



January 29, 2020

VIA ELECTRONIC SUBMISSION

The Honorable Sonny Perdue
Secretary
U.S. Department of Agriculture
1400 Independence Ave., S.W.
Washington, D.C. 20250

Re: Establishment of a Domestic Hemp Production Program (Docket No. AMS-SC-19-0042)

Dear Secretary Perdue:

The U.S. Small Business Administration's Office of Advocacy (Advocacy) submits the following comments in response to the U.S. Department of Agriculture's Agricultural Marketing Service (AMS) interim final rule titled: "*Establishment of a Domestic Hemp Production Program*" published on October 31, 2019.¹ This interim final rule outlines the policies and procedures by which States, Indian tribes, and AMS itself will administer programs for the production of hemp in the United States. Advocacy appreciates AMS' swift action to provide regulation and necessary guidance to state departments of agriculture, tribes and this emerging industry. Advocacy is concerned about the potential effects the rule will have on small entities nationwide. Advocacy urges the agency to reconsider certain requirements of the rule as outlined below, and to consider alternatives proposed herein, and by several states and small entities.

The Office of Advocacy

Advocacy was established pursuant to Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA), so the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),² as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),³ gives small entities a voice in the

¹ Establishment of a Domestic Hemp Production Program, 84 Fed. Reg. 58522 (October 31, 2019).

² 5 U.S.C. § 601 et seq.

³ Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et seq.).



409 3rd Street SW / Washington, D.C. 20416
Phone: (202)-205-6533 / advocacy.sba.gov

rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small business and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.⁴ The agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.⁵

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."⁶

Background and Procedural History

The Controlled Substances Act of 1970⁷ was enacted to regulate the manufacture, distribution, and use of certain psychotropic substances. The Act defines marijuana as "all parts of the plant *Cannabis sativa* L., whether growing or not; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin".⁸ Hemp was originally included among the list of controlled substances as well.

The Food and Drug Administration ("FDA") distinguishes between hemp and marijuana based on the definition of hemp provided in section 297a of the Agricultural Marketing Act of 1946. Hemp is "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 (THC) concentration of not more than 0.3 percent on a dry weight basis."⁹ THC is the chemical substance found within the cannabis plant, that at high concentrations produces a psychotropic effect. Thus, the FDA classified any of the parts of the plant *Cannabis sativa* L. with a delta-9 THC concentration of *greater* than 0.3 percent on a dry weight basis as marijuana and subject to Controlled Substances Act regulation. This restriction on the production of hemp changed in 2014 with the passage of the Agricultural Act of 2014 which allowed for a pilot program for hemp production for research purposes.¹⁰

Hemp as a crop has many uses, including as a fiber substitute for wood, rope, clothing, and many other commercial products. Hemp is also used in farming of livestock, biodiesel, and in cannabidiol (CBD) pharmaceutical products. Given its many uses, Congress in 2018 revisited hemp's status as a

⁴ Small Business Jobs Act of 2010 (Pub. L. No. 111-240) § 1601.

⁵ *Id.*

⁶ 5 U.S.C. Sec. 601 note.

⁷ 21 U.S.C. §801. et. seq.

⁸ *Id.* at §802(16)(A).

⁹ Agricultural Marketing Act of 1946, §297A (1) (1946). *See also FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*, United States Food & Drug Administration. (Dec. 31, 2019), <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>.

¹⁰ Pub. L. No. 113-79 (2014).

controlled substance. In 2018, the Agricultural Improvement Act (hereinafter “Farm Bill” or “2018 Farm Bill”) was signed into law and exempted hemp from the Controlled Substances Act’s regulatory authority altogether.¹¹

The law requires that AMS establish and administer a program for the production of hemp in the United States.¹² Under these laws, AMS is to establish sampling and testing guidelines, engage in data collection activities, and review and approve state and tribal plans for those jurisdictions who wish to administer their own programs. If a state or tribe does not wish to administer a program in its own jurisdiction, AMS may administer a program at the federal level.¹³ The language is clear that for those states where the production of hemp is prohibited, state law governs, and there is to be no preemption of states’ rights. The Farm Bill does, however, indicate that states must allow for interstate transport of hemp and hemp products.¹⁴

On October 31, 2019, in response to this law, AMS published an interim final rule establishing a domestic production program in the U.S.¹⁵ Because the agency chose to publish the action as an interim final rule, it is already in effect, and runs through November 1, 2021, or until such time that the agency publishes a final rule.

Key Features of the Rule

The interim final rule outlines several requirements that plan administrators and producers alike must meet in order to engage in approved production activities.

States must ensure that requirements for record keeping, reporting, testing, sampling, and disposal of non-compliant products are met in their plans. The plans are then submitted to AMS for approval, and only after AMS has approved the plan, is it permissible for the state to implement it. The plan administered by AMS directly has the same requirements and procedures; however, producers apply directly to AMS. Advocacy has outlined those requirements that are pertinent to our comments here:

1. Hemp samples must be collected and tested for THC concentration within 15 days prior to harvest.¹⁶
2. Testing of samples for THC concentration must be completed at a DEA-registered laboratory.¹⁷
3. Testing concentrations must include total THC, which is the sum of THC and its acid derivative THCA, where total THC accounts for the conversion of delta-9 THCA into THC.¹⁸
4. Crops that test above 0.3 percent THC will be deemed non-compliant and must be disposed of. Producers whose crop tests above 0.5 percent total THC concentration will incur a negligence violation. Producers who receive three negligence violations

¹¹ Pub. L. No. 115-334. §12619(a)(2)(B) (2018).

¹² Pub. L. No. 115-334. §10113, Sec. 297B(a) (2018).

¹³ *See id.* at Sec. 297C (a).

¹⁴ *See id.* at Sec. 297B (a).

¹⁵ 84 Fed. Reg. 58522 (2019).

¹⁶ *See id.* at 58524.

¹⁷ *Id.*

¹⁸ *Id.*

in a five-year period will be ineligible to produce hemp for five years from the date of the third violation. Negligence violations are not subject to criminal charges and prosecution, provided a requisite culpable mental state is not met. This ensures that producers whose crops test above 0.3 percent (hereinafter “hot” or “non-compliant”) are not automatically subject to criminal prosecution if proper care has been taken to grow compliant crops.¹⁹

5. The measure of uncertainty used by each individual lab will be used in testing results. For example, a result of 0.35 percent with a lab specified measure of uncertainty of +/- 0.06, would have a distribution range of 0.29-0.41 percent. Because 0.3 percent is within this range, the sample would be deemed compliant. If, however, 0.3 percent or less was not in the distribution range, the sample would be non-compliant.²⁰
6. Current approved testing methodologies include gas or liquid chromatography; however, the rule states that similarly reliable methods may be allowed.²¹
7. The rule requires the “flower” of the plant to be tested only. Supplemental sampling guidelines issued by AMS suggest that only the top 1/3 of the plant is to be tested.²²

Small Entities are Concerned About the “Chilling Effects” of the Rule

Following publication of the interim final rule, Advocacy engaged in significant outreach efforts with growers, producers, extractors, laboratories, state universities, and experts in hemp law and policy in over 20 states. Advocacy attended symposiums and spoke with numerous small entities via teleconferences, in-person meetings, and site visits.

Small businesses are deeply concerned about the impact this interim final rule and subsequent final rule will have on their ability to be competitive in the hemp industry. The rule has already had a chilling effect on industry. Producers in certain states have stopped growing altogether until they can be certain about what the requirements are. In other states, producers have indicated that buyers have not renewed their contracts. Some have indicated that if the rule is finalized as written, the risk of losing their economic investment due to mandatory disposal is so great that they will reconsider whether to grow hemp at all.

Small hemp producers have significant startup costs. As with other crops, they have the cost of land, seeds, equipment, and labor. For many producers, production is labor-intensive. Small producers reported estimates of thousands of dollars per acre in labor costs alone. In addition, hemp producers have licensing and other regulatory costs not typically incurred by producers of other crops. Small entities indicated that only those businesses with adequate capital and large-scale operations would be able to survive and comply with the requirements of the rule.

Advocacy also spoke with state departments of agriculture who expressed strong concern as to the additional burdens they would incur as a result of the rule. Such burdens include budget and staffing constraints and duplicative record-keeping and reporting requirements. Some states have indicated

¹⁹ See *id.* at 58526.

²⁰ See *id.* at 58525.

²¹ *Id.*

²² See *id.* at 58524. See also “Sampling Guidelines for Hemp Growing Facilities” available at Docket No. AMS- SC-19-0042.

that the rule puts such a large strain on their resources that they are considering whether to “opt-out” of administering a hemp production plan themselves in favor of AMS administering the plan directly. These concerns, while not discussed in greater detail here, should also be carefully considered in implementing a final rule, as ultimately state burdens may be directly passed to small producers in the form of delayed responses to license applications, renewals, and appeals; testing backlogs; duplicative reporting requirements; new license fees; and other programmatic issues.

Advocacy’s Comments on the Rule

In speaking with small entities, Advocacy heard numerous comments on areas of the rule that heighten the uncertainty inherent in the hemp industry, and subject producers to unpredictably high costs and therefore need to be revised. AMS should analyze and weigh the costs and benefits of alternative approaches for small business flexibility. Advocacy has summarized the key comments and provided further recommendations on selected features of the rule below. This list is not exhaustive, Advocacy strongly urges the agency to review and consider all small business concerns with the rule.

I. AMS should work to find a consistent method for testing THC levels that aligns with the statute, does not create additional burdens, and that uses reliable testing methodology.

In the interim final rule, AMS requires that the concentration of THC in a sample collected for testing include the sum of delta-9 THC and THCA (total THC) on a dry weight basis.²³ The requirement calls for an accounting of the conversion of THCA to THC. The language of the Farm Bill states that AMS must include a procedure for testing delta-9 THC using post-decarboxylation or other similarly reliable methods.²⁴ Advocacy is concerned that requiring the level to be calculated as a sum would produce a substantially high number of “hot” readings because the testing process itself converts THCA into THC. This conflated number of “hot” readings has the potential to inaccurately classify compliant crops as non-compliant simply because of the testing methodology used.

In addition, several state programs currently only test delta-9 THC concentrations and feel confident that producers are not selling “hot” crops. This should indicate to AMS that any fears about not including converted THCA in the final measurement will not result in “hot” crops being sold into commerce. Finally, the requirement set forth by AMS stating that the concentration level should account for the conversion of THC to THCA seems confusing when compared with the text of the Farm Bill, in which there is no mention of “conversion.” Advocacy encourages AMS to carefully review the language in the Farm Bill, and the definition of hemp as defined by the Controlled Substances Act in determining whether this calculation should include converted THCA.

In addition, there are concerns that the gas and liquid chromatography methods of testing in many instances may also overstate the THC levels in the sample. Advocacy strongly encourages AMS to approve additional reliable methods for testing that may produce more accurate results.

²³ See *id.* at 58524.

²⁴ *Id.*

II. A shortage of DEA registered labs compounds uncertainty in the industry; this requirement should be revised.

Another requirement of the interim final rule is that testing be conducted at DEA registered labs.²⁵ AMS concedes that there are very few DEA registered labs nationwide, and in fact, in some states there is not even one DEA registered lab.

This requirement has the potential to affect not just producers, but also small laboratories. In order to become a DEA registered lab, a laboratory must go through specific time-consuming registration requirements and pay new fees beyond any other certifications they already possess.²⁶

Producers are greatly burdened by this requirement. Due to the shortage of DEA registered labs, and the inevitable backlog in receiving testing results, producers will have to wait to harvest and risk having their crop go “hot” while waiting for a result. Producers may also be forced to harvest their crop before receiving a determination, in which case they risk expending substantial resources only to have their product disposed of. AMS should consider viable alternatives to this requirement. For example, in those states where hemp production programs already exist, AMS can consider using those labs that are equipped to handle disposal of non-compliant crops, such as universities and state departments of agriculture. These labs are already trained in testing methodology and proper disposal, and they should be considered viable labs for testing hemp.

Advocacy is also concerned that the requirement to test all hemp products is onerous and will contribute to the additional backlog in receiving testing results. AMS should consider moving to a targeted or respective sampling-based approach at least or until AMS can guarantee that there would not be significant delays in receiving testing results from labs.

III. AMS should lengthen the 15-day testing window as it may force farmers to spend money on non-compliant crops.

The interim final rule requires that hemp samples be tested 15 days prior to harvest.²⁷ Almost all stakeholders that Advocacy spoke with said that this is too narrow a window for testing. Many

²⁵ *Id.*

²⁶ In order to acquire Drug Enforcement Administration (DEA) registration to conduct chemical analyses of controlled substances, an analytical laboratory must initiate an application. Laboratories that have not previously registered with the DEA must complete DEA Form 225, which requires the applicant to provide identifying information like addresses, tax identification number (TIN), the type of business activity conducted, and the schedule of controlled substances to be handled. An applicant must provide state-controlled substances license or registration numbers if applicable, as federal DEA registration is based upon the applicant’s compliance with state and local laws. The application also requests information regarding the laboratory’s organizational structure, including the names, address, and social security numbers of any investors, owners, officers, and key employees and corporate filings. A physical description of the facility and security protocols are required for diversion purposes. Lastly, the curriculum vitae or biography of the scientist overseeing the laboratory is required to ensure scientific competency. The application fee for a new DEA Form 225, to be paid upon submission of the application, is \$244; this cost also applies to a Renewal Form 225, which must be completed annually to maintain a valid registration. See “Application for Registration Under Controlled Substances Act of 1970 (New Applicants Only)”, Drug Enforcement Administration, available at <https://apps.deadiversion.usdoj.gov/webforms/jsp/regapps/common/newAppLogin.jsp>. See also “Registration Categories and Fees”, Drug Enforcement Administration, available at <https://www.deadiversion.usdoj.gov/drugreg/categories.htm>.

²⁷ *Id.*

producers indicated that there are several variables that can lengthen a harvest period including weather, equipment failure, labor shortages, and testing backlogs. They said that under the new requirement, there will be even greater testing backlogs that will prohibit them from being able to harvest within the specified timeframe. Harvest is where most small producers expend a great amount of upfront costs. Small producers simply cannot justify spending money to harvest the crop before receiving a test result only to learn that the crop is non-compliant and must be disposed of. If the test results come back “hot,” less expensive harvesting methods can be used to collect the non-compliant product. A producer should not be forced to harvest his crop, expending a large amount of monetary resources, without confirmation. AMS should reconsider this requirement and think through alternatives that would make the rule feasible for producers, taking into consideration its other requirements for testing such as the DEA registered lab requirement, the availability of testing facilities to conduct the tests in a timely manner (see above), and any other small entity considerations.

IV. AMS should establish an acceptable margin of error for testing THC concentrations rather than relying solely on a lab’s measure of uncertainty.

Under the interim final rule, a producer must dispose of a crop that tests above 0.3 percent total THC. Furthermore, crops that test above 0.5 percent total THC will result in a finding of “negligence” which affects the license of the producer.²⁸ AMS states that due to the loss in economic value of a producer’s investment, there should be a high degree of certainty that concentration levels are measured accurately.²⁹ Despite acknowledging this, the agency goes on to state that rather than provide a margin of error that may account for a host of issues that arise while testing, the agency will rely solely on each individual lab’s measure of uncertainty, which accounts only for errors that may arise in the testing process.³⁰

This is problematic. First, “measure of uncertainty” does not account for several other errors that may occur. By using each individual lab’s measure of uncertainty, AMS omits the possibility of errors in sampling, transport, pre-testing preparation, and many other activities which may occur prior to the sample being tested in the lab. By not establishing its own threshold margin of error, AMS is overlooking the fact that test results may be unreliable for a host of reasons, many of which are not accounted for in a lab’s measure of uncertainty. Advocacy suggests that AMS itself establish a comfortable margin of error that allows for a range above 0.3 percent so that producers have certainty that any potential errors have been accounted for. Understanding that the statute is clear as to what is defined as a controlled substance, the agency should at least give producers some leeway by establishing a threshold that more accurately accounts for analytical variances and unintentional errors.

Second, by allowing the measure of uncertainty to be individually applied at each lab, AMS could inadvertently be supporting less reliable methodology or the potential for abuse in the integrity of the testing procedure, as those labs with more favorable measures of uncertainty will be sought out more often. This is yet another reason why AMS should itself set a reasonable margin of error on which producers can rely.

²⁸ See *id.* at 58525.

²⁹ See *id.* at 58524.

³⁰ See *id.*

Advocacy is concerned that AMS is creating a rule that is so stringent, that producers will lose their entire economic investment, the very thing that the agency itself stated it wanted to avoid. By creating a rule that allows for little to no room for error, AMS is discouraging producers because the risk is too great. This is clearly contrary to the intent of the rule and the statute. Advocacy strongly urges AMS to revisit this issue and find a suitable alternative that both aligns with the statute but does not create a detrimental effect on the industry. In setting this margin of error, AMS should also revisit the 0.5 percent negligence threshold as accounting for errors may result in needing to raise this limit as well.

V. AMS should allow for remediation prior to destruction of crops, as uncertainty surrounding negligence findings and crop disposal increase a producer's risk exposure.

The interim final rule calls for the destruction of non-compliant crops³¹; however, under the 2018 Farm Bill provision, the language simply states “disposal” of the non-compliant crop. Furthermore, the Farm Bill language calls for plans to include a date by which a producer can *correct* the negligent violation.³² The language is silent as to what “correct” means; however, many states currently allow for remediation and retesting of non-compliant materials. Given AMS’ requirement in this rulemaking that the crop be destroyed, AMS should consider alternatives to destruction that would allow a producer to recover at least some revenue from the crop. Destruction of a hemp crop means that producers lose the entire market value of their crop. The value of a crop can vary based on the characteristics of the crop and market conditions, but for all small hemp producers, it is a large loss.

For small producers, hemp requires significant upfront investment and risk. In addition to the cost of land, seed, and equipment, hemp production can be labor intensive. Some small producers reported to Advocacy that they budget thousands of dollars per acre in labor costs. In making an investment, producers must consider all the risks of production, including the potential for destruction of the crop. Producers take due care in selecting seeds and tending their crops to manage THC levels and the risk of destruction to an extent. Even the most diligent producers, however, cannot fully control growing conditions such as temperature, weather, and the genetics of neighboring crops, nor can they always control the timing or precision of the testing.

While many stakeholders have stated that remediation itself has costs associated with it, and that for some producers the integrity of their product is destroyed and thus they cannot expect to get the same profit for the remediated material, this may offer at least some financial risk reduction if AMS is not willing to revisit the initial threshold question for establishing a negligence amount. Producers have also proposed several alternatives to the rule that could reduce the frequency of crop destruction. AMS should assess, estimate, and discuss the differences in risk to producers over each alternative suggested by small producers and consider how those differences in risk may affect decisions to produce hemp.

VI. AMS should test a larger portion of the plant, as testing only the top one-third of the plant is an inaccurate representation of how it will be used and raises the risk of test failure.

³¹ See 84 Fed. Reg. 58522, 58526.

³² See *id.*

The interim final rule requires that only the top one-third portion of the plant be collected for sampling.³³ While it's true that the largest concentration of THC in the plant is in the flower, this is not an accurate representation of the how the crop will be harvested and used. Rather, by requiring that only the top one-third of the plant be tested, AMS is ensuring that many crops will test "hot" thus further chilling the hemp market unnecessarily. Advocacy heard from several stakeholders who said that they use each part of the plant for a certain purpose and that only testing the flower is not an accurate representation of how the crop will be used. AMS should reconsider allowing for sampling of a larger portion of the overall plant which provides for a much more accurate representation of how the plant will be used in commerce.

VII. AMS should consider other implications of the rule including shipping, law enforcement issues, and import competition.

Some stakeholders also indicated problems with their products being seized in other states and deemed an illegal substance. Given that the Farm Bill expressly allowed for the interstate transport of hemp material, Advocacy encourages AMS to consider a standardized shipping manifest or other instrument for ensuring that products will not be stopped and seized during interstate transport.

Additionally, Advocacy encourages AMS to establish an inter-agency working group to consider, recommend and implement training and education efforts for law enforcement, the United States Postal Service, and packing and shipping companies so that they are aware of the legal status of hemp and hemp products. This will help to ensure that producers are not criminalized for transporting hemp products that are deemed compliant.

Another source of uncertainty for small hemp producers is how imported hemp and hemp products will be regulated. If imported hemp and hemp products will be less regulated than domestic hemp, domestic producers may find they have a competitive disadvantage. Lack of clarity on international competition increases the difficulty of assessing the value of a crop. Clearing up uncertainty about imports will help domestic producers make better business decisions.

Conclusions and Recommendations

Advocacy appreciates AMS' swift action to establish a domestic hemp production program in the U.S. Advocacy is concerned, however, about the effects the interim final rule will have on small domestic hemp producers. Several of the provisions of the rule impose unnecessary burdens on small entities as written. Many of the sampling and testing requirements should be revisited and alternatives should be considered and analyzed to minimize the burden to small producers.

Advocacy urges AMS to give full and thorough consideration to the above issues and recommendations. If you have any questions or require additional information, please contact me or Assistant Chief Counsel Prianka Sharma at (202) 205-6938 or by email at prianka.sharma@sba.gov.

³³ See *id.* at 58524. See also "Sampling Guidelines for Hemp Growing Facilities" available at Docket No. AMS- SC-19-0042.

Sincerely,

/s/

Major L. Clark, III
Acting Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/

Prianka P. Sharma
Assistant Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/

Kailyn Townsend
Law Clerk
Office of Advocacy
U.S. Small Business Administration

Copy to: Paul Ray, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget