

COMMENTS:

Establishment of a Domestic Hemp Production Program; Comment Period Reopened

Docket. No. AMS-SC-19-0042: Agricultural Marketing Service, USDA; Request for Comments.

October 8, 2020

NATIONAL CANNABIS INDUSTRY ASSOCIATION
SCIENTIFIC ADVISORY COMMITTEE

Tiffany Coleman, Chair



National Cannabis Industry Association
TheCannabisIndustry.org

The purpose of these comments, provided by the National Cannabis Industry Association’s Scientific Advisory Committee, is to inform AMS of established industry knowledge related to the final rule and make requests for clarification where statements appear confusing. The table below lists requests by section with specific comments for each section.

Section	Comments
Executive Summary	No Comments
1: Measurement of Uncertainty for Sampling	NCIA recommends the measurement of uncertainty (MU) for laboratory activities is aligned with ASTM International’s Standard Guide for Reporting Uncertainty of Test Results and Use of the Term Measurement Uncertainty in ASTM Test Methods [ASTM E2655 - 14(2020)] and AOAC International’s Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals .
2: Liquid Chromatography Factor, 0.877	<p>NCIA continues to recommend the calculation for THC concentration to be the total of THC and 87.7% of THCa in a laboratory setting. This is aligned with the standard for testing for cannabinoids AOAC Official Method 2018.11 Quantitation of Cannabinoids in Cannabis Dried Plant Materials, Concentrates, and Oils which has been validated across several laboratories as appropriate recovery factors for THC and THCa.</p> <p>In addition, it would be inappropriate to modify this analytical calculation based on existing technology for the extraction of cannabinoids from biomass as efficiencies will continue to advance. The inability of current technology to maintain close to 100% efficiency between starting materials and finished products does not negate the science regarding the calculation of the presence of THC or THCa in the starting material. Indeed, some products do not even utilize refinement and utilize the raw ingredient without any extraction or dilution, such as, smokable hemp products.</p>

Section	Comments
<p>3: Disposal and Remediation of Non-Compliant Plants</p>	<p>NCIA recommends that the USDA should allow the remediation of hemp plants that test over the 0.3% THC concentration threshold, rather than requiring immediate mandatory disposal under DEA regulations.</p> <p>In order for remediation to occur, a remediation plan should be generated and maintained on file for regulatory review by the state authority or the USDA within 30 days of determining plants are non-compliant with the THC concentration threshold. The remediation plan should describe at a minimum the remediation method, parties involved, quality assurance measures, and timeline for completion. If a remediation plan is not submitted, it should be required that disposal occurs. On-farm disposal methods provided in the guidance issued on February 27, 2020 should remain allowable.</p> <p>Remediation options could include:</p> <ul style="list-style-type: none"> ● Removal or degradation of THC through processing. There are proven methods to remove THC from hemp during processing. USDA should allow for the quarantine and monitored transfer of noncompliant hemp to a processor, which will then remove or convert sufficient THC within the hemp to render all finished products made from it compliant with the 0.3% THC concentration threshold. ● Diversion to Fiber Market. Diverting non-compliant hemp to processing for non-consumable products like paper, plastics, and biofuel would seemingly alleviate any public safety concern raised by non-compliant hemp. Diversion could include both stalks and flower, or require destruction of flower and allow diversion of stalks. Either method would allow producers to make some use of their hemp plants, alleviating complete economic loss. This is also a much more sustainable practice.
<p>4: Negligence</p>	<p>NCIA acknowledges that through natural biological processes an expected THC conforming plant may become non-THC conforming through no fault of the farmer.</p> <p>The on-going testing that may need to be in place for a farmer, who has planted and expects conforming plants, caused by fluctuations in weather and potential delays in harvesting may be unavailable or of exorbitant cost to the farmer.</p> <p>Appropriate monitoring and control, combined with disposal or remediation of nonconforming plants should be sufficient to establish a lack of negligence, regardless of the THC level in the plant.</p> <p>We propose this requires the following items: chain of custody on seeds from a licensed seed provider for conforming hemp seeds, agricultural plan for planting and harvesting which when followed would provide conforming plants, evidence that on-going testing was occurring but which did not indicate that nonconformance had occurred or was going to occur prior to harvest, and appropriate measurements taken once nonconforming plants were detected to dispose or remediate the problem promptly.</p>

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5: Interstate Commerce	<p>Comments Previously Submitted:</p> <p>By not significantly addressing issues of interstate commerce in the interim rules, USDA has created a regulatory environment where the interstate shipment of hemp plants—while explicitly allowed in the 2018 Farm Bill—is still subject to the risk of seizure while in transport. This is because local law enforcement assumes all Cannabis is Marijuana until proven otherwise. If the USDA wants to promote the adoption and feasibility of both individual state hemp production plans, as well as the USDA plan, it must implement rules preventing the seizure of compliant hemp in interstate commerce.</p> <p>To make it easy to identify compliant hemp, USDA should consider implementing a two-part system that would allow hemp transporters to provide shipment information and then demonstrate their compliance to law enforcement officers in the event of a traffic stop or inspection. Below are options for the USDA to consider:</p> <ul style="list-style-type: none"> ● Allow for the submission of shipping manifests or itineraries in the FSA Database. While the FSA is currently set to include at a minimum the address and geospatial location where the hemp is grown, the acreage of the grow, and the license number under a hemp production plan, it does not provide any information that would help a transporter demonstrate that the specific hemp in transit is compliant with both state and federal regulations. <p>By allowing for the submission of shipping manifests and itineraries that could be viewed in conjunction with the other required information, law enforcement could easily do roadside compliance checks on a particular shipment of hemp.</p> <ul style="list-style-type: none"> ● Affix “USDA Approved” tags to all containers in a shipment. <p>USDA should consider creating specialized tags that can be affixed by a USDA, State, or Tribal inspector to hemp being prepared for transport. These tags could contain the registrant’s ID number and could be linked to the documents and information disclosed in the FSA database.</p> <p>These options would be possible with minimal additional cost expenditures and would protect hemp farmers and transporters from losing their compliant hemp products in roadside traffic stops, while building upon the systems USDA has already planned to put in place.</p>

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<p>6: 15-Day Harvest Window</p>	<p>NCIA acknowledges that harvesting an entire crop within 15 days may not be feasible, especially given weather, labor and equipment constraints put upon farmers.</p> <p>Established cannabis sativa growth science indicates that the production of THCa occurs in the final days and weeks of flowering. Many hemp varieties have a flowering phase which is between 8 and 10 weeks, with the majority of the THCa production happening in the second half of that period. There is evidence that THCa can increase 1-2% in the final week of flower in marijuana plants and there is no evidence to suggest that a THCa producing hemp plant would not also continue to produce THCa during this time period, but in smaller quantities.</p> <p>In addition, flushing activities that often occur during the last 2 to 4 weeks of the flower phase can exacerbate this production of cannabinoids by feeding the plant and forces the plant into a hormonal growth pattern as it tries desperately to produce seeds and fend off predators.</p> <p>As such, NCIA recommends that the USDA define a process that the licensed lab tested THC percentage is maintained from testing until the completion of the harvest window. This program should acknowledge that THC percentages may increase during the harvest window, but that a farmer, transporter, or processor is not negligent if this occurs. A “USDA Approved” tag for these materials would be appropriate, as discussed in our comments to item #5.</p> <p>The time from samples being taken, sample test results being received, and harvest being completed depending on the State can be longer than 15 days. Depending on the method of harvest, harvesting of an acre can take from an hour to multiple days. Test results can be received between 2 days and 2 weeks depending on the laboratory performing the testing. For farms with more than an acre, the combined time from testing and harvesting will exceed the 15-day window.</p> <p>That will leave crops unharvested and potentially unable to be harvested in the field and damage farmers and farmland.</p>
<p>7: Hemp Seedlings, Microgreens, and Clones</p>	<p>NCIA agrees that licensing of these facilities and control of seed and clone inventories is appropriate and that testing for THC is not appropriate during a portion of the plants lifecycle which does not include THC production.</p> <p>NCIA recommends an approach that utilizes chain of custody before and after the production of Hemp Seedlings, Microgreens, and Clones such that nonconforming plants in later production can be tied back to the specific genetics of the seedlings or clones. There are many phenotypes seen even in seeds from a single hemp plant and if the intent is to limit nonconforming THC cultivars from entering the marketplace then a chain of custody system would assist in this, without requiring any additional testing at the seedling, microgreen, or clone production facility.</p>

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<p>9: Sampling Methodology— Flower vs. Whole Plant</p>	<p>Heterogeneity of cannabis plants is a well-known issue for analytical testing facilities around the country. NCIA recommends a three-pronged approach to the sampling of flowering hemp plants.</p> <p>1) Establish the purpose of the hemp plant as part of the licensing for cultivars grown for hurd, fiber, and seeds which have a small flowering head with feet long stalks. The cannabinoid content of the stalks of these plants will have less than 2% of the total cannabinoids produced by the plant. The flowering head becomes a waste product for these products. As such, it would seem appropriate to test the stalks of these plants as the high cannabinoid biomass is intended to be a waste product.</p> <p>2) Establish the purpose of the hemp plant as part of the licensing for cultivars grown for cannabinoid production as these plants are smaller with many flowering heads on the plant and total biomass that contains cannabinoids is much greater. As such, it would seem appropriate to test the flowers of these plants as the non-flower portions of the plant is intended to be a waste product.</p> <p>3) Establish the purpose of the hemp plant as part of the licensing for cultivars grown for reasons other than the above and sample them the entirety of the plant as there is no determined waste product.</p>
<p>10: Sampling Methodology— Homogenous Composition, Frequency, and Volume</p>	<p>NCIA agrees that homogeneous sampling is important and difficult. Our recommendation is to utilize an established sampling standard from ANSI/ASQ Z1.9 the method is defined to provide a confidence level of 95%, it is scalable based on batch size and batch can be defined in many different units. Acres, plants, expected pounds of material to be harvested.</p> <p>It seems the most appropriate to align the batch with the number of plants, as the number of plants per acre and the number of pounds per plant vary based on the cultivar. An established farmer could sample fewer plants by using the loosened criteria for the AQL and a new farmer with potentially higher risk could utilize a tightened AQL with more samples taken to confirm conformity.</p> <p>It seems that if ANSI/ASQ Z1.9 is good enough for military applications, healthcare products, textiles, and food that it should be sufficient to provide a homogenous sample from various batch sizes for agricultural hemp.</p> <p>NCIA agrees that different types of intended uses change the risk of diversion based on the prevalence of potentially higher d9-THC in some cultivars. However, as discussed in the comments on Sampling Methodology - Flower vs Whole Plant, we believe that the appropriate differentiation is the method of sampling, not the number of samples to be taken based on the intended usage of the plant.</p>
<p>11: Sampling Agents</p>	<p>Thank you for having the sampling agents be trained and certified to do this work. It may be easier if AMS goes with an established quality inspection training and certification program such as is provided by ASQ, and then any licensed quality inspector would be capable of taking these samples and using a chain of custody to send them to a licensed testing facility. https://asq.org/cert/quality-inspector</p>

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<p>12. DEA Laboratory Registration</p>	<p>NCIA is concerned that there are not enough DEA-registered analytical labs available to perform this work for the industry. As of today, the USDA lists 67 DEA-registered analytical labs in the United States. Many of which are actually local drug testing labs or pharmaceutical contract manufacturers who were already established DEA-registered laboratories not focused on the hemp industry. State Certified and ISO accredited labs that have been testing cannabis and hemp for the last decade are not eligible to be DEA registered because of the presence of cannabis at their facility prior to hemp legalization and the DEA registration requirement. These labs are the most experienced with the complicated cannabis matrix and are being excluded from being allowed to test hemp under this requirement. Experienced labs are vital to this industry since THC allowable limits are exceptionally low and the industry needs precise and accurate testing to verify compliant hemp.</p> <p>DEA Laboratory Registered testing facilities do not exist in all states and localities. There are not currently testing labs in the following states per the USDA list: Alabama, Alaska, Arkansas, Connecticut, Delaware, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Massachusetts, Montana, Nebraska, Nevada, New Hampshire, New Mexico, Oregon, Rhode Island, South Dakota, West Virginia, Wyoming.</p> <p>If the State Certified and ISO accredited existing laboratories were added to this list, more states and localities would have access to faster local testing and generally increase the capacity for testing. The paucity of available testing facilities is already an issue contributing to the concern of farmers which we have commented on in section 6. NCIA is concerned, as indicated in our comment to section 5 that some individuals or corporations transporting legal hemp may be caught up in interstate issues, and request that test samples be included in the USDA rules for allowing transportation of test materials between licensed farms and manufacturers and licensed testing laboratories.</p> <p>If the requirement for DEA laboratory registration is not removed, it should at least be postponed until more established laboratories can be registered to eliminate the issues with long lead times for test results. NCIA requests assistance with development of a “grandfather” program to allow existing state certified laboratories to gain DEA Laboratory Registration, if this requirement is not removed.</p> <p>NCIA recommends removal of the DEA Laboratory Registration requirement and instead allow for State certified and ISO accredited laboratories that are responsible for chain of custody, reporting, and disposal of noncompliant hemp in the same methods defined for farmers and discussed in response to request for comment item 3: Disposal and Remediation of Non-Compliant plants. Disposal of limited quantities of noncompliant samples is much less burdensome than disposal of acres of noncompliant plants and can be handled in a controlled and documented method to prevent diversion to the black THC markets.</p>

Sincerely,

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