VERMONT

AGENCY OF AGRICULTURE, FOOD & MARKETS

Response summary for Cannabis Quality Control Program document 7-10-20; finalized 8-21-20

Section 1 Overview

1. Section 1.1 a.-d., What is meant by "testing protocols" does it mean standard operating procedures, sampling methods, frequencies, testing requirements?

   Section 1.1 a.-d. is directly from Vermont law and outlines that the Agency must establish a quality control program that includes testing, setting action limits for contaminants, and to certify laboratories. While the Agency is not specifically establishing testing protocols within this the cannabis quality control program it does outline that validated methods are expected, with standard operating procedures. A certified lab is expected to adopt and follow a Quality Management System (QMS) or a Quality System Management (QSM).

2. Section 1.1 d., This entire document only pertains to "certifying testing labs…" subsection?

   This document is a companion document to the Vermont Hemp Rules (the rules). The rules, which will become effective on May 21, 2020 outline testing requirements for crops, concentrates, and products, and includes the regulations regarding label guarantees. The certified lab document supports these requirements and puts in place the program to certify labs.

3. Section 1.1 a.-d., Do hemp concentrates fall under these rules, as it is listed as an intermediate in the definitions but has action levels in the tables?

   Yes, hemp concentrate, a process intermediate, is included in the Vermont Hemp Rules (effective May 21, 2020). In order to protect public health, safety and welfare testing is required on hemp concentrate as outlined in both the Vermont Hemp Rules and in the proposed lab certification document. The Agency set action limits for concentrates because it is a commodity added to numerous end products.

Section 2 Definitions

1. Section 2.14, How is dry weight determined?

Dry weight for plant material is defined as < 13 %; labs must establish a method for determining dryness referencing established methods. AOAC is currently working on methods for dryness for harvested hemp for release later in 2020, which certified labs should monitor (see Program section 4.2., changes that improve recoveries). AOAC recently issued guidelines on drying hemp (to address current USDA sampling process of sending in 'wet' material to labs). AOAC official method 2018.11 (4/2020) now includes a dry weight procedure (100C for 5 hours in a vacuum oven at < 5 torr).

2. Section 2.23, Should a reference material be a “known” homogeneity? (Unknown homogeneity used in the document). Another comment asked if Certified or Standard Reference Material (CRM, SRM) would be appropriate here.

Reference material was confusing and removed from the document. CRM and SRM are not defined as they are not used in the document.

3. Sections 2.22 & 2.23 (and Hemp Rules Section 3 Definitions (3.38)), Questions the definition of Processor lot number & Process Lot. In particular, who is the processor and whose process lot number is required to be on the final product (Hemp Rule Section 11.4.(f)) after a series of formulations?

The processor who extracts the biomass must give the concentrate their unique processor number. Companies who make products using this concentrate can create their own lot/process number, but it must be traceable to the original process lot

4. Section 2.29 Total THC, USDA indicates that d9-THC can be determined on post decarboxylated samples; does the Agency have a position on this approach?

The Agency had required that THCA and CBDA be reported on a CoA, which would have required LC analysis or GC analysis (with derivatization). The Agency will allow postdecarboxylation results for compliance results (as allowed by USDA IFR) and clarify THCA and CBDA acid requirements for reporting in section 6.9. Definitions were added to clarify decarboxylation, in section 2. A compliant crop must meet the Vermont Hemp Rule compliance limits for d9-THC (0.3 %) with the additional limitation (1.0%) for total THC. Decarboxylated sample results must be clearly labeled on the CoA.

Section 3 Application

1. Section 3.1, Request to define the Agency.

Agency has been clarified in section 3.1 and added to the definitions section (2).

2. Section 3.1, Where do we get an application?

The Agency has not yet made the application available, but a draft of the application form is included with this stakeholder review material.

3. Section 3.4, Are site visits performed as verification or part of application? Will recertification require another visit? Does the Agency plan to perform unannounced visits?

The Agency may perform a site visit for initial certification of the lab. Recertification site visits may be done if needed to assess deficiencies or added competencies. Site visits verify facilities and processes outlined in the QSM (or QMS) plan, as well allow for clarification of QSM documentation. Accreditation site visits may be used for this verification. The Agency has no plans for unannounced visits, but unannounced visits can be done as a part of investigations.

4. Section 3.5.a.(now 4.1.b), How is the Agency documenting “demonstrating adherence to ISO…” (as an alternative to accreditation) and is the Agency qualified to assess this?

The Agency is replacing "documentation demonstrating adherence to ISO…" with "The laboratory is working towards/ has applied for an ISO 17025 based accreditation" in section 4.1.b, and with recognized resources for methods and validations listed in section 4.2. The Agency will review lab qualifications but will not audit or accredit. Methods must still be validated, and SOPS written per section 4.2. In the application for laboratory certification, the ISO adherence statement was changed to an attestation including ISO/IEC 17025 based formats are followed for all hemp testing.

5. Section 3.3.g, Proficiency standards- The Agency asked for proficiency standard results if available- a response states they may not be results for hemp matrix.

The Agency still wants to see the latest round of proficiency tests in areas that the lab is applying for certification. These results document the lab's capability for the parameters tested, but not necessarily the hemp matrix.

6. Section 3.7, "A person registered with the Secretary to test hemp shall allow inspection of the lab" – The respondent thinks this should be "A lab registered…".

This was changed to "A laboratory certified with the Agency…" and the reasons for inspection were added: certification, random inspections, and investigations.

7. Section 3.3.b., Can you please provide more detail on what the Quality Assurance Manual should entail? We currently adhere to ISO/IEC17025 and they do not require a QA manual. Is this something that we will have to put together in addition to SOPs and ISO documentation?

This was changed to include "or a system of documenting performance of the laboratory's Quality Control System" to reflect ISO 17025 (2017 version) changes to QA manual requirements. The lab must document their Quality Management System (or Quality System, or QSM). The Association of Public Health Laboratories (APHL) is one source for writing a quality manual (see reference section 9).

8. Section 3.4, A request for information about what the additional charges for site visits may be. Is it just the cost of travel? Is there a flat fee or daily fee…? The application form states, "not to exceed costs," which makes me think that it's just the cost of travel.

Additional charges have been eliminated; the Agency reserves the right to follow protocols for fees charges for repeated corrective visits.

9. Section 3.5, I know that it's in the hemp rule, so maybe this is set in stone, but it seems like having all certifications expire on December 31st is going to make a lot of work for you in December! Another questions if reapplication is required in January, if certification is granted in August.

The Agency has changed this date to a "rolling" registration of one year.

10. Section 3.8 Reciprocal State certifications, can a certified lab apply for Vermont certification of a test performed by an out of State partner lab?

No, this subcontracting (or using affiliated labs for testing) is not allowed by the program. Labs analyzing compliance samples for the Cannabis Quality Control Program must be certified for the tests they are issuing CoAs for.

11. Section 4.1.b, As the Lab Certification Program is new to Vermont for the Hemp Industry, the recommended guideline to allow labs to work towards accreditation makes sense. This lab also noted that accreditation was a several month process, that would require time, resources, and money.

The Agency will allow non-accredited labs to apply for certification, with the requirements for section 4 to be met. There is a reduced scope of testing allowed for non-accredited labs, in section 4.1.b.

Section 4 Standards for Laboratory Certification

1. Section 4.1.b., same question as section 3.5.a. above (demonstration adherence to ISO).

   This is addressed above for section 3.5.a.

2. Section 4.2 (changed to 4.3) Proficiency standards questioned "assist the Agency with proficiency testing"? In addition, a question if the State has sponsored a proficiency testing scheme? They go on to suggest that it would be interesting to have the Agency do a round robin proficiency test as a pilot study.

   Changed "assist the Agency with" to "participate in" proficiency testing. The Agency has not set up a proficiency test for hemp.

3. The Agency added language in section 4.2.c1.b, "All laboratories must follow updated industry and standard methods for testing" since testing methods are still being developed for hemp. For example, industry updates for dryness testing and homogenization grinding for improved cannabinoid recoveries need to be monitored.

4. Section 4.3 comment on proficiency testing, "Emerald Scientific Test; well intentioned, but it's very expensive...and the acceptance ranges …are really wide."

Emerald Scientific seems to be one of the few providers for all testing areas of hemp; this limits the scope of hemp proficiency testing that is commercially available. The Standards acknowledge this lack of tests in section 4.3 by stating "as proficiency tests become available".

5. Section 4.2, Is the Agency making the distinction between method validation and methods verification?

Validation is typically done when accepted methods are unavailable, or accepted methods are modified. Verification is typically done using accepted (official, approved) methods that have been validated by other labs. The Agency is requesting referenced methods and protocols used by the lab in the application (analytical methods worklist). The Agency lists recognized agencies in section 4.2, and suggested references in section 9.

Section 5 Quality Management System

1. Section 5.1.a, Is a QA manual required?

Yes, the manual the Agency requires, documents the labs Quality Management System (or Quality System, or QSM). This manual may be called a Quality Manual, QA Manual, or other. All accredited labs must have documentation of their QMS. The Association of Public Health Laboratories (APHL) is one source for writing a quality manual (see reference section 9).

2. Section 5.1 for validation, a comment recommends removing LOD since it cannot be validated, as LOQ or Limit of Determination are more appropriate. They also recommend AOAC Appendix K as a reference document.

   LOD was eliminated from the document and Appendix K was added as a reference.

3. Section 5.1 for Quality Control Samples, suggests that these samples should be matrix samples when possible, and control limits be 95% C.I.

   The document has left these "as is"; allowing the laboratory to use accreditation or referenced documents to build their own Quality Management System.

Section 6 Certificate of Analysis (CoA), Submission of Samples, and Documentation

1. Section 6.1, The draft document initially stated that only certified labs could issue COAs; results from non-certified labs would be "reports". Labs want to issue results in their format.

The Agency changed 6.1 to state "Only Certificates of Analysis (CoAs), issued by a laboratory certified by the Cannabis Quality Control Program, will be accepted as proof of compliance with the Vermont Hemp Rules. A result issued by a laboratory that is not certified by the Cannabis Quality Control Program to conduct testing in that area, shall not be considered a certified result nor accepted as proof of compliance with the Vermont Hemp Rules."

2. Section 6.2, Do farmers/producers have to send documents to the lab, and the lab track them? Where do we find these forms?

Yes, a farmer must send in a copy of the pre-harvest sampling form that is available on the Agency website along with the request for analysis/test, when samples are submitted to a lab. The pre-harvest sampling form documents the sample origin and helps identify the plant material. A request for analysis/test is a form developed by the certified laboratory, which may also serve as the CoC. The laboratory retains this documentation for all its samples and analyses, which can be done electronically.

3. Section 6.6. Does dry weight mean corrected to zero or 13%, (the definition in section 2) implies 13%)?

To determine hemp dry weight, a lab follows a validated drying method (to a value under 13 %); this dry weight is used in the final calculation for chemical reporting levels. AOAC is developing

method guidance on the drying of harvested hemp crops, which a laboratory may choose to adopt and incorporate into its SOPs.

4. Sections 6.5 and 6.9 The reviewer questions what "a COA shall contain:" including the photo portion. The reviewer suggests that for some of the COA contents the onus should be put back on the farmer. A similar question, what is the minimal content requirement of a CoA?

The required information in a CoA is found in new sections 6.5 and 6.9, including additional requirements for harvest lots and trim flower process lots, hemp products and hemp infused products, and hemp concentrates. All optional information including the photo have been removed from the contents of a CoA.

Section 7 Reporting by Certified Laboratories

1. Section 7.1 (and the lab application), regarding results exceeding action limits, questions if sharing results with the Agency is a privacy breach with the client. Another comment that this requirement (also in the hemp rule section 9.1.a) seemed burdensome to the certified lab, with added liability/ responsibility. Suggested that the burden should be on the grower to report to the Agency.

Reporting results to VAAFM is a requirement of the Vermont Hemp Rule in Section 9.1 for a harvest lot that exceeds the acceptable potency level or the required action limits. Laboratories that decide to become certified by VAAFM to conduct testing for purposes of compliance will be required to report their exceedance results to VAAFM. Certified laboratories are also required to report results to the registrant that requested testing, and the registrant has the responsibility to report to VAAFM, as well. Laboratories that choose not to become certified laboratories, their results will not be used for the purposes of compliance with the Vermont Hemp Rules would not be required to report their results.

2. Section 7.1, Asks if out of compliance reporting only applies to Vermont registered growers and processors? They also question if there is a precedent for this required reporting, including potency and contaminants?

Only Vermont registered hemp growers and processors need to send non-compliant CoAs to the Agency. (Compliancy requirements are listed in the Hemp Rule sections 7.5 and 8.3.) Potency compliance is required by State and Federal laws. The Agency will document non-compliant products, and review the destruction plans as part of the Hemp Rule section 9.2.

3. Section 7.1, Is it intended that the clock for the 24 hour requirement start once the result is obtained or confirmed. What about retesting, resampling, or confirmatory analysis by another lab?

Reporting to the Agency is to be within 24 hours from the time the CoA is issued. Laboratories need to follow their protocols regarding retesting or confirmatory analysis. If a crop has not been harvested, field resampling may be done. CoAs should be issued for all samples where testing has been completed. All non-compliant CoAs for harvest lots must be sent to the Agency; retesting which shows compliancy should also be sent to the Agency.

Section 8 Certified Laboratory Deficiencies- no comments.

Section 9 References – no comments.

Section 10 Tables

Table 1 sampling requirements

1. For Solids, should the sampling scheme "Mix material if uniform" be written as "Mix material if not uniform"?

No, the document refers to a product of uniform size/type of blended solids, that typically stay in the container for mixing; while non-uniform solid (plant) material may require a representative sampling plan, mixing and grinding. Changed to "Mix uniform material in a product container".

2. Sampling guidance slightly blurs the lines between submitters and lab responsibility for sampling. Is there an expectation that certified labs will play a role in product specification? The commenter added references to Good Lab Practices (GLP) and Food and Drug Administration (FDA) guidelines.

The purpose of Table 1 is for the lab to follow documented plans to obtain a representative sample. Submitters of samples are responsible for taking and sending representative samples to the lab; the lab is responsible for collecting pre-harvest sampling forms from growers. No expectation by the Agency for lab product specification development. There are hemp rule requirements for processors that an SOP be maintained for each product formulation (section 6.9.b). Sampling references form recognized sources are allowed; the document list AOAC recommendations from their approved hemp method 2019.003. Because of the multiple sources for sampling, the table was changed from "Sampling Requirements" to "Sampling Guidance".

Table 2 Testing requirements

1. Note 5, Why are heavy metals required when an orchard crop was grown?

Orchards may use metals for biocides and insecticides. The Agency requires a soils test, or metals testing of hemp and hemp products.

2. Notes 5 and 6, Why not test all crops for metals, and organic producers for pesticides- otherwise we are taking someone's word and not accounting for pesticide drift.

The Agency will maintain requirements, see 1 above regarding metal testing for former orchards. Certified organic crops do not need to be tested for pesticides; drift and inappropriate use is enforceable under the Agency's pesticide program. In addition, certified organic farms must meet annual testing requirements for NOFA and other organizations.

3. Note 7, is not referenced in Table 2. Another question on note 7, should the lab request land use information form the grower, to be sure "other contaminants" need to be analyzed?

This additional note is from the Hemp Rule for growers using biosolid applied properties. Land use is a grower's responsibility, to ensure proper land use and testing is done.

4. Residual Solvents required for concentrates, the comment suggests requiring testing for all solvents used in the manufacturing process (cleaning, extraction, refinement).

The Agency requires this analysis only when solvents are used in the extraction process. Several lab solvents that have industry limits, were added to the parameter list- see Table 8 comments.

Table 3 Potency parameters and limits

1. Questions on product label values (requiring within 10% of label value). One suggestion is to reduce this to 5%. Another suggestion using "and not to exceed 1%" for Total THC product labelling.

   The document uses ± 10% of labelled values to include a diverse group of infused products including baked goods. If a Total THC value is reported, it must be within 10% of the labelled amount; and to be compliant < 1 % Total THC by weight of the product.

2. The reviewer asks if in the note (*) "concentrations" should be changed to concentrates. They also ask if the final statement "Hemp concentrates are not hemp products or hemp infused products" is correct.

   The note was changed to concentrates. The final statement is correct because hemp concentrates are not finished end consumer products.

Table 4 Moisture parameters and limits

1. Should the water activity (Aw) action limit be set lower than 0.70? Microbial growth is completely inhibited at an Aw of < 0.6, and I've seen 0.65 as a common action limit (see ASTM D8196-18).

   The literature states under 0.70 is the practical level at which yeasts and molds growth stops, while pathogenic bacteria stop growing at < 0.87. The Agency will update this level to 0.65 to cover the measurement uncertainty of Aw at 0.70, and to mirror other state action levels.

Table 5 Microbiological parameters and limits

1. Two respondents expressed concern that action limits were set below several recommendations, and most crops would not pass at this level. In addition, some

Vermont approved natural pesticides use “helpful” bacteria that might be detected during testing.

The action levels for Total Aerobic Microbial, and Total Combined Yeast and Mold counts were changed to American Herbal Pharmacopoeia recommendations (a recognized industry source), which aligns with several other State’s action levels for cannabis.

Table 6 Metal parameters and limits

1. A question asking if Copper will be required. A second question, is why the proposed action limits are 10 ppm for both trim and concentrates?

The Agency is removing Copper form the required metals list. Copper sulfate is one of the few organic approved fungicides for crops, and it is often used in orchards. Copper has also been shown to uptake in hemp plants from soil. Copper based products are not on the approved pesticide list for hemp. The Agency will consider research testing for Copper of crops or when suspected use of Copper products has occurred.

Table 7 Pesticide parameters and limits

1. Background for the parameter list (anticipated questions).

First 12 compounds suggested by 2016 Cannabis testing proposal; parameters and action limits are for EPA residue levels on crops (lowest level adopted here, or State/organization levels).The Agency added five parameters which have been detected in hemp crops in the U.S., and used the action limits from other States.

2. A question if Spinosyn action limit of 0.01 ppm is for each A and D isomer?

This is for each isomer, which puts us closer to other State limits.

Table 8 Residual Solvents and Limits

1. Can the Agency comment on how action limits (lower than most State and USP levels) were set? At the very low levels, lab background could cause exceedances, if considered a “solvent not permitted for extraction” in the Agency’s document. In addition, the low 1 ppm action limits may be difficult to meet using industry methods with GC/FID detection.

The original action limits were recommended for medical cannabis in Vermont, at inhalable limits. Action limits were changed to industry standards for edible or concentrates, since the required testing is for those products (not smokable trim flower). New parameters were added for common solvents with industry action limits. The specific prohibited extraction solvents were added to the table.

END- RJS