

September 6, 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%;

- 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. VAAFMM 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 FFDCFA

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



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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

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 use of dispensaries licensed under 18 V.S.A. chapter 86, to mitigate a hemp crop and as an outlet for excess THC was removed under Act 44, therefore Section 14 will be amended accordingly. The Agency will define 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.