



October 8, 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; Comment Period Reopened (85 Fed. Reg. 55363; September 8, 2020).

Dear Secretary Perdue:

The Office of Advocacy (Advocacy) of the U.S. Small Business Administration submits the following comments in response to the reopening of the public comment period for the U.S. Department of Agriculture's Agricultural Marketing Service (AMS) interim final rule titled: "*Establishment of a Domestic Hemp Production Program.*"¹ Advocacy is concerned about the potential effects the rule will have on small businesses if it is finalized without modifications. Advocacy urges the agency to reconsider certain requirements of the rule, and to consider regulatory alternatives outlined below, 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 rulemaking process. For all rules that are expected to have a significant economic impact on a

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.).



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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 1970 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."⁷ 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."⁸ 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.⁹

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 through the Agricultural Improvement Act of 2018 (hereinafter "the 2018 Farm Bill" or "the Farm Bill") removed hemp

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. § 802(16)(A).

⁸ 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>.

⁹ Pub. L. No. 113-79 (2014).

from the list of controlled substances¹⁰ and tasked USDA’s Agricultural Marketing Service (AMS) with establishing and administering a program for the production of hemp in the United States.¹¹ 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.¹² 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’ policies. The Farm Bill does, however, indicate that states must allow for interstate transport of hemp and hemp products.¹³

On October 31, 2019, AMS published an interim final rule establishing a domestic production program in the U.S.¹⁴ 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 as the agency publishes a final rule. AMS solicited public comments on the interim final rule until January 29, 2020. On October 8, 2020, AMS reopened the comment period for the rule and outlined several key provisions for which it was seeking additional comments and information.¹⁵ This letter responds to the provisions outlined in the reopened comment period.

Key Features of the Rule

The interim final rule outlines several requirements that plan administrators and hemp farmers alike must meet in order to engage in approved production activities, including:

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 Drug Enforcement Administration (DEA) registered laboratory.¹⁷
3. 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 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.¹⁸

¹⁰ Pub. L. No. 115-334. §12619(a)(2)(B) (2018).

¹¹ *Id.* at §10113, Sec. 297B(a) (2018).

¹² *Agricultural Marketing Act.* at Sec. 297C (a).

¹³ *Id.* at Sec. 297B (a).

¹⁴ 84 Fed. Reg. 58522 (2019).

¹⁵ Establishment of a Domestic Hemp Production Program; Comment Period Reopened, 85 Fed. Reg. 55363 (September 8, 2020).

¹⁶ 84 Fed. Reg. 58522 at 58524.

¹⁷ *Id.*

¹⁸ *Id.* at 58526.

4. 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. The measure of uncertainty does not account for pre-sampling variables.¹⁹
5. Current approved testing methodologies include gas or liquid chromatography; however, the rule states that similarly reliable methods may be allowed.²⁰
6. 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.²¹
7. The rule requires destruction of non-compliant crops.²²

The Interim Final Rule Stifles Small Businesses’ Participation in the Industry

Advocacy has engaged in significant outreach with small hemp farmers, producers, laboratories, universities and other experts in the hemp industry both during the initial comment period, and this subsequent reopened comment period.

Small businesses remain deeply concerned about the impact this rule will have on their ability to legally grow hemp should the rule be finalized without any modifications. The rule has already stifled the industry as many farmers have chosen not to grow hemp this year until they are certain about what the requirements are, and whether they can produce compliant crops without the risk of a total loss of their investment due to mandatory destruction of hot crops. In some instances, they have noted that the rules are so stringent that they feel as though they are being set up to fail.

Small hemp farmers have significant startup costs. As with other crops, they have the cost of land, seeds, equipment, and labor. For many farmers, especially those in extraction, harvest is labor-intensive. Even those farmers that grow for fiber, oil and seed, the cost of harvest is high due to a lack of available equipment. Small farmers reported estimates of thousands of dollars per acre in labor costs alone. In addition, hemp farmers have licensing and other regulatory costs not typically incurred by producers of other crops. Some hemp farmers are new to agriculture, and do not grow other crops. They therefore do not already have land and equipment for farming, and do not have a fallback if their hemp crop fails. Finally, because hemp is a nascent industry, it has the potential to attract new farmers provided the regulations are not so restrictive as to inhibit industry growth. Only those businesses with adequate capital and capacity for large-scale operations would be able to survive and comply with the requirements of the rule.

¹⁹ *Id.* at 58525.

²⁰ *Id.*

²¹ *Id.* at 58524. *See also* “Sampling Guidelines for Hemp Growing Facilities” available at Docket No. AMS- SC-19-0042.

²² *Id.* at 5858526.

Advocacy's Comments on the Rule

Certain areas of the rule heighten uncertainty, and subject farmers to a risk of non-compliance and unpredictably high costs. Advocacy filed comments on this rule previously,²³ and hereby provides 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 allow for remediation and on-farm disposal of non-compliant crops so that farmers do not experience a total revenue loss.

The interim final rule calls for the destruction of non-compliant crops;²⁴ however, under the 2018 Farm Bill, 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 farmer can *correct* a negligent violation.²⁵ The statutory language is silent as to what “correct” means; however, many states currently allow for remediation and retesting of non-compliant materials. AMS does not currently allow for disposal or “correction” of non-compliant crops, which runs contrary to the language in the Farm Bill. While small farmers varied in their method of remediation, and some indicated that for those growing for extraction purposes the current methods of remediation would be too costly to result in a sellable product, having this as an alternative to total destruction will allow farmers to develop techniques and technology that may in the future ensure they do not lose their investment.

Destruction of a hemp crop results in a total loss of the market value of the crop. This loss is devastating to small farmers. While it is difficult to estimate because of hemp price volatility, hemp biomass prices were as high as \$40 a pound in July 2019 and fell to under \$10 per pound by January 2020.²⁶ Estimating the cost of production of hemp provides an approximation of the losses the grower experiences when a non-compliant crop must be disposed of under AMS’ rule. Costs of hemp production vary depending on the intended use for the crop. Hemp grown for extraction (CBD), for example, typically requires more labor, and more expensive seeds or transplants than hemp grown for fiber, oil, or seed.

Penn State Extension has published some per-acre costs of production listed below. Their estimates include preparing soil, fertilizing, planting, permitting, testing, and harvest expenses. These are likely underestimates, however, of the actual production cost, as they do not include the cost of pesticides, rent, or opportunity costs, and the estimates assume farmers already own some equipment, which is not necessarily the case for small farmers. These estimates show that for a small farmer, the risk of having to destroy their crop if it is non-compliant may be too high to justify growing hemp at all, especially without any alternatives to destruction of non-compliant crops.

²³ See Comments of the SBA Office of Advocacy, Establishment of a Domestic Hemp Production Program (84 Fed. Reg. 58522) (filed January 29, 2020).

²⁴ 84 Fed. Reg. 58522, 58526.

²⁵ *Id.*

²⁶ Kristine Owrarn, *Hemp Prices Plunge as CBD Demand Falls Short: Cannabis Weekly*, BLOOMBERG, January 26, 2020, available at <https://www.bloomberg.com/news/articles/2020-01-26/hemp-prices-plunge-as-cbd-demand-falls-short-cannabis-weekly>.

Cost of production per acre by type of crop

Type of Crop	Cost of production per acre
Industrial Hemp Fiber ²⁷	\$553.84
Industrial Hemp Grain ²⁸	\$621.49
Industrial Hemp CBD ²⁹	\$13,768.80

As an alternative to complete destruction of a non-compliant crop, AMS should allow for remediation with back-end testing and certification that a hot crop will not leave the farm and enter the stream of commerce. While techniques, success, and willingness vary based on the intended purpose for which the hemp is grown, some small farmers indicated that remediation can be accomplished by purchasing equipment and processing on-site (such as through pyrolysis or adding additional biomass). AMS could therefore allow the farmer to remediate by whatever method they choose so long as the non-compliant crop does not leave the farm and is immediately tested again after the chosen method is performed. This is especially true of those farms that grow for purposes other than extraction.

If the crop once again tests hot, AMS should give the farmer the option for on-farm disposal such as mulching, mowing, or burying the crop. While this still results in a loss of investment for the farmer, at a minimum it allows them to use the crop for some purpose on the farm such as soil fertilization, or livestock bedding.

Another complicating factor is that the regulations only provide licenses to hemp farmers and not processors who receive the crops after they are harvested. These processors often own the expensive equipment necessary for remediation but are unwilling to accept a hot crop in order to be able to remediate it because they could be liable under the regulation. While some farmers indicated that the cost to have their crop remediated at a processing facility is too high, others felt that if processors had a chance to develop and update technology, this cost would go down over time. AMS should consider establishing or allowing for a processor certification program so that processors can accept and remediate non-compliant crops and then immediately submit them for testing before they leave the processing facility. This would once again offer the farmer a second chance to recover at least some of the value of their crop and make growing hemp less of a financial risk. Instead of a total loss of the crop value, farmers could recoup at least some of their costs of production. Though remediation techniques do not seem to be widely practiced now, allowing farmers to have such options may lead to an expansion in remediation practices as the hemp market matures.

²⁷ Lynn Kime, *Industrial Hemp Fiber Production Budget*, PENN STATE EXTENSION, available at <https://extension.psu.edu/industrial-hemp-fiber-production-budget>.

²⁸ Lynn Kime, *Industrial Hemp Grain Production Budget*, PENN STATE EXTENSION, available at <https://extension.psu.edu/industrial-hemp-grain-production-budget>.

²⁹ Lynn Kime, *Industrial Hemp CBD Production Budget*, PENN STATE EXTENSION, available at <https://extension.psu.edu/industrial-hemp-cbd-production-budget>.

II. AMS should lengthen the 15-day harvest window as it is too narrow, and simply unworkable for farmers.

The interim final rule requires that hemp samples be tested 15 days prior to harvest.³⁰ Because AMS does not specify whether this is calendar days or business days, it is being interpreted as calendar days. This window is too narrow. There are several variables that can lengthen a harvest period including weather, equipment failure, labor shortages, and testing backlogs. This is especially true of hemp farmers who grow for extraction and often harvest their crop by hand, painstakingly cutting each individual plant. In the Pacific Northwest for example, having several consecutive days of rain during the harvest season can significantly stall harvesting beyond the current 15-day window. Similarly, in southeastern states, the risk of natural disasters during the harvest season also complicates being able to harvest within the 15-day window. Finally, many small farmers cannot afford the types of equipment necessary to harvest by machine. Traditional combines do not work to harvest hemp and retrofitted machinery is costly, and not yet widely available.

Farmers who do not have test results available within a 15-day window, or who cannot complete harvest within the window, may lose the value of their crop. This value is a substantial loss to small farmers as indicated previously. Even indoor growers who do not have to worry about weather delays and are able to complete harvest within the 15-day window may find it necessary to pay a premium to expedite testing or to spend additional resources to harvest quickly. Many states cited lengthy testing backlogs stating that even when expedited, test results could take longer than five days to be received. A longer window allows farmers to avoid loss of the crop, expediting fees, or higher harvesting costs.

Finally, because harvest is where most small growers expend a great amount of upfront costs, they simply cannot justify spending money to harvest 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 farmer should not be forced to harvest his crop, expending a large amount of monetary resources, without confirmation.

AMS should at a minimum consider making the harvest window 15 business days to align with laboratory hours of operation. Advocacy strongly suggests however, that AMS increase the harvest window to 30 days to allow for maximum flexibility in ensuring that farmers can harvest their hemp crop while accounting for variables that may arise.

III. Testing should include more than just the top one-third of the plant as this better reflects how the plant will be used and ensures that there will not be an inflated number of hot crops.

The interim final rule requires that only the top one-third portion of the plant be collected for sampling.³¹ By requiring that only the top one-third of the plant be tested, AMS is potentially inflating the number of crops that will test “hot” and is inaccurately sampling the plant based on how it will actually be used. The largest concentration of THC is in the flower; only testing this top

³⁰ 84 Fed. Reg. 58522 at 58524.

³¹ *Id.* at 58524. *See also* “Sampling Guidelines for Hemp Growing Facilities” available at Docket No. AMS- SC-19-0042.

portion of the plant is not an accurate representation of the plant's use, especially when used for fiber, seed, and oil. When more of the biomass is added to the sample, the THC concentration is not as high. By using AMS' current testing method, farmers harvesting for fiber, oil and seed which uses more of the plant than just the flower would be penalized for producing an otherwise compliant crop. As Advocacy has previously stated, AMS should allow for sampling of a larger portion of the overall plant which provides for a more accurate representation of how the plant will be used in commerce.

IV. AMS should reconsider its measurement of uncertainty for sampling to account for variables in pre-sampling activities.

In its interim final rule, AMS does not address potential variables in pre-sample collection activities including bagging and transporting the samples. This may result in inaccurate testing results as it is unclear how and whether labs account for pre-sampling uncertainty for activities that occur prior to the sample reaching the lab. Advocacy supports the inclusion of pre-sampling uncertainty methodology as this is important in ensuring that samples are tested accurately and that there is not an inflated number of hot tests. Advocacy would encourage AMS to either allow labs to use their own pre-sampling measurement of uncertainty formula or propose for public comment its own formula, allowing for adequate and appropriate public engagement and review of the data and methods used to create the formula.

V. The requirement that labs be DEA registered overburdens labs and farmers.

The interim final rule requires that testing be conducted at DEA registered labs.³² AMS concedes that there are very few DEA registered labs nationwide, and in fact, in some states there are none. The shortage of DEA registered labs and the inevitable backlog in receiving testing results will force farmers to risk having their crop go hot while waiting for a result, or otherwise harvest their crop before receiving a determination, thereby expending financial resources on a potentially non-compliant crop.

AMS should consider viable alternatives to this requirement. Nationwide labs are already testing hemp samples and disposing of those that are non-compliant. These labs are trained in testing methodology and proper disposal, and they should be considered viable labs for testing hemp without being subject to additional regulatory requirements and certification. The requirement creates an unnecessary air of suspicion and another layer of regulatory hurdles to an already stifled industry. If AMS does not remove this requirement, it should delay implementation until the agency can be certain that there are enough DEA registered labs in each state to meet the volume of crops that need to be sampled.

Finally, 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 as opposed to testing all crops, at least or until AMS can guarantee that there would not be significant delays in receiving testing results from labs.

³² *Id.* at 58524.

Conclusions and Recommendations

Advocacy appreciates AMS reopening the comment period to consider additional comments and recommendations in advance of issuing a final rule. Advocacy is concerned that if finalized without modification the rule will inhibit small business growth. Advocacy urges AMS to give full and thorough consideration to the above issues and proposed regulatory alternatives. 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.

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