

Docket No. AMS-SC-19-0042

BEFORE

**U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE**

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE

ESTABLISHMENT OF A DOMESTIC HEMP PRODUCTION PROGRAM

January 29, 2020

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Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, importers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

On October 31, 2019, the U.S. Department of Agriculture (USDA), Agricultural Marketing Service (AMS or the Agency) issued the Interim Final Rule (IFR)¹ titled “Establishment of a Domestic Hemp Production Program.” As mandated by the Agricultural Improvement Act of 2018 (2018 Farm Bill),² the IFR outlines provisions for AMS “to approve plans submitted by States and Indian Tribes for the domestic production of hemp.” The IFR also “establishes a Federal plan for producers in States or territories of Indian Tribes that do not have their own USDA approved plan.”

AHPA’s members are engaged in all stages of the commerce of herbs and herbal products, including the growth and processing of plant extracts and other ingredients, as well as manufacturing, distribution, and sale of finished products such as teas and dietary supplements, plant extracts, and bulk botanical commodities. Relevant here, the herbs and herbal products include plants and derivatives of *Cannabis sativa* L. that qualify as hemp under federal law.³ AHPA’s members therefore have a vested interest in the requirements of the IFR that could ultimately impact the lawful cultivation of hemp and the availability and costs of hemp and its derivatives marketed as herbs or in herbal products.

AHPA’s comments as presented here request numerous significant revisions for consideration, either as immediate changes to the Interim Final Rule where possible, or as changes to be incorporated into the Final Rule to be promulgated in 2021.

¹ 84 Fed. Reg. 58,522 (Oct. 31, 2019).

² The Agriculture Improvement Act of 2018, Pub. L. No. 115 – 334.

³ The Agricultural Marketing Act of 1946, section 297A, defines hemp 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.” 7 U.S.C. § 1639o(1).

Comments are presented on the IFR as well as the separate documents titled “Sampling guidelines for hemp growing facilities” (sampling guidelines) and “Testing guidelines for Identifying Delta-9 Tetrahydrocannabinol (THC) Concentration in Hemp” (testing guidelines).

AMS has indicated the IFR will be in effect for two years, and as such will impact hemp production during both the 2020 and 2021 hemp growing seasons. AHPA strongly recommends that AMS consider the opening of a second IFR public comment period to take place toward the conclusion of the 2020 growing season. This will allow AMS to receive comments and collect information about hemp producers’ and other stakeholders’ experiences under the provisions of the IFR as currently drafted. Such feedback will help to more clearly identify any specific problematic elements of the IFR and provide an opportunity for critical course corrections if needed prior to the 2021 growing season. Such an additional comment period will also provide for this “real world” feedback to be considered for incorporation into the Final Rule when issued in 2021. It is vital that the content of the Final Rule be considered in the context of actual experience with the provisions established in the IFR to best ensure the success of the emerging hemp industry.

AHPA notes that a number of states have already announced that they will continue to operate their hemp production programs under the provisions of the 2014 Farm Bill for the 2020 growing season, in lieu of submitting updated state hemp production plans for USDA approval under the IFR.⁴ This includes Kentucky, one of the leading hemp-producing states, and the home state of Senate Majority Leader Mitch McConnell, who advocated for the inclusion of the hemp provisions in the 2018 Farm Bill. The reasons provided for such reticence include the timing of the release of the IFR in late 2019 and that the technical details stipulated in the IFR represent significant implementation challenges to states. Further, some states cite the lack of qualified analytical laboratories that meet the requirements defined in the IFR, among other considerations. Many of these considerations are the subject of AHPA’s comments and will be further detailed in the sections of this submittal.

AHPA observes that some of the content of the preamble and specific provisions of the IFR convey a seeming bias against hemp (as a member of the *Cannabis* spp. of plants), despite the 2018 Farm Bill legalizing its production and removing it from the scope of the Controlled Substances Act. Certain aspects of the IFR imply that

⁴ <https://hempindustrydaily.com/maryland-vermont-extend-pilot-programs-for-2020-season/>

regulators view the hemp trade as likely to be engaged in illegal activity, rather than working from the assumption that farmers are growing hemp using good faith efforts to comply with stringent limits on tetrahydrocannabinol (THC) content. AHPA has identified in its comments where such possible bias against hemp and its status as a legal crop unfortunately appear to exist.

Comments on Subpart B (State and Tribal Hemp Production Plans) and Subpart C (USDA Hemp Production Plan)

Unless noted otherwise, the following comments apply equally to the provisions of the IFR describing State and Tribal Hemp Production Plans (Subpart B) and the USDA Hemp Production Plan (Subpart C).

The IFR’s requirement to test hemp crops for THC content within 15 days prior to harvest does not provide a sufficient amount of time to reliably complete THC compliance testing and harvest activities [§§ 990.3(2)(i), 990.24(a), 990.26(a)]

AHPA strongly recommends that the Agency either specify a pre-harvest period of at least 30 days for the initial years of the USDA domestic hemp production program or allow states and tribal governments that submit hemp production plans to specify a pre-harvest period that has been demonstrated to function effectively within their jurisdictions. AHPA finds that several of the states that are currently operating hemp production programs under the provisions of the 2014 Farm Bill have specified pre-harvest sampling periods up to 30 days in length,⁵ so the specification of a 15-day pre-harvest period is likely to be disruptive to hemp producers’ ability to readily sample, test, and initiate the harvest of their crop within this much shorter timeframe. AHPA member companies have expressed concern that, even with the longer pre-harvest sampling periods, a number of other variables can impact the ability to meet pre-harvest testing requirements, such as lengthy laboratory turnaround times for compliance testing, an inability to secure the necessary equipment and labor to perform the harvest within the specified period, and unfavorable or unexpected weather conditions or natural events at the time of scheduled harvest (e.g., the recent California wild fires that required evacuations during the expected hemp harvesting period). Further, AHPA believes that wait times for compliance testing could be exacerbated by the IFR requirement that testing facilities must be DEA registered and the apparent AMS position that such laboratories will be responsible for drying samples.

One alternative is to allow for the planned harvest of a hemp crop after sampling, with the stipulation that the harvested crop must be quarantined and may not enter into commerce until the completion of the THC compliance testing. Moreover, as operational data are collected and the hemp production industry matures, it may be possible to decrease the length of the pre-harvest period in the future.

⁵ For example, Oregon’s industrial hemp program requires a 28-day pre-harvest testing window ([OAR 603-048-0600](#)) and Colorado’s industrial hemp program specifies a 30-day pre-harvest testing window ([8 CCR 1203-23](#)).

Additionally, AMS has provided insufficient explanation regarding how it determined that 15 days was the appropriate time frame for the post-sample harvest window. While the IFR claims that the 15-day time frame is sufficient time to account for variables, such as rain, while ensuring that the THC level as tested reflects harvested plant material, it does not explain why, for instance, a 20-, 25-, or 30-day time would not be appropriate.⁶ The IFR does not discuss, consider, or rule out alternate time ranges that could have been adopted (including those time ranges currently in place in some states operating under the 2014 Farm Bill), or discuss the potential impacts and costs on growers in states of the IFR's (unnecessarily) shorter time frame.

AHPA also notes that the USDA hemp production plan allows for a second 15-day period (with an additional testing sample) if the harvest is not completed within a 15-day window following sampling (§ 990.26(a) and (b)), but this flexibility is not provided in the State and Tribal hemp production plan provisions. AHPA recommends AMS clarify that State and Tribal plans may provide for an additional 15-day pre-harvest window as permitted under the USDA hemp production plan.

Law enforcement should not perform sampling of hemp plant material for pre-harvest testing; USDA should clarify the meaning of “designated person”

As currently drafted, the IFR requires that “a Federal, State, local, or Tribal law enforcement agency or other Federal, State, or Tribal designated person” perform the collection of hemp plant material for pre-harvest testing. AHPA has the following concerns with this provision:

- AHPA appreciates that the IFR grants State and Tribal governments that submit hemp production plans for USDA approval the autonomy to designate the appropriate personnel to perform compliance sampling within their jurisdiction. However, the IFR does not set forth the limitations, if any, on what categories of persons may be designated to conduct compliance sampling. States with industrial hemp programs operating in compliance with the 2014 Farm Bill may have already invested significant resources in the training or qualification of personnel to perform this function, but it remains unclear on the face of the IFR whether AMS would permit such personnel to continue to conduct compliance sampling.
- The performance of a scientific and technical task such as the representative sampling of natural plant material in the field requires specific knowledge and

⁶ 84 Fed. Reg. at 58,524.

training that many State, Tribal, and local law enforcement agencies may lack. AHPA is concerned that States and Tribes will need to expend significant resources to appropriately train a sufficient number of persons qualified to perform sampling correctly. Involvement of law enforcement potentially diverts limited resources away from more critical enforcement priorities.

- Reference to the involvement of law enforcement in the hemp sampling process perpetuates misconceptions about the legality of the hemp industry and appears to presume that the plant material is a controlled substance, which hemp is not.

AHPA recommends that AMS clarify which persons may be “designated” to collect samples by State and Tribal governments submitting hemp production plans. AHPA understands that in some states with existing hemp programs, such as Oregon, the hemp testing laboratories that are performing the THC compliance testing also conduct the sampling of plant material. Such an approach can help ensure that the personnel conducting the sampling are appropriately trained in procedures for the sampling of natural plant material such as hemp, chain of custody practices, avoidance of contamination, adequate labeling of samples, and other practices that ultimately can influence the analytical test results for the hemp crop.

AHPA also notes that the sampling requirements of the IFR include the following provisions in sections 990.3(a)(2)(iv) and 990.24(d):

Representatives of the sampling agency shall be provided with complete and unrestricted access during business hours to all hemp and other cannabis plants, whether growing or harvested, and all land, buildings, and other structures used for the cultivation, handling, and storage of all hemp and other cannabis plants, and all locations listed in the producer license.

This provision, in combination with the fact that the default pre-harvest sampling agents under the IFR are Federal, State, and Tribal law enforcement representatives except where persons are specifically designated, seems to associate the now legal hemp industry with potential illegal activity. While AMS has explained that USDA may audit licensees, requiring access to all areas of a licensee’s facilities, the IFR does not provide an adequate justification for the necessity of sampling agents having such unfettered access. While AHPA acknowledges that State and Tribal licensing agencies, as well as USDA, may require such access for auditing purposes or when a hemp producer is known or suspected to have committed a violation, such broad access provisions are more appropriate to the required hemp production plan

enforcement procedures or corrective actions for confirmed violations than to the routine compliance sampling of an unharvested hemp crop. Such access should also be limited only to cannabis plant material being cultivated as hemp.

Analytical laboratories should not have to be DEA-registered to perform THC compliance testing for hemp production programs

AHPA is opposed to the requirement that DEA-registered laboratories must be used to perform the hemp production program THC compliance testing for the following reasons:

- Some states have no laboratories⁷ at present, while some have very few, perhaps only one, that currently meet this criterion, which presents a laboratory capacity testing issue for hemp production programs.
- This limited testing capacity issue will likely be exacerbated by the current mandate of a 15-day pre-harvest testing window.
- Requiring DEA-registration for laboratories represents a significant investment of time and expense for additional laboratories to register, participate, and potentially mitigate the capacity issue.
- DEA registration is an administrative recognition of a laboratory's practices, but it does not reflect an assessment of the quality of its work.
- Mandating DEA registration for hemp testing laboratories perpetuates misconceptions about the legality of the hemp industry and appears to presume that the plant material is a controlled substance.
- Some laboratories that are currently performing this testing for state programs operating under the 2014 Farm Bill may not qualify if they also test marijuana samples in states where such products have been legalized. This may eliminate many experienced and otherwise qualified laboratories from providing services to the hemp industry.

For these reasons, AHPA strongly recommends that DEA registration not be a mandatory requirement for analytical laboratories to perform THC compliance testing for hemp production plans.

⁷ The Hemp Analytical Laboratories Tool, accessible at <https://www.ams.usda.gov/rules-regulations/hemp/dea-laboratories>, indicates that several states, including Maryland, Delaware, New Mexico, and West Virginia have no laboratories that meet the baseline requirements.

In a related matter, AMS discusses in the IFR preamble that it is considering the inclusion of a requirement that laboratories be accredited to ISO 17025⁸ for cannabinoid analysis in order to provide THC compliance testing. AHPA strongly supports this suggestion. AHPA further believes that this accreditation should be the primary requirement for the qualification of labs to provide testing services under a Federal, State, or Tribal program.

AMS should allow for a reasonable retesting process for THC compliance

While both the IFR and the separately published testing guidelines referenced in the IFR contemplate the ability of the hemp producer to request a retest if it is believed the testing result for the THC level is in error, as currently drafted, neither document explicitly allows for consideration of the retest result itself, as indicated in § 990.3(a)(3)(i) (emphasis added):

Any test of a representative sample resulting in higher than the acceptable hemp THC level shall be conclusive evidence that the lot represented by the sample is not in compliance with this part.

The compliance process must allow for the fact that sampling and laboratory inconsistencies and errors are likely to occur, and a non-compliant test result may be reported into the USDA information sharing system in error. A hemp producer should have access to a process that would provide for retesting of the hemp lot in question by the same laboratory or another qualified laboratory as the situation may warrant. A single test with a non-compliant result can necessitate the destruction of a lot (i.e., a farmer's investment of many thousands of dollars) or form the basis of a finding of negligence. Accordingly, a defined process for retesting and consideration of additional analytical results is critical to the hemp production plan, especially in its earliest years when farmers are still learning about which cultivars are best suited for their regional growing conditions or certain growing practices, and laboratories are refining cannabinoid analytical techniques. Allowing for a reasonable retesting process would be protective of the interests of both farmers and the Agency when so much is at stake with a single test result.

⁸ ISO/IEC 17025 (2017) General requirements for the competence of testing and calibration laboratories

Setting the negligence threshold at 0.5% THC does not provide sufficient protection for hemp producers

AHPA appreciates that the IFR provides a safe harbor for THC concentration below which hemp producers will not be considered to have committed a negligent violation of a USDA, State, or Tribal hemp production plan, as applicable. However, AHPA is concerned that a safe harbor limit of not more than 0.5% THC, as defined in the IFR, is too low for the many new hemp producers to reliably meet. A hemp producer may take all precautions available to produce a compliant hemp crop, such as use of certified seed and use of hemp cultivars that have consistently produced compliant plants in other regions, and still produce a crop that exceeds the current 0.5% THC threshold. This threshold is also likely to be too low considering the recommended sampling protocol currently includes collection of only flowering plant material and does not include additional plant parts that would result in a THC level more representative of the entire plant. This narrow range of THC content for determining negligent violations may dissuade potential hemp growers from producing hemp. It may also encourage established farmers to discontinue their production in future growing seasons.

Further, the IFR does not explain, or attempt to explain, how AMS concluded that a 0.5% THC threshold was appropriate.⁹ AHPA requests that AMS fully describe the considerations and factors underlying its decision to set the safe harbor threshold at 0.5% THC.

AHPA recommends that AMS institute a threshold of not more than 1.0% THC as an alternative, at least for the first several years of full-scale domestic hemp production. This will allow for the establishment of certified seeds and known cultivars that reliably produce compliant hemp plants in specific growing regions and using certain growing practices. State programs should also be examined for other models of acceptance thresholds, such as the one used in Vermont, which defines the “acceptable potency level” of a hemp crop to be a delta-9 THC concentration of 0.3 percent or less and a total theoretical tetrahydrocannabinol concentration of one percent or less on a dry weight basis.¹⁰

⁹ 84 Fed. Reg. at 58,526.

¹⁰ See State of Vermont definition of “acceptable potency level” at <https://agriculture.vermont.gov/sites/agriculture/files/documents/PHARM/hemp/Certificate%20of%20Analysis%20Interpretation%20and%20Determining%20compliance.pdf>

Acceptable disposal of non-compliant plant material should include other methods besides crop destruction

Currently, the IFR allows for a single method of disposal for hemp plant material that exceeds the acceptable hemp THC level – destruction in compliance with DEA reverse distributor regulations. This ignores the many other potential uses for the hemp biomass, such as production of fiber, building materials, biofuel, biochar, etc. AMS’s policy also ignores the possibility that the non-flower portions of a plant are generally lower in THC and may continue to meet the definition of “hemp” at 7 U.S.C. § 1639o(1), even where such plant’s floral material exceeds the 0.3% THC limit. Thus, whenever possible, farmers should be allowed to repurpose the crop for other product streams besides human or animal consumption as a means of recouping the financial investment in growing the crop. This is especially important if crop insurance programs do not cover loss of the crop due to non-compliant THC levels for which the farmer is not negligent. Allowing for other methods of disposal is also consistent with the language of the 2018 Farm Bill, which uses the term “disposal” and not “destruction” in reference to non-compliant hemp plants or products.¹¹

AMS should review established state programs currently operating under the 2014 Farm Bill for other models on disposal and repurposing of non-compliant hemp crops. Along with the options cited above, AHPA is aware that some states allow for non-compliant hemp to be used for research purposes (Colorado) or to enter their state legal marijuana programs (Vermont). At minimum, the IFR should be modified to allow THC content testing, upon request, of non-floral plant material slated for disposal. If such material meets the definition of hemp, AMS should permit growers to repurpose such material as described above.¹²

AHPA asks that AMS confirm that § 990.3(a)(3)(iii)(E) applies to disposal of hemp plant material in the possession of the analytical laboratory that is found to be non-compliant. This section otherwise describes the standards for the analytical testing of THC levels and may be better positioned as a separate subsection. It may also be advisable for AMS to add text related to laboratory disposal of non-compliant hemp material in the lab’s possession to the testing guidelines, which currently does not address this topic.

¹¹ 7 U.S.C. §§ 1639p(a)(2)(A)(iii), 1639q(a)(2)(C).

¹² The IFR notes that “non-compliant acres...have zero value as hemp.” 84 Fed. Reg. at 58,546. However, if AHPA’s suggestion is adopted, non-compliant acres would have a non-zero value, and growers may be able to recoup a portion of the growing costs, thus lessening the overall risk for growers.

The felony restrictions section should include the defined term “key participants”

AHPA notes that the current language of the “felony conviction restrictions” in § 990.6(e)(3) seems to allow State or Tribal hemp production plans to extend the felony restrictions to any employees of a hemp production entity:

For producers that are entities, the State or Tribal plan shall determine which employee(s) of a producer shall be considered to be participating in the plan and subject to the felony conviction restriction for purposes of paragraph (e)(1) of this section.

This conflicts with the language of the IFR preamble, which indicates the felony restrictions should extend only to “key participants” as defined under § 990.1:

Key participants. A sole proprietor, a partner in partnership, or a person with executive managerial control in a corporation. A person with executive managerial control includes persons such as a chief executive officer, chief operating officer and chief financial officer. This definition does not include non-executive managers such as farm, field, or shift managers.

AHPA recommends rewording § 990.6(e)(3) to apply the felony restriction to only those persons that qualify as “key participants” as follows:

For producers that are entities, the State or Tribal plan shall specify how the State or Tribe will determine which employee(s) of ~~a producer~~ the entity qualify as key participants (as defined in § 990.1), and shall be considered to be participating in the plan and subject to the felony conviction restriction for purposes of paragraph (e)(1) of this section.

Comments on Subpart D (Appeals)

The scope of appeals processes should include technical issues

The appeals processes outlined in § 990.40 addresses licensing and administrative issues only. Technical components of the USDA hemp production program such as sample identification and collection, sample drying and preparation, and procedures used for analytical testing should be included in the available appeals processes. All of these activities may introduce errors and inconsistencies into whether the hemp crop is ultimately determined to have an “acceptable hemp THC level.” An appeal procedure thus should be available to remedy disputes regarding the proper performance of these activities.

As AHPA previously noted in these comments, the testing guidelines includes reference to a retesting option, but it does not address how to incorporate the results of such a retest into the determination of whether a lot of hemp meets the “acceptable hemp THC level.” Broadening the appeals process to include technical matters germane to the ultimate determination of compliance further protects farmers from unwarranted enforcement action and preserves government enforcement resources.

Comments on Subpart E (Administrative Provisions)

The provision regarding interstate transportation of hemp should specify the controlling THC test result to avoid legal disputes

AHPA appreciates the IFR's clear and concise confirmation of the lawfulness of interstate transportation of hemp provided in § 990.63. However, AHPA is concerned that legal challenges may be brought against entities transporting hemp interstate if the IFR does not provide that the hemp's tested THC concentration, if falling within the "acceptable hemp THC level," cannot be taken as definitive evidence that the plant material is hemp. Accordingly, AHPA suggests that AMS clarify that Cannabis plant material that has been subject to analytical testing and has been demonstrated to be in compliance with the given hemp production plan qualifies as hemp for the purposes of the interstate transportation provision at § 990.63.

AMS acknowledges in the preamble that the IFR's definition of "acceptable hemp THC level" does not alter the statutory definition of hemp (i.e., not more than 0.3% THC on a dry weight basis):

It bears emphasis that this rule does not alter Federal law with regard to the definition of hemp or marihuana. As stated above, the 2018 Farm Bill defines hemp as the plant species *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 THC of not more than 0.3 percent on a dry weight basis. Likewise, the Federal (CSA) definition of marihuana continues to include those parts of the cannabis plant as specified in 21 U.S.C. 802(16) (and derivatives thereof) that contain more than 0.3 percent delta-9 THC on a dry weight basis. The foregoing provisions of Federal law remain in effect for purposes of Federal criminal prosecutions as well as Federal civil and administrative proceedings arising under the CSA. However, for purposes of this rule (i.e., for purposes of determining the obligations of licensed hemp growers under the applicable provisions of the 2018 Farm Bill), the term 'acceptable hemp THC level' is used to account for the uncertainty in the test results."¹³

¹³ 84 Fed. Reg. at 58,525.

This means that harvested hemp that meets the “acceptable hemp THC level” but that may exceed the Federal Controlled Substances Act limit for THC could be considered a controlled substance by law enforcement during interstate transportation. This potential inconsistency highlights the importance of designating the hemp production plan compliance test (which documents the “acceptable hemp THC level” was met) as the prevailing test in any legal dispute about whether the hemp material is compliant during interstate transportation. AHPA recommends incorporating language that establishes the “acceptable hemp THC level” as the legal standard for identification of hemp during interstate transportation into § 990.63.

Comments on the Sampling Guidelines for Hemp Growing Facilities

Hemp sampling protocols should be designed to achieve a more representative compliance testing sample

AHPA appreciates that AMS has published companion sampling guidelines that provide details on a sampling protocol for hemp. Following discussions with AHPA member companies regarding these guidelines, AHPA submits the following comments:

- AHPA notes that, although the sampling protocol was issued as a guideline, as written, it appears to be binding with regard to how hemp must be sampled; AMS should clarify that the published sampling guidelines only put forth one manner in which hemp samples may be taken and that there may be other procedures that would also satisfy the rule’s sampling requirements.
- The sampling protocol as presented does not adequately allow for variability in the population of hemp plants with respect to the number of plants recommended for sampling per acre. For example, the provided guidelines recommend sampling of a minimum of one (1) plant per acre, which may not be sufficient to capture uncertainty for such a newly established crop. A sampling protocol that more adequately addresses the uncertainty of the plant population will help protect farmers from unnecessary findings of negligent violations.
- Some states operating hemp programs in compliance with the 2014 Farm Bill have established detailed hemp sampling protocols and should be allowed to continue to utilize those practices to avoid unnecessary disruption to their hemp producers.¹⁴
- The sampling guidelines direct sampling agents to collect only flower material from cannabis plants for delta-9 THC concentration testing. The 2018 Farm Bill does not mandate that only flowers must be tested for assessing a plant’s THC level, and the IFR provided no rationale for such determination. AMS must provide a non-arbitrary rationale for why it has determined that only hemp floral material will be sampled for compliance testing purposes. Such limited collection of plant material will not reflect the true average THC content of the whole plant or of the crop. Additionally, sampling of only flowering material ignores that some hemp producers will be growing hemp for

¹⁴ For example, Oregon has an established detailed hemp sampling protocol that can be accessed at <https://www.oregon.gov/ODA/shared/Documents/Publications/NurseryChristmasTree/SamplingProtocol.pdf>.

production of seed and stalk for purposes other than production of cannabinoids. Moreover, because hemp floral materials have a higher THC concentration than hemp leaves, seeds, and stalks, there is a distinct possibility that plant materials that meet the definition of hemp at 7 U.S.C. § 1639o(1) will be determined to be non-compliant and destroyed.

Again, AHPA’s review of state sampling protocols indicates that some states have more diverse sampling requirements that include collection of additional parts of the hemp plant including leaves and stalk.¹⁵ The more parts of the plant that are sampled, the more representative the analytical results will be of the THC content of the plant as a whole.

¹⁵ See Vermont Agency of Agriculture, Food & Markets; Hemp Pre-Harvest Sampling and Testing Protocol for a Taxonomic Determination and Compliance, https://agriculture.vermont.gov/sites/agriculture/files/documents/PHARM/hemp/VTHP_SOP_Pre-HarvestSamplingTesting_07022019.pdf, and Kentucky Department of Agriculture; Hemp Program – Procedures for Sampling, THC Testing, and Post-Testing Actions, https://www.kyagr.com/marketing/documents/HEMP_LH_Procedures_for_Sampling_THC-Testing_and_Post-Testing_Actions.pdf.

Comments on the Testing Guidelines for Identifying Delta-9 Tetrahydrocannabinol (THC) Concentration in Hemp

Again, AHPA appreciates that AMS has provided separate, more detailed testing guidelines for use by analytical laboratories that will conduct the compliance testing to ensure that sampled hemp plant material has an acceptable hemp THC level as defined in the IFR. However, AHPA has serious concerns about the burden that will be placed on laboratories under the terms of the IFR and testing guidelines. AHPA has the following comments regarding the THC analytical procedures as presented in the testing guidelines. Incorporation of these comments will clarify several of the critical steps in conducting the analysis of THC for the legal hemp production industry.

Approval of alternate testing protocols

The testing guidelines indicate the following (emphasis added):

Alternative testing protocols must be requested of USDA in writing and approved in writing by USDA, provided they meet the requirements of this guidance.

AHPA requests that AMS clarify how the Agency intends to evaluate whether alternate testing protocols meet the requirements of the testing guidelines. This information will be vital to an applicant seeking approval for an alternate testing protocol. Such details include the required documentation considered sufficient to demonstrate the equivalency of an alternate testing protocol to that which the Agency has provided as the testing guidelines.¹⁶

AMS should provide a public list of approved THC analytical methods

AHPA notes that the testing guidelines state the following (emphasis added):

At a minimum, analytical testing of samples for delta-9 tetrahydrocannabinol concentration levels must use post-decarboxylation or other similarly reliable methods approved by the Secretary.

Similar language appears in § 990.25(b) of the IFR. AHPA requests that AMS clarify whether the Secretary has approved any such analytical methods to date, since

¹⁶ Additionally, AHPA notes that the testing procedure was issued as guidance, meaning that it is not and cannot be binding on parties. See *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 382-83 (D.C. Cir. 2002) (finding that guidance document's use of binding language rendered it an improperly promulgated legislative rule). If AMS intends for all testing protocols to be approved, AMS would need to incorporate this concept into the IFR or Final Rule itself.

several methods beyond the few cited in the IFR are currently in use at analytical laboratories. AMS should also announce to the industry the bases for the Secretary's approval (or disapproval) of additional proposed methods and where information regarding any additional approved methods will be located. It is essential that AMS communicate to analytical laboratories the process for achieving such approval, such as how analytical methods are required to be submitted to AMS for consideration and what data and information must be included in such a submittal.

The testing guidelines also state that “[l]aboratories shall meet the AOAC International standard method performance requirements (SMPR) for selecting an appropriate method.” While AHPA agrees that a reference to AOAC International criteria is appropriate for identification of appropriate methods, AHPA recommends that AMS be more specific in identifying the relevant SMPR. AHPA suggests the following language:

Laboratories shall select methods for THC determination that meet the requirements in AOAC SMPR 2019.003¹⁷ and/or other applicable official standards as they become available.

Also, AOAC International is currently developing an SMPR for moisture determination that will be relevant to the testing guidelines. AHPA recommends that AMS endorse this SMPR upon its completion and that the Agency afford due consideration to endorsement of any future related AOAC International work products.

Hemp sample preparation procedures are overly burdensome for analytical laboratories

As written, the testing guidelines indicate that analytical laboratories are responsible for the initial drying step of the fresh sampled hemp material, which ensures that the sample can be prepared for size reduction prior to analytical testing for THC. This seems to indicate that the laboratory is responsible for the initial drying of the botanical material intended for analysis. AHPA has the following concerns with this provision:

- Analytical laboratories are not typically prepared to have to dry large amounts of plant material prior to sample preparation. This means many laboratories will have to establish procedures and procure additional space and equipment in order to perform this step, adding costs to the overall process.

¹⁷ AOAC International SMPR 2019.003. Standard Method Performance Requirements (SMPRs®) for Quantitation of Cannabinoids in Plant Materials of Hemp (Low THC Varieties *Cannabis* sp.)

- The guidelines should further stipulate the conditions under which this initial drying step takes place (e.g., with respect to temperature and humidity) as they can influence the quality of the hemp sample and, in particular, the levels of cannabinoids measured.
- This drying step can represent several days in the overall testing process, which could prolong wait times for test results, and which provides further support for a pre-harvest testing window longer than 15 days (as discussed above).

The testing guidelines also indicate the analytical laboratory is to “mill and ‘manicure’ [the] sample through a wire screen no larger than 1.5 x 1.5mm to discard mature seeds and larger twigs and stems.” While this is another important step in the sample preparation process, having the laboratory personnel de-select some portions of the available dried hemp plant parts can introduce uncontrolled bias and inter-laboratory variability in the composition of the sample and potentially exclude non-cannabinoid producing plant parts from being part of the test material. Inclusion of plant parts such as twigs and stems will result in a THC analysis that is more representative of the hemp plant as a whole as compared to analyzing just the THC level of the flower. If stems and seeds are present in the sampled hemp material, they should remain part of the prepared test material. Most laboratories would prefer to homogenize and test samples on an as-received basis.

In summary, there exist significant opportunities to introduce inconsistencies between laboratories in these sample preparation steps, and AMS should critically examine these testing guidelines for ways to improve clarity and reduce the chance of divergent approaches between laboratories. AHPA recommends that the testing guidelines reference established standards for the selection and drying of botanical material samples, such as those from United States Pharmacopoeia (USP)¹⁸ and the European Pharmacopoeia.¹⁹

¹⁸ United States Pharmacopoeia (USP) National Formulary, General Chapter 561, Articles of Botanical Origin (accessed at <https://www.usp.org/sites/default/files/usp/document/our-work/DS/2015-dsc-chapters-561-616-1010-1092.pdf>) and General Chapter 731, Loss on Drying (accessed at https://hmc.usp.org/system/files/general-chapters/GC-Pdfs_2019/731_%20LOSS%20ON%20DRYING.pdf).

¹⁹ European Pharmacopoeia, 10th edition (2019). Accessible at https://www.edqm.eu/en/en/european_pharmacopoeia_10th_edition.

Determination of moisture content during analytical process requires clarification

The “General Sample Preparation and Testing Procedures” outlined in the testing guidelines (Steps 1 through 7) require clarification, as AHPA finds that confusion exists between the following items:

- 1) The Step 2 post-harvest drying procedure (to process the fresh cut from the field wet material into a “dried” material with 5-12% moisture); and
- 2) The Step 5 analytical moisture determination method (either by a titration procedure or an oven loss on drying) to be performed on material containing 5-12% moisture for use in calculating and reporting THC on “a dry weight basis” (as opposed to reporting on an “as-is basis”).

AHPA provides the following suggestions for inclusion to provide needed clarification:

- 1) Step 2 in the testing guidelines says: “Dry sample to remove the majority of water.”

Suggested change for clarity: “Dry fresh plant material to within the range of 5-12% moisture to remove the majority of the water in a manner that does not affect cannabinoid concentrations.”

- 2) Step 5 in the testing guidelines says: “Determine moisture content or dry to a consistent weight (meeting criteria).”

Suggested change for clarity: “Determine moisture content by a scientifically valid method such as titration or drying to constant mass.”

AHPA also suggests changing the term “consistent weight” to “constant mass” throughout the testing guidelines.

Calculation of measurement of uncertainty requires clarification

AHPA agrees that it is appropriate to allow for the application of the measurement of uncertainty (MU) in determining the acceptable hemp THC level under the IFR. However, AMS should clarify the procedure for calculating the MU in the testing guidelines.

The guidelines include an equation referring to the variables “uncertainty of repeatability” (u_r) and “uncertainty of reproducibility” (u_R). AHPA finds that confusion exists regarding how to apply this equation as presented in the testing guidelines, since reproducibility (R) as a variable generally refers to how reproducible the results of an analytical method are across multiple laboratories employing the same method (interlaboratory reproducibility). AMS should clarify that the inclusion of the variable

“uncertainty of reproducibility” does not necessarily mean the MU must be calculated using data from multiple laboratories, if indeed AMS intends to allow each laboratory to determine the MU based on its individual analytical data and not through interlaboratory studies.

Conclusion

In summary, AHPA strongly supports the important role that USDA is playing in the establishment of an accessible and thriving hemp industry in the U.S. This crop represents a viable economic opportunity for many new and established farmers. Further, multiple diverse industries can utilize hemp and its derivatives in the manufacture of numerous products such as foods and beverages, dietary supplements, fiber and fabrics, biofuel, and other industrial products. The issuance of federal regulations for hemp production in the form of the IFR represent an important step forward for this crop.

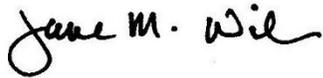
As outlined in its comments above, AHPA also believes that there exists significant room for improvement in the IFR and the subsequent Final Rule. From discussions with our members and other hemp industry associations, we expect that AHPA's comments will be consistent with the major concerns expressed by other stakeholders. We look forward to AMS's careful consideration of AHPA's comments submitted in response to the IFR and the related sampling and testing guidelines. In particular, AHPA strongly recommends that AMS conduct another public comment period towards the conclusion of the 2020 hemp growing season. This would allow for consideration of first-hand experience with the IFR provisions to be considered in the formulation of the Final Rule in 2021.

AHPA greatly appreciates the opportunity to present comments on this matter and can be available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact AHPA if clarification or additional discussion is needed on the issues raised in these comments.

Respectfully submitted,



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