Vermont as defined in Section 3 by Registrantsregistrants of the Vermont Hemp Program;
- ~~(b) is grown and processed by Registrants that to the satisfaction of the Agency document practices and conditions with the potential to reduce risks for contaminants in locations including and not limited to cultivation areas, and storage, drying, and processing facilities;~~
- (b) Vermont Hemp is a hemp crop, hemp product, or hemp-infused product exclusively grown and processed in Vermont by registrants that demonstrate compliance with all requirements enumerated by the Secretary;
- (c) Vermont Hemp is tested by a certified laboratory and proven to be compliant with the acceptable potency level and contaminant action levels, as applicable; and
- (d) Compliant Vermont Hemp is compliant with the Vermont Hemp Program's labeling requirements in Section 1011.

~~12.4.12.3. The Registrant must~~ Any registrant that wishes to use the Vermont Hemp brand must annually apply for certification of meeting all the requirements of Vermont's Hemp brand annually to the Agency, using Agency-supplied forms provided by the and must meet all Agency requirements.

### **Section 13** Inspection, Research and Record Reviews

- 13.1. The Agency shall conduct annual registrant inspections of Registrants, which may or may not be at random to verify that hemp is not produced in violation of state and federal law, to ensure compliance with these Rules.
- 13.2. The Agency may inspect a Registrant'sregistrant's premises, machinery, equipment and, facilities, any crop during any growth phase, and/or any hemp product or hemp-infused product during processing or storage. ThisThe inspection may include the taking ofcollecting samples, taking photographs and/or video, talking to registrants and/or witnesses, and/or inspecting records. The inspection of records, and inspection ofmay also include inspecting equipment and/or vehicles used in thefor growing, processing or transport oftransporting hemp crops, hemp products, and/or hemp-infused products, and taking any other reasonable measure to evaluate compliance with these Rules.
- 13.3. The Agency may inspect any retail location offering hemp products or hemp-infused products. This inspection may include the taking of samples of such products.
- 13.4. The Agency may use any hemp crop samples to conduct genetic testing and/or research the potential of taxonomic determinations of hemp cultivars or varieties grown.

### **Section 14** Enforcement

- ~~14.1. Negligent violations.~~

14.1. Violations.

(a) ~~If the Secretary determines that a person who has produced hemp has negligently~~ registrant violated any provision of 6 V.S.A. Chapter 34 or these Rules, the person must correct their negligent violation(s). Secretary may require corrective action, revoke the Agency's registration, issue and enforce a stop sale order, take administrative enforcement action, refer a matter to the Attorney General for civil enforcement, and/or refer a matter to law enforcement for potential criminal enforcement.

Examples of negligent violations that will, at minimum, require corrective action are as follows:

- ~~i. a person who is registered with the Hemp Program negligently fails~~ failure to provide a legal description of the land on which they produce where hemp is produced;
- ~~ii. a person produces hemp and negligently fails to obtain a registration from the Hemp Program;~~
- ~~ii. a person who is registered~~ failure to appropriately register with the Hemp Program and negligently produces Agency;
- ~~iii. failure to produce Cannabis sativa L. with a delta-9 tetrahydrocannabinol concentration of greater than 0.3 but no greater than one percent~~ that complies with the required acceptable potency level.
- ~~iv. a person who is registered with the Hemp Program and negligently produces Cannabis sativa L. with a delta-9 tetrahydrocannabinol concentration of more than 0.3 percent on a dry weight basis and a total theoretical tetrahydrocannabinol concentration greater than one percent dry weight basis, or a type I or type II cultivar.~~

~~(b) To~~ When instructed to correct their negligent a violation(s), a person who has negligently violated Chapter 34 or these Rules must, the registrant shall:

- ~~i. propose a written corrective action plan to the Agency within 10 days of receipt of any notice of violation a proposed corrective action plan that includes. The plan shall also include a proposed date of for completion of the correction action plan;~~
- ~~ii. obtain written Agency approval from the Agency for the corrective action plan once the plan is acceptable;~~
- ~~iii. comply with the approved corrective action plan; and~~
- ~~iv. report twice annually to the Secretary on their compliance with these Rules in writing every six months for the next two calendar years.~~
- ~~iv. A corrective action plan for a person who has registered with explaining how the Hemp Program registrant is complying with Chapter 34 and who these Rules.~~

~~(c) A registrant that negligently violates these Rules by producing~~ produces Cannabis sativa L. with a delta-9 tetrahydrocannabinol concentration greater than 0.3 but no greater than one percent on a dry weight basis shall include a requirement that that exceeds the Registrant:

- ~~i. enter into an agreement with a dispensary registered under 18 V.S.A. chapter 86 for the separation of the delta-9 tetrahydrocannabinol from the hemp crop, return of the hemp~~

- ~~crop to the person registered with the Secretary, and retention of the separated delta-9 tetrahydrocannabinol by the dispensary;~~
- ~~ii. sell the hemp crop to a dispensary registered under 18 V.S.A. chapter 86; or~~
- ~~iii. arrange for the Secretary to destroy or order the destruction of the hemp crop.~~
- ~~(d)(c) A person who is registered with the Hemp Program and negligently produces Cannabis sativa L. with a delta-9 tetrahydrocannabinol concentration of more than 0.3 percent on a dry weight basis and a total theoretical tetrahydrocannabinol concentration greater than one percent dry weight basis, or a type I or type II cultivar acceptable potency level shall arrange for the Secretary to destroy or order the destruction of the hemp crop.~~
- ~~(e) A person who negligently violates these Rules shall not as a result of that violation(s) be subject to any criminal or civil enforcement action by the federal or state government.~~
- ~~(f)(d) A person who negligently violates these Rules three times in a five-year period shall be ineligible to produce hemp for a period of five years beginning on the date of the third violation. The Secretary, for good cause shown, may choose to impose a different penalty.~~

#### 14.2. Other violations.

If the Secretary determines that a person who has produced hemp has ~~registrant intentionally, willfully, and/or knowingly~~ violated Chapter 34 or these Rules with a culpable mental state greater than negligence, the Agency shall ~~immediately report~~ will take more significant enforcement action than if the registrant made a good faith effort to comply with the person to the United States Attorney General and the Vermont Attorney General as required by Section 10113 of the Agriculture Improvement Act of 2018, Public L. No. 115-334 law and these Rules.

### Section 15 Exemptions

15.1. Sections 6, 7, 8, 9, and 11 of these Rules shall do not apply when the hemp product:

- (a) is seed or seed oil for consumption and considered "Generally Recognized as Safe" by the U.S. United States Food and Drug Administration; or
- (b) is not intended for consumption and will be used for fiber, building material, or as animal bedding, and is not ~~part of an~~ subject to the Secretary's order of destruction of a hemp crop from the Secretary, or stop sale order.

### Section 16 Severability

The provisions of this rule are severable. If any provision of this rule is invalid, or if any application of this rule to any person or circumstance is invalid, the invalidity shall not affect any other provisions or applications which can be given effect without the invalid provision or application.

### ~~Section 16~~ Section 17 Effective Dates ~~Date~~

All except the following sections

- ~~(a)~~ This rule shall become effective on its date of adoption.

- i. ~~Section 11 and;~~
- ii. ~~Section 12 shall become effective on July 1, 2020.~~

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Text

Vermont Hemp Rules

**Section 1** Authority and Purpose

- 1.1 The Secretary of the Agency of Agriculture, Food and Markets (Agency) adopts the Vermont Hemp Rules pursuant to 6 V.S.A. Chapter 34. Chapter 34 authorizes the Secretary to adopt rules to implement the chapter and the State Hemp Program (Vermont Hemp Program). The Secretary is required to adopt rules establishing how the Agency will conduct research and establishing requirements for the registration of processors of hemp and hemp-infused products.
- 1.2 The Secretary establishes the Vermont Hemp Program (Hemp Program) to conduct research and regulate the growing, processing, testing, and marketing of industrial hemp and hemp products in the State.
- 1.3 The Agency expects to continue operating Vermont's pilot program pursuant to the 2014 federal Farm Bill for the 2020 growing season. After the General Assembly updated Chapter 34 following enactment of the Agriculture Improvement Act of 2018, Pub. L. No. 115-334, the United States Department of Agriculture (USDA) issued an Interim Final Rule (IFR) in late 2019 that makes important distinctions from the pilot program. USDA informed the Agency that it could continue to operate its pilot program during the 2020 growing season, and the Agency plans to do so. As federal law develops and evolves, the Agency continues to evaluate it, continues to propose pragmatic changes, and will continue to evaluate how hemp may be grown, produced, and regulated in the State of Vermont. Compliance with these Rules does not guarantee compliance with other legal requirements, and each registrant is personally responsible for complying with all applicable state and federal laws.

**Section 2** Applicability

- 2.1. A person who plans to or grows, processes, or tests hemp or hemp products in the State:
  - (a) must register annually with the Vermont Hemp Program;
  - (b) must register all hemp cultivation, drying, storage areas, and/or processing sites with the Hemp Program; and
  - (c) must comply with the Vermont Hemp Rules (Rules).
- 2.2. A person is not required to register with the Hemp Program to sell hemp products or hemp-infused products in Vermont.

**Section 3** Definitions

- 3.1. Acceptable potency level means a hemp crop that has a delta-9 tetrahydrocannabinol concentration of 0.3 percent or less on a dry weight basis. This initial requirement accords with the federal 2014 Farm Bill. As an additional policy limitation implemented to protect public safety, the Agency also requires that the total theoretical tetrahydrocannabinol concentration not exceed one percent on a dry weight basis. The acceptable potency level may change as the law develops following the 2020 growing season.

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- 3.2. Agency means the Vermont Agency of Agriculture, Food and Markets.
- 3.3. Biomass means harvested hemp including the stalks and leaves and may include flowers/buds and/or seeds.
- 3.4. Broad spectrum means a concentrate extracted from hemp containing cannabinoids except THC which has been removed.
- 3.5. Cannabidiol or CBD is one of the naturally occurring cannabinoids found in the Cannabis sativa L. plant.
- 3.6. Cannabinoid means any of a group of closely related chemical compounds which include THC (tetrahydrocannabinol), THCA (tetrahydrocannabinolic acid), CBD (cannabidiol), CBDA (cannabidiolic acid), CBN (cannabinol), CBG (cannabigerol), CBC (cannabichromene), CBL (cannabicyclol), CBV (cannabivarin), THCV (tetrahydrocannabivarin), CBDV (cannabidivarin), CBCV (cannabichromevarin), CBGV (cannabigerovarin), CBGM (cannabigerol monomethyl ether), CBE (cannabielsoin), CBT (cannabicitran), and other active constituents that are naturally occurring in the Cannabis sativa L. plant.
- 3.7. Cannabinoid content refers to the test-verified levels of specific cannabinoids in a harvest or process lot.
- 3.8. Certificate of analysis means a certified laboratory's report describing its analytical testing and results.
- 3.9. Certified laboratory means a laboratory certified by the Agency under 6 V.S.A. § 567.
- 3.10. Consumable means a hemp product or hemp-infused product intended for human consumption.
- 3.11. Consumption means human ingestion, inhaling, or topically applying to skin or hair.
- 3.12. Contaminant means a pesticide, solvent, heavy metal, mycotoxin, foreign material, bacterial and/or fungal impurity introduced through cultivation or processing.
- 3.13. Crop means hemp grown following proper registration through the Agency.
- 3.14. Cultivar means a plant variety with known characteristics that has been grown and produced by humans.
- 3.15. Cultivation area means one (1) contiguous tract of land, indoor facility or greenhouse used to produce or intended to be used to produce hemp.
- 3.16. Delta-9 tetrahydrocannabinol, also referred to as "THC," is the principal psychoactive cannabinoid found in the Cannabis sativa L. plant.
- 3.17. Distillate means a concentrate where a segment of cannabinoids from an initial extraction are selectively concentrated through heating and cooling, with all impurities removed.

- 3.18. Drying or storage area means any area where hemp is dried or stored. A drying or storage area may include areas where harvested hemp is confined, housed, or stored, whether inside or outside of any structure.
- 3.19. Dry weight means the weight of plant material with no greater than 13% moisture content.
- 3.20. Food means articles of food, drink, confectionery, or condiment for human consumption, whether simple, mixed, or compound, and all substances and ingredients used in the preparation thereof.
- 3.21. Full spectrum means a hemp product or hemp-infused product that is:
- (a) derived from a hemp concentrate;
  - (b) contains cannabinoids, aromatics, essential vitamins and minerals, fatty acids, protein, chlorophyll, flavonoids, and terpenes; and
  - (c) has not been reformulated or has not had cannabinoid isolates or distillates added to it.
- 3.22. Grow may be used interchangeably with the word "produce" or "cultivate" and means:
- (a) planting, cultivating, harvesting, or drying hemp, and/or
  - (b) selling, storing or transporting hemp.
- 3.23. Grower means a person who is registered with the Agency to produce hemp crops.
- 3.24. Handle means to possess hemp crops for any period of time on premises owned, leased, operated, or controlled by a registrant. "Handle" also means to possess hemp crops for any period of time other than during transport from a registrant's premises to another registrant's premises or out-of-state recipient. "Handle" does not mean possession of hemp products or hemp-infused products.
- 3.25. Harvest lot means a grower's harvested hemp produced during a single growing season in a contiguous area containing the same cultivar or variety.
- 3.26. Harvest lot number means a unique numerical identifier that begins with the last four digits of a grower's registration number, followed by the year of harvest, and a unique number to identify the harvest lot.
- 3.27. Hemp means the plant *Cannabis sativa* L. and any part of the plant, including the seeds and all derivatives, extracts, cannabinoids, acids, salts, isomers, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. The cultivation of hemp shall be subject to and comply with the required agricultural practices adopted pursuant to 6 V.S.A. § 4810.
- 3.28. Hemp concentrate means a process intermediate obtained by separating cannabinoids from a hemp crop using a mechanical, chemical or other process which consists primarily of cannabinoids. Hemp concentrate is not a hemp product or hemp-infused product as defined by these rules.

- 3.29. Hemp crop means a standing or harvested crop or biomass. Use of “hemp crop” or “hemp crops” includes both the singular and plural usages whenever appropriate and shall be read to be inclusive of both forms whenever possible.
- 3.30. Hemp product or Hemp-infused product means all product that satisfies the required tetrahydrocannabinol concentration level for hemp, derived from, or made by, processing hemp plants and/or plant parts, that are prepared in a form available for commercial sale, including cosmetics, personal care products, food intended for animal or human consumption, cloth, cordage, fiber, fuel, paint, paper, construction materials, plastics, and any product containing one or more hemp-derived cannabinoids, such as cannabidiol.
- 3.31. Ingredient means any substance that is used in the manufacture of a hemp product or hemp-infused product that is intended to be present in the finished process lot.
- 3.32. Isolate means a concentrate that is more than 95 percent comprised of a single cannabinoid compound created by a chemical process.
- 3.33. Label Guarantee is the declared minimum or maximum amount of individual cannabinoid content in a hemp product or hemp-infused product.
- 3.34. Negligence means the failure to exercise the level of care that a reasonably prudent person would exercise in complying with Chapter 34 of Title 6 of Vermont law and these rules.
- 3.35. Person means:
- (a) an individual, sole proprietor, or any form of partnership, corporation, association, unincorporated organization, trust, or other legal or commercial entity, including a joint venture or affiliated ownership, or
  - (b) any individual or entity affiliated with any other individual or entity for profit, consideration, or any other beneficial interest derived from agricultural management, including lessors and lessees.
- 3.36. Personal use means cultivating hemp on less than 0.5 acres for an individual’s own use, when no hemp crop, hemp product, or hemp-infused product enters commerce from cultivation areas registered for this purpose.
- 3.37. Process means a processor’s storing, drying, trimming, handling, compounding, and/or conversion of hemp crops into hemp products or hemp-infused products. “Process” includes processing hemp from single or multiple growers, and transporting, aggregating, or packaging hemp. “Process” also includes manufacturing hemp products or hemp-infused products from hemp concentrate.
- 3.38. Processor means a person who is registered with the Agency to process hemp crops. A retail establishment selling hemp products or hemp-infused products is not a processor.
- 3.39. Process lot means: any amount of hemp concentrate, hemp product or hemp-infused product of the same type, processed at the same time using the same ingredients and same standard operating procedures.

- 3.40. Process lot number means a unique numerical identifier that begins with the last five digits of a Processor's registration number, followed by the year of processing, and a unique number to identify the process lot.
- 3.41. Processing site means a single parcel of land and all infrastructure on that parcel used for the processing or intended processing of hemp.
- 3.42. "Produced in Vermont" means hemp products or hemp-infused products that are derived from hemp crops exclusively grown and processed in Vermont, and the products are formulated in Vermont in compliance with these Rules.
- 3.43. Registrant means a person registered with the Hemp Program.
- 3.44. Tetrahydrocannabinolic acid (THCA) is the precursor of delta-9 THC.
- 3.45. Total theoretical tetrahydrocannabinol content (or total theoretical THC) is the maximum amount of possible delta-9 tetrahydrocannabinol in a hemp crop if total conversion were to occur. The calculated amount is determined as follows:

the sum of the concentration of delta-9 tetrahydrocannabinol added to the amount of tetrahydrocannabinolic acid after it is multiplied by 0.877 on a dry weight basis and reported to two significant figures. The mathematical equation follows:

$$\text{Total theoretical THC} = ([\text{delta 9 THC}] + ([\text{THCA}] * 0.877))$$

- 3.46. Whole plant means an extract that contains water and lipid soluble plant compounds.

#### Section 4 Program Registration Requirements

- 4.1. To register as a Grower or Processor with the Hemp Program, a person must apply by submitting the Agency's completed application form, the required documentation, and registration fee (collectively, the "application"). The person's application must include the location including GPS coordinates of all cultivation areas, drying or storage areas, and/or processing sites where the person plans to grow or process hemp. A person's cultivation, drying, storage areas, and/or processing sites are registered with the Hemp Program when the person receives the Agency's written notice of registration.
- (a) To process an application, the Agency may request additional documents to verify the information provided in the submitted application.
- (b) The application is not complete unless and until all requested documents are provided and the registration fee is received. The Agency may reject any incomplete application. A person whose application is rejected as incomplete may reapply for registration at any time.
- (c) A person who materially falsifies any information in an application shall be ineligible to participate in the Hemp Program. The duration of the ineligibility shall be at the

Secretary's discretion after evaluating the applicant's conduct. If the applicant is permitted to reapply, the applicant must exclusively provide accurate information.

- (d) To register multiple cultivation areas or processing sites, a person may submit a single application identifying all cultivation areas and/or processing sites associated with that application that includes all appropriate registration fee(s).
- (e) Public information provided to the Agency as part of a person's application may be publicly disclosed and all information may be provided to law enforcement agencies without notice to the person.

- 4.2. Any change to registration information must be approved by the Agency before it may become effective. Registrations may not be sold or transferred by a person to any other person.
- 4.3. Registrations expire on December 31 of each year. A new application for registration must be submitted for each calendar year.
- 4.4. A person holding a valid registration on the date these Rules are adopted or amended will be considered registered for the remainder of the calendar year in which the Rules are adopted or amended.
- 4.5. A registrant shall exclusively operate within the terms of the specific type of registration issued and shall not exceed the scope of that authorized activity. As examples, a registrant licensed to test hemp shall not also grow or process it, and a registrant authorized to grow hemp for personal use shall not use it for anything other than personal use.

**Section 5 Growing, Transferring and Selling, Recordkeeping, and Reporting Requirements for Growers**

- 5.1. A grower is responsible for demonstrating compliance with the acceptable potency level for all hemp crops.
- 5.2. A grower shall only grow hemp crops in registered cultivation areas and only handle hemp crops in registered drying and storage area.
- 5.3. When a grower transfers or sells hemp crop, clones, or plants, the grower must:
  - (a) provide a copy of a certificate of analysis for the cultivar being transferred or sold; and
  - (b) offer a list of any pesticides used in the cultivation of a hemp crop, clones, or plants.
- 5.4. A grower must assign each harvest lot a harvest lot number.
- 5.5. For a minimum of three (3) years from harvest date, a grower shall maintain the following records for each harvest lot organized by harvest lot number:
  - (a) Records of all purchases of hemp seed, starts, and clones, which shall include:
    - i. the date of purchase;
    - ii. the cultivar name;
    - iii. the name and address of the seller and the Agency-issued license number for each seed dealer or nursery dealer;

- iv. a certificate of analysis by a certified laboratory demonstrating the cultivar's compliance with the required acceptable potency level; and
  - v. a copy of the map submitted during the registration process that shows the cultivation area where the cultivar was grown.
- (b) Records of all hemp crop transfers to each in-state and/or out-of-state processor, which shall include:
- i. the date(s) of harvest and transfer;
  - ii. the name and address of each processor and its registration number; and
  - iii. an estimate of the dry weight of hemp transferred measured in pounds.
- (c) Copies of all sampling and testing records to demonstrate compliance with Vermont Pre-Harvest Sampling Protocols, and the testing required by these Rules including all certificates of analyses performed by certified laboratories.

5.6. A grower shall make all records available to the Agency for inspection upon request.

5.7. A grower shall annually submit a report to the Agency by December 1 detailing the total acreage of hemp planted, harvested, and if applicable, disposed or destructed. This information shall be publicly available upon request provided it is presented in a form which does not disclose the identity of individual persons, households, or businesses from whom the information was obtained, or whose characteristics, activities, or products the information is about. See 6 V.S.A. § 61.

**Section 6** Processing, Transferring and Selling, Recordkeeping, and Reporting Requirements for Processors

6.1. A processor is responsible for demonstrating compliance with the acceptable potency level for hemp products and/or hemp-infused products offered for sale or transfer.

6.2. A processor shall only use lipid, ethanol, or carbon dioxide (CO<sub>2</sub>) botanical extraction methods, solvent free mechanical extraction methods, or other extraction methods which the Agency pre-approves in writing. All other methods of botanical extraction, including use of butane, propane, hexane and other hydrocarbons is prohibited.

6.3. A processor shall not use synthetic cannabinoids in the production of any hemp product or hemp-infused product.

6.4. A processor shall only process hemp crops at registered processing sites.

6.5. A processor must notify the Agency in writing of any processing site closure within 10 business days.

6.6. A processor, at the time of processing, must assign a process lot number to each lot of hemp concentrate, hemp product, and/or hemp-infused product extracted or formulated by the processor.

6.7. A processor shall only transfer or sell hemp concentrate for the purpose of reformulation into hemp products or hemp-infused products to:

- (a) the grower of the hemp crop if the grower is also a processor, or
  - (b) to another processor.
- 6.8. For a minimum of three (3) years from the date of processing a process lot, a processor shall maintain the following records for each extracted hemp concentrate organized by process lot number:
- (a) Records of all hemp crop(s) received by harvest lot number including:
    - i. The name, address, and registration number of the grower for any amount of hemp crop transferred to the processor;
    - ii. Date(s) each hemp crop was received;
    - iii. Amount of hemp measured in pounds as received;
    - iv. Copies of sampling and testing records as required by Vermont Pre-Harvest Sampling Protocols and these Rules; and
    - v. Certificates of analyses from certified laboratories.
  - (b) Records of hemp crops the processor receives from out-of-state, including:
    - i. The name and address of the out-of-state grower for any amount of hemp crop received;
    - ii. The out-of-state grower registration number in the respective state;
    - iii. Date the hemp crop was received;
    - iv. Amount of hemp crop measured in pounds as received; and
    - v. Certificates of analyses for hemp crop potency.
  - (c) Certificates of analyses from certified laboratories organized by process lot number and detailing cannabinoid content for any hemp concentrate a processor produced.
- 6.9. For a minimum of three (3) years from the date of processing a process lot, a processor that formulates hemp products or hemp-infused products and offers a label guarantee, shall maintain the following records organized by hemp product or hemp-infused product process lot number:
- (a) Copies of records from harvest lots as outlined in Section 6.8 that are used to formulate each product;
  - (b) The standard operating procedure for formulating each product;
  - (c) Certificates of analyses from certified laboratories demonstrating the cannabinoid content of each product; and
  - (d) A copy of each product's label, as required in Section 11.
- 6.10. A processor of hemp products or hemp-infused products that offers no label guarantee of any specific quantity of cannabinoids in the product shall be required to maintain records of formulation, including certificates of analyses for the hemp concentrate, used in product formulation, but shall not be required to maintain records of certificates of analyses for every process lot of the finished product.
- 6.11. A processor shall make these records available to the Agency for inspection upon request.
- 6.12. When requested and in a format described by the Agency during the annual registration process, a processor shall provide the total dry weight (measured in pounds) of the hemp crop handled in the preceding year. This information shall be publicly available upon request provided it is presented in a form which does not disclose the identity of individual persons,

households, or businesses from whom the information was obtained, or whose characteristics, activities, or products the information is about. See 6 V.S.A. § 61.

**Section 7**     Testing Requirements for Growers

- 7.1. A grower must test hemp crops for compliance with these Rules.
- 7.2. A grower must test each harvest lot for potency levels to be reported on a dry weight basis, including reporting total theoretical tetrahydrocannabinol concentration.
- 7.3. A grower must test all harvest lots for the following substances:
  - (a) target pesticides established in the Cannabis Quality Control program, unless it is a certified organic crop; and
  - (b) heavy metals when the property was previously used for orchard crops or a land use other than farming as defined in the Required Agricultural Practices Rule, unless a recent soil test demonstrates that the heavy metals are within the action limits for soils as authorized in the Cannabis Quality Control Program.
  - (c) testing for other potential contaminants when the Agency of Natural Resources has approved the property for biosolid application.
- 7.4. All hemp crop testing required by these Rules shall be conducted by a certified laboratory. This requirement excludes soil tests for heavy metals.
- 7.5. A harvest lot complies with the acceptable potency level and contaminant action limits under these Rules when a certified laboratory's certificate of analysis demonstrates as follows:
  - (a) a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis,
  - (b) a total theoretical THC concentration that does not exceed one percent, and
  - (c) contaminant levels below the action limits for pesticides and heavy metals established in the Cannabis Quality Control program.
- 7.6. When a harvest lot does not satisfy the acceptable potency level the grower must dispose of or destroy the hemp crop in accordance with Section 14.
- 7.7. When a harvest lot does not satisfy the heavy metal and/or pesticide action limits established in the Cannabis Quality Control Program the grower must either mitigate or destroy the harvest lot. The harvest lot may not be sold as trim flower to the consumer.

**Section 8**     Testing Requirements for Processors

- 8.1. A processor must ensure that all hemp products and hemp-infused products comply with these Rules.
- 8.2. A processor must have all process lots tested according to Table 1 for potency, water activity, pesticides, heavy metals, mycotoxins, and bacterial and fungal contaminants by sample type.

Table 1, Testing Requirements

Sample type	potency	moisture or water activity	mycotoxins, bacterial and fungal	heavy metals	pesticides	Residual solvents
<b>Plant material</b>						
Trim flower	Note 1	Each process lot	Each process lot	Note 1	Note 1	N/A
<b>Concentrates</b>						
Liquids	Each process lot		Each process lot	Each process lot	Each process lot	Note 3
Solids	Each process lot		Each process lot	Each process lot	Each process lot	Note 3
<b>Infused products</b>						
Liquid-infused products (tinctures, water based)	Note 4		Note 2	Note 1 or 2	Note 2	N/A
Solid-infused products, edibles, tablets	Note 4		Note 2	Note 1 or 2	Note 2	N/A

Note 1: Testing completed for harvest lot is sufficient for showing compliance.

Note 2: Testing completed for trim flower or hemp concentrate is sufficient for showing compliance.

Note 3: Residual solvents are tested only if solvent-based extraction techniques are used.

Note 4: Please apply Section 8.3 (a) for potency.

8.3. A hemp product or hemp-infused product process lot complies with these Rules when the following terms apply:

- (a) a certified laboratory's certificate of analysis demonstrates that the product meets the acceptable potency level or the processor's formulation demonstrates compliance with the acceptable potency level, and
- (b) a certified laboratory's certificate of analysis demonstrates compliance with Section 8.2 and that contaminant levels are below action limits for pesticides, heavy metals, mycotoxins, and bacterial and fungal contaminants as established in the Cannabis Quality Control program.

8.4. When a hemp product or hemp-infused product does not meet the acceptable potency level and/or the required action limits, the product must be disposed of or destroyed in accordance with Section 14.

**Section 9 Reporting and Disposal, Destruction, or Mitigation Requirements**

- 9.1. If a harvest lot exceeds the acceptable potency level or the required action limits in the Cannabis Quality Control Program, then the following conditions apply:
- (a) The certified laboratory shall send the certificate of analysis containing the result and the testing request form within 24 hours of completing the harvest lot test to:
    - i. the Agency by certified mail or electronically to an individual identified by the Agency, and
    - ii. the registrant who requested the testing.
  - (b) The registrant, within 48 hours of receiving the certificate of analysis, shall provide the following information to the Agency by certified or electronic mail (to an Agency-identified individual):
    - i. a copy of the certificate of analysis for the harvest lot;
    - ii. a copy of the map used during the registration process depicting the harvest lot cultivation area; and
    - iii. the proposed action plan for disposal, destruction, or mitigation.
  - (c) Failure to notify the Agency within 48 hours as required may result in enforcement under Vermont law.
  - (d) A harvest lot exceeding the acceptable potency level shall not be processed into hemp concentrate or used to formulate hemp products or hemp-infused products. Concentrate, products or infused products created from such a harvest lot may result in the disposal or destruction of those concentrates or products.
- 9.2. The proposed action plan for disposal and destruction of harvest lots or process lots shall be reviewed and approved by the Agency prior to implementation.
- 9.3. The registrant is responsible for the full cost of disposal, destruction, and/or mitigation.

**Section 10** Requirements for Handling Hemp Crops, Hemp Products and Hemp-Infused Products

- 10.1. Registrants shall only handle hemp crops that have an acceptable potency level.
- 10.2. Registrants shall not formulate or sell a hemp product or hemp-infused product that exceeds the acceptable potency level.

**Section 11** Requirements for Labeling Hemp Products and Hemp-infused Products

- 11.1. All guaranteed hemp products or hemp-infused products produced in Vermont must be labeled and traceable to a certificate of analysis for all cannabinoid content label guarantees.
- 11.2. Registrants must label consumable hemp products and hemp-infused products in accordance with this section.
- 11.3. All label claims using the term "whole plant," "isolate," "full spectrum," "broad spectrum," and/or "distillate" shall comply with the applicable definition contained in these rules.
- 11.4. All labels for consumable hemp products or hemp-infused products grown or processed in Vermont must contain the following information:
  - (a) The name and principal mailing address of the processor of the hemp product or hemp-infused product;
  - (b) A statement that the product contains ingredients that are derived from "hemp;"
  - (c) An accurate statement of the quantity of the content in weight, measure, or numerical count;
  - (d) When offering a guarantee, the guaranteed amount of any listed cannabinoid contained in the product by serving size measured in milligrams, milliliters, or grams;
  - (e) A statement that the product contains THC, if applicable; and
  - (f) A process lot number.
- 11.5. If a product is sold as a dietary supplement and in compliance with federal Food and Drug Administration manufacturing standards and label requirements, those label requirements supersede this Rule's Section 11.4 (a)-(f) label requirements.

**Section 12** Vermont Hemp Products and Hemp-Infused Products

- 12.1. The Secretary establishes and adopts the Vermont Hemp brand under its authority in 6 V.S.A. Chapter 21.
- 12.2. Vermont Hemp is a hemp crop, hemp product, or hemp-infused product that satisfies the following standards and is certified by the Agency:
  - (a) Vermont Hemp is produced in Vermont as defined in Section 3 by registrants of the Vermont Hemp Program;
  - (b) Vermont Hemp is a hemp crop, hemp product, or hemp-infused product exclusively grown and processed in Vermont by registrants that demonstrate compliance with all requirements enumerated by the Secretary;
  - (c) Vermont Hemp is tested by a certified laboratory and proven to be compliant with the acceptable potency level and contaminant action levels; and

(d) Vermont Hemp is compliant with the Vermont Hemp Program's labeling requirements in Section 11.

12.3. Any registrant that wishes to use the Vermont Hemp brand must annually apply for certification using Agency-supplied forms and must meet all Agency requirements.

**Section 13** Inspection, Research and Record Reviews

13.1. The Agency shall conduct annual registrant inspections, which may or may not be at random, to ensure compliance with these Rules.

13.2. The Agency may inspect a registrant's premises, machinery, equipment, facilities, any crop during any growth phase, and/or any hemp product or hemp-infused product during processing or storage. The inspection may include collecting samples, taking photographs and/or video, talking to registrants and/or witnesses, and/or inspecting records. The inspection may also include inspecting equipment and/or vehicles used for growing, processing or transporting hemp crops, hemp products, and/or hemp-infused products, and taking any other reasonable measure to evaluate compliance with these Rules.

13.3. The Agency may inspect any retail location offering hemp products or hemp-infused products. This inspection may include taking samples of such products.

13.4. The Agency may use any hemp crop samples to conduct genetic testing and/or research the potential of taxonomic determinations of hemp cultivars or varieties grown.

**Section 14** Enforcement

14.1. Violations.

(a) If the Secretary determines that a registrant violated any provision of 6 V.S.A. Chapter 34 or these Rules, the Secretary may require corrective action, revoke the Agency's registration, issue and enforce a stop sale order, take administrative enforcement action, refer a matter to the Attorney General for civil enforcement, and/or refer a matter to law enforcement for potential criminal enforcement.

Examples of violations that will, at minimum, require corrective action are as follows:

- i. failure to provide a legal description of the land where hemp is produced;
- ii. failure to appropriately register with the Agency;
- iii. failure to produce *Cannabis sativa* L. that complies with the required acceptable potency level.

- (b) When instructed to correct a violation, the registrant shall:
  - i. propose a written corrective action plan to the Agency within 10 days of receipt of any notice of violation. The plan shall also include a proposed date for completion of the correction action plan;
  - ii. obtain written Agency approval for the corrective action plan once the plan is acceptable;
  - iii. comply with the approved corrective action plan; and
  - iv. report to the Secretary in writing every six months for the next two calendar years explaining how the registrant is complying with Chapter 34 and these Rules.
- (c) A registrant that negligently produces Cannabis sativa L. with a delta-9 tetrahydrocannabinol concentration that exceeds the acceptable potency level shall arrange for the Secretary to destroy or order the destruction of the hemp crop.
- (d) A person who negligently violates these Rules three times in a five-year period shall be ineligible to produce hemp for a period of five years beginning on the date of the third violation. The Secretary, for good cause shown, may choose to impose a different penalty.

**14.2. Other violations.**

If the Secretary determines that a registrant intentionally, willfully, and/or knowingly violated Chapter 34 or these Rules, the Agency will take more significant enforcement action than if the registrant made a good faith effort to comply with the law and these Rules.

**Section 15 Exemptions**

- 15.1. Sections 6, 7, 8, 9, and 11 of these Rules do not apply when the hemp product:
  - (a) is seed or seed oil for consumption and considered "Generally Recognized as Safe" by the United States Food and Drug Administration; or
  - (b) is not intended for consumption and will be used for fiber, building material, or animal bedding, and is not subject to the Secretary's order of destruction or stop sale order.

**Section 16 Severability**

The provisions of this rule are severable. If any provision of this rule is invalid, or if any application of this rule to any person or circumstance is invalid, the invalidity shall not affect any other provisions or applications which can be given effect without the invalid provision or application.

**Section 17 Effective Date**

**This rule shall become effective on its date of adoption.**

VERMONT **GENERAL ASSEMBLY**

## The Vermont Statutes Online

### **Title 6 : Agriculture**

#### **Chapter 034 : Hemp**

(Cite as: **6 V.S.A. § 561**)

#### **§ 561. Findings; intent**

(a) Findings.

(1) Hemp has been continuously cultivated for millennia, is accepted and available in the global marketplace, and has numerous beneficial, practical, and economic uses, including: high-strength fiber, textiles, clothing, biofuel, paper products, protein-rich food containing essential fatty acids and amino acids, biodegradable plastics, resins, nontoxic medicinal and cosmetic products, construction materials, rope, and value-added crafts.

(2) The many agricultural and environmental beneficial uses of hemp include: livestock feed and bedding, stream buffering, erosion control, water and soil purification, and weed control.

(3) The hemp plant, an annual herbaceous plant with a long slender stem ranging in height from four to 15 feet and a stem diameter of one-quarter to three-quarters of an inch is morphologically distinctive and readily identifiable as an agricultural crop grown for the cultivation and harvesting of its fiber and seed.

(4) Hemp cultivation will enable the State of Vermont to accelerate economic growth and job creation, promote environmental stewardship, and expand export market opportunities.

(5) Section 10113 of the Agriculture Improvement Act of 2018, Pub. L. No. 115-334 authorizes the growing, cultivation, and marketing of industrial hemp under a U.S. Department of Agriculture approved State program.

(b) Purpose. The intent of this chapter is to establish policy and procedures for growing, processing, testing, and marketing hemp and hemp products in Vermont that comply with federal law so that farmers and other businesses in the Vermont agricultural industry can take advantage of this market opportunity. (Added 2007, No. 212 (Adj. Sess.), § 2; amended 2013, No. 84, § 1; 2017, No. 143 (Adj. Sess.), § 5; 2019, No. 44, § 1, eff. May 30, 2019.)

VERMONT **GENERAL ASSEMBLY**

## The Vermont Statutes Online

### Title 6 : Agriculture

#### Chapter 034 : Hemp

(Cite as: 6 V.S.A. § 564)

#### § 564. State Hemp Program; registration; application; administration

(a) The Secretary shall establish and administer a State Hemp Program to regulate the growing, processing, testing, and marketing of industrial hemp and hemp products in the State.

(b)(1) A person shall register annually with the Secretary as part of the State Hemp Program in order to grow, process, or test hemp or hemp products in the State. A person shall apply for registration or renewal of a registration on a form provided by the Secretary. The application shall be accompanied by the fee required under section 570 of this title. The application or renewal form shall include:

(A) the name and address of the person applying for or renewing a registration;

(B) whether the person is applying to grow, process, or test hemp or hemp products;

(C) for a person applying as a grower:

(i) the location and acreage of all parcels where hemp will be grown;

(ii) a statement that the seeds obtained for planting are of a type and variety that do not exceed the federally defined tetrahydrocannabinol concentration level of hemp;

(D) for a person applying as a processor, the location of the processing site;

(E) for a person applying to test hemp or hemp products, the location of the site where testing will occur and any proof of certification required by the Secretary; and

(F) any additional information that the Secretary may require by rule.

(2) The Secretary may verify the information provided in the application or renewal form under subdivision (1) of this subsection and on any maps accompanying the application or renewal form and may request additional information in order to perform a review of an application for registration or renewal.

(c) The Secretary may deny an application for registration or renewal if the applicant:

(1) does not provide all the information requested on the application or renewal form;

(2) fails to submit the fee required under section 570 of this title;

(3) fails to submit additional information requested by the Secretary under subsection (a) of this section; or

(4) does not, as determined by the Secretary, satisfy the requirements of section 10113 of the Agriculture Improvement Act of 2018, Pub. L. No. 115-334 for participation in the

Program.

(d) A person registered under this section may purchase or import hemp genetics from any state that complies with the federal requirements for the cultivation of industrial hemp.

(e) A person registered with the Secretary under this section to grow, process, or test hemp crops or hemp products shall allow the Secretary to inspect hemp crops, processing sites, or laboratories registered under the State Hemp Program. The Secretary shall retain tests and inspection information collected under this section for the purposes of research of the growth and cultivation of industrial hemp.

(f) The name and general location of a person registered under this section shall be available for inspection and copying under the Public Records Act, provided that all records produced or acquired by the Agency of Agriculture, Food and Markets related to the location of parcels where hemp will be grown, including coordinates, maps, and parcel identifiers, shall be confidential and shall not be disclosed for inspection and copying under the Public Records Act. (Added 2007, No. 212 (Adj. Sess.), § 2; amended 2013, No. 84, § 1; 2017, No. 143 (Adj. Sess.), § 5; 2019, No. 44, § 1, eff. May 30, 2019.)

VERMONT **GENERAL ASSEMBLY****The Vermont Statutes Online****Title 6 : Agriculture****Chapter 034 : Hemp**

(Cite as: **6 V.S.A. § 566**)

**§ 566. Rulemaking authority**

(a) The Secretary may adopt rules to provide for the implementation of this chapter and the Program authorized under this chapter, which may include rules to:

(1) require hemp to be tested during growth for tetrahydrocannabinol levels;

(2) authorize or specify the method or methods of testing hemp, including, where appropriate, the ratio of cannabidiol to tetrahydrocannabinol levels or a taxonomic determination using genetic testing;

(3) require inspection and supervision of hemp during sowing, growing season, harvest, storage, and processing; and

(4) require labels or label information for hemp products in order to provide consumers with product content or source information or to conform with federal requirements.

(b) The Secretary shall adopt rules establishing how the Agency of Agriculture, Food and Markets will conduct research within the Program for industrial hemp.

(c) The Secretary shall adopt rules establishing requirements for the registration of processors of hemp and hemp-infused products. (Added 2007, No. 212 (Adj. Sess.), § 2; amended 2013, No. 84, § 1; 2017, No. 143 (Adj. Sess.), § 5; 2019, No. 44, § 1, eff. May 30, 2019.)

VERMONT **GENERAL ASSEMBLY****The Vermont Statutes Online****Title 6 : Agriculture****Chapter 034 : Hemp**(Cite as: **6 V.S.A. § 570**)**§ 570. Registration fees**

(a) A person applying for a registration or renewal under section 564 of this title annually shall pay the following fees:

(1) for an application to grow less than 0.5 acres of hemp for personal use: \$25.00;

(2) for an application or renewal of registration to grow or process hemp seed for food oil production, grain crop, fiber, or textile: \$100.00;

(3) except as provided for in subdivision (4) of this subsection, for an application or renewal of registration to grow, process, or grow and process hemp commercially for floral material production, viable seed, or cannabinoids, including cannabidiolic acid (CBDA), cannabidiol (CBD), cannabinol (CBN), cannabigerol (CBG), cannabichromene (CBC), or tetrahydrocannabivarin (THCV), the following fee based on the greater of the number of acres planted or the weight of hemp or viable seed processed:

Acres of Hemp Grown or Fee

Pounds of Hemp Processed or

Viable Seed Cultivated

Annually for Floral Material or

Cannabinoids

Less than 0.5 acres or less than 500 pounds \$100.00

0.5 to 9.9 acres or less than 10,000 pounds \$500.00

10 to 50 acres or less than 50,000 pounds \$1,000.00

Greater than 50 acres or greater than

50,000 pounds \$3,000.00

(4) for an application or renewal of registration to operate exclusively within an indoor facility in order to grow, process, or grow and process hemp commercially for floral material production, viable seed, or cannabinoids, including cannabidiolic acid (CBDA), cannabidiol (CBD), cannabinol (CBN), cannabigerol (CBG), cannabichromene (CBC), or tetrahydrocannabivarin (THCV), the following fee based on the size of the indoor facility:

(A) for a facility with an area of 500 square feet or less: \$1,000.00; and

(B) for a facility with an area greater than 500 square feet: \$2,000.00.

(5) for an application or renewal of registration as a laboratory certified to conduct testing of hemp and hemp products as part of the Agency's cannabis control program: \$1,500.00.

(b) A person registered to grow, process, or grow and process hemp for floral material production, viable seed, or cannabinoids shall not grow more acres of hemp per year than the amount identified in a registration without first notifying the Secretary and paying an additional registration fee if necessary under subsection (a) of this section.

(c) The registration fees collected under this section shall be deposited in the special fund created by subsection 364(e) of this title and shall be used for the administration of the requirements of this chapter. (Added 2019, No. 44, § 1, eff. May 30, 2019.)

VERMONT **GENERAL ASSEMBLY**

## The Vermont Statutes Online

### Title 6 : Agriculture

#### Chapter 021 : Grades And Standards For Farm Products

(Cite as: 6 V.S.A. § 179)

#### § 179. Regulations; fees

(a) The Secretary may adopt rules and regulations for carrying out the purposes of this chapter.

(b) The Secretary may charge fees for inspection of farm and agricultural commodities or storage facilities and for the establishment of reasonable tolerances incident to proper grading of agricultural products. Any inspection fees charged pursuant to this section shall be sufficient to recover the Agency's costs of inspection, including payment for the inspector's time, and shall be retained by the Agency to reimburse these expenses. In addition, the Secretary may accept fees collected by or for producer organizations for promotional activities. Such fees shall be retained by the Secretary and segregated into separate producer accounts for use to promote agricultural products. (Amended 1975, No. 217 (Adj. Sess.), § 3; 1989, No. 257 (Adj. Sess.), § 2; amended 2003, No. 42, § 2, eff. May 27, 2003.)



# Proposed Rules Postings

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## Search Rules

### Deadline For Public Comment

Deadline: Jul 05, 2019

Please submit comments to the agency or primary contact person listed below, before the deadline.

### Rule Details

Rule Number:	19P045
Title:	Vermont Hemp Rules
Type:	Standard
Status:	Proposed
Agency:	Agency of Agriculture, Food and Markets
Legal Authority:	6 V.S.A. § 564; 6 V.S.A. § 566; 6 V.S.A. § 179
Summary:	This rule establishes registration requirements for cultivators and processors of hemp and hemp infused products; requirements for testing for contaminants and potency including establishing the ratio of cannabidiol to tetrahydrocannabinol for a crop to qualify as hemp, and using genetic testing to make a taxonomic determination that a crop is

considered hemp; requirements for record keeping, and labeling of products for consumer protection and quality control; that the Agency will collect information from registrants for research purposes and that the information is protected under 6 V.S.A. Section 61; a Vermont brand and grades.

**Persons Affected:**

Individuals and companies that will grow and process hemp, certified laboratories, consumers, law enforcement, State of Vermont, bank and insurance industries, USDA Agricultural and Marketing Service and Farm Service Agency, University of Vermont Extension Service, technical service providers, landowners.

**Economic Impact:**

These rules may impact small scale growers and processors producing small batches of products containing cannabinoids derived from hemp crops. The necessary record keeping, testing and labeling requirements could be considered onerous or costly. The potential costs of compliance testing can run between \$50 and \$100 per hemp harvest lot and process lot. However, the industry and consumers will benefit from rules that set standards and expectations, resulting in Vermont products that are compliant with delta-9 THC potency requirements and free from contaminants.

**Posting date:**

May 22,2019

## Hearing Information

### Information for Hearing # 1

Hearing date: 06-27-2019 1:00 PM   
 Location: Brandon Town Hall  
 Address: 1 Conant Square  
 City: Brandon  
 State: VT  
 Zip: 05733  
 Hearing Notes:

## Contact Information

### Information f

Level: Primary  
 Name: Cary Giguere  
 Agency: Agency of Agriculture, Food and Markets

Address: 116 State Street  
City: Montpelier  
State: VT  
Zip: 05620-2901  
Telephone: 8028286531  
Fax: 8028282361  
Email: [cary.giguere@vermont.gov](mailto:cary.giguere@vermont.gov)  
[SEND A COMMENT](#)  
Website <https://agriculture.vermont.gov/public-health-agriculture-resource-r>  
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## Keyword Information

Keywords:

hemp program  
agriculture  
hemp processor  
cannabinoid

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Vermont Lawyer ( <a href="mailto:hunter.press.vermont@gmail.com">hunter.press.vermont@gmail.com</a> )	Attn: Will Hunter

**FROM:** Louise Corliss, APA Clerk

**Date of Fax:** May 21, 2019

**RE:** The "Proposed State Rules " ad copy to run on

**May 30, 2019**

**PAGES INCLUDING THIS COVER MEMO:**

**4**

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If you have questions, or if the printing schedule of your paper is disrupted by holiday etc. please contact Louise Corliss at 802-828-2863, or E-Mail [louise.corliss@vermont.gov](mailto:louise.corliss@vermont.gov), Thanks.

## PROPOSED STATE RULES

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By law, public notice of proposed rules must be given by publication in newspapers of record. The purpose of these notices is to give the public a chance to respond to the proposals. The public notices for administrative rules are now also available online at <https://secure.vermont.gov/SOS/rules/>. The law requires an agency to hold a public hearing on a proposed rule, if requested to do so in writing by 25 persons or an association having at least 25 members.

To make special arrangements for individuals with disabilities or special needs please call or write the contact person listed below as soon as possible.

To obtain further information concerning any scheduled hearing(s), obtain copies of proposed rule(s) or submit comments regarding proposed rule(s), please call or write the contact person listed below. You may also submit comments in writing to the Legislative Committee on Administrative Rules, State House, Montpelier, Vermont 05602 (802-828-2231).

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Vermont Residential Building Energy Standards (RBES).

Vermont Proposed Rule: 19P041

AGENCY: Department of Public Service

CONCISE SUMMARY: The provisions of these standards regulate the design of building envelopes for adequate thermal resistance and low air leakage and the design and selection of mechanical, ventilation, electrical, service water-heating and illumination systems and equipment which will enable effective use of energy in residential building construction. It is intended that these provisions provide flexibility to permit the use of innovative approaches and techniques to achieve effective utilization of energy.

FOR FURTHER INFORMATION, CONTACT: Kelly Launder, Department of Public Service, 112 State Street, Montpelier, VT 05620 Tel: 802-828-4039 Email: [kelly.launder@vermont.gov](mailto:kelly.launder@vermont.gov) URL: <https://publicservice.vermont.gov>.

FOR COPIES: Allison Wannop, Department of Public Service, 112 State Street Montpelier, VT 05620 Tel: 802-828-5543 Email: [allison.wannop@vermont.gov](mailto:allison.wannop@vermont.gov).

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Vermont Commercial Building Energy Standards (CBES).

Vermont Proposed Rule: 19P042

AGENCY: Department of Public Service

CONCISE SUMMARY: The provisions of these standards regulate the design of building envelopes for adequate thermal resistance and low air leakage and the design and selection of mechanical, ventilation, electrical, service waterheating and illumination systems and equipment which will enable effective use of energy in commercial building construction. It is intended that these provisions provide flexibility to permit the use of innovative approaches and techniques to achieve effective utilization of energy.

FOR FURTHER INFORMATION, CONTACT: Barry Murphy, Department of Public Service, 112 State Street, Montpelier, VT 05620 Tel: 802-828-3183 Email: [barry.murphy@vermont.gov](mailto:barry.murphy@vermont.gov) URL: <https://publicservice.vermont.gov>.

FOR COPIES: Allison Wannop, Department of Public Service, 112 State Street Montpelier, VT 05620 Tel: 802-828-5543 Email: [allison.wannop@vermont.gov](mailto:allison.wannop@vermont.gov).

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## Vermont Wetland Rules.

Vermont Proposed Rule: 19P043

AGENCY: Agency of Natural Resources

CONCISE SUMMARY: This rule amendment proposes to classify the Beaver Meadows Wetland Complex, in Ripton Vermont, as a Class I wetland. The proposed Class I change appears in Appendix A of the Rule.

FOR FURTHER INFORMATION, CONTACT: Laura Lapierre, Agency of Natural Resources Main Building, 2<sup>nd</sup> Floor, One National Life Drive, Montpelier, VT 05620-3522 Tel: 802-490-6177 Fax: 802-828-1544 Email: [laura.lapierre@vermont.gov](mailto:laura.lapierre@vermont.gov) URL: <https://dec.vermont.gov/watershed/laws#rulemaking>.

FOR COPIES: Hannah Smith, Agency of Natural Resources, One National Life Drive, Davis 2, Montpelier, VT 05620-3802 Tel: 802-461-0818 Fax: 802-828-1544 Email: [hannah.smith@vermont.gov](mailto:hannah.smith@vermont.gov).

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## 2019 Vermont Materials Management Plan: Reducing Solid Waste and Increasing Recycling and Composting.

Vermont Proposed Rule: 19P044

AGENCY: Agency of Natural Resources

CONCISE SUMMARY: The intended impact of the 2019 Materials Management Plan (MMP or Plan) is to reduce Vermont's waste generation and improve the state's recycling and composting rates. It also strives to provide convenient options for safe disposal of household hazardous waste, rather than being landfilled. This 2019 MMP amends the previous Plan, which was adopted in 2014, and changes the structure and layout of the previous Plan to make it more concise. Sections include: Introduction, Statutory Authority, Vermont's Waste, Plan Priorities, Market and Facilities Assessment, Solid Waste Implementation Plan Requirements and Approval Process, and Performance Standards for both the Agency and municipal solid waste management entities (SWMEs) for the five-year Plan period.

FOR FURTHER INFORMATION, CONTACT: Cathy Jamieson Agency of Natural Resources 1 National Life Drive, Davis 1, Montpelier, VT 05620 Tel: 802-522-5938 Fax: 802-828-1011 Email: [cathy.jamieson@vermont.gov](mailto:cathy.jamieson@vermont.gov) URL: <https://dec.vermont.gov/waste-managment/solid>.

FOR COPIES: Josh Kelly, Agency of Natural Resources, 1 National Life Drive, Davis 1 Montpelier, VT 05620 Tel: 802-522-5897 Fax: 802-828-1011 Email: [josh.kelly@vermont.gov](mailto:josh.kelly@vermont.gov).

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## Vermont Hemp Rules

Vermont Proposed Rule: 19P045

AGENCY: Agriculture, Food & Markets

CONCISE SUMMARY: This rule establishes registration requirements for cultivators and processors of hemp and hemp infused products; requirements for testing for contaminants and potency including establishing the ratio of cannabidiol to tetrahydrocannabinol for a crop to qualify as hemp, and using genetic testing to make a taxonomic determination that a crop is considered hemp; requirements for record keeping, and labeling of products for consumer protection and quality control; that the Agency will collect information from registrants for research purposes and that the information is protected under 6 V.S.A. Section 61; a Vermont brand and grades.

FOR FURTHER INFORMATION, CONTACT: Cary Giguere; Vermont Agency of Agriculture, Food and Markets;

116 State Street, Montpelier, VT 05620-2901; Tel: 802-828-6531 Fax: 802-828-2361 Email:  
[cary.giguere@vermont.gov](mailto:cary.giguere@vermont.gov) URL: <https://agriculture.vermont.gov/public-health-agriculture-resource-management-division/hemp-program/hemp-program-rule>.

FOR COPIES: Stephanie Smith; Vermont Agency of Agriculture, Food and Markets; 116 State Street,  
Montpelier, VT 05620-2901 Tel: 802-828-1732 Fax: 802-828-2361 Email: [stephanie.smith@vermont.gov](mailto:stephanie.smith@vermont.gov)

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