



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 990

[Doc. No. AMS-SC-19-0042; SC19-990-2 IR]

Establishment of a Domestic Hemp Production Program;

Comment Period Reopened

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule; reopening of comment period.

SUMMARY: The Agricultural Marketing Service (AMS) is providing an additional thirty (30) days for public comments on the interim final rule (IFR) that established the Domestic Hemp Production Program on October 31, 2019. Reopening the comment period gives interested persons an additional opportunity to comment on the IFR. Comments are solicited from all stakeholders, notably those who were subject to the regulatory requirements of the IFR during the 2020 production cycle.

DATES: The comment period for the interim final rule published on October 31, 2019, at 84 FR 58522, is reopened. Comments must be received by [Insert date 30 days after date of publication in the FEDERAL REGISTER]

ADDRESSES: Interested persons are invited to submit written comments concerning this Notice. Comments should be submitted via the Federal eRulemaking portal at *www.regulations.gov*. Comments may also be filed with Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250-0237; or mailed to USDA/AMS/Specialty Crops Program Hemp Branch, 470 L'Enfant Plaza SW, PO Box 23192, Washington DC 20026. Comments may also be sent via electronic mail to *farmbill.hemp@usda.gov*. All comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *www.regulations.gov*. All comments submitted in response to this rule will be included in the record and will be made available to the public.

FOR FURTHER INFORMATION CONTACT: Bill Richmond, Branch Chief, U.S. Domestic Hemp Production Program, Specialty Crops Program, AMS, USDA; 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or Email: *William.Richmond@usda.gov* or Patty Bennett, Director, Marketing Order and Agreement

Division, Specialty Crops Program, AMS, USDA at the same address and phone number above or

Email: *Patty.Bennett@usda.gov*.

Small businesses may request additional information on this Notice by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or Email: *Richard.Lower@usda.gov*.

SUPPLEMENTARY INFORMATION: The IFR (84 FR 58522, October 31, 2019) was issued under Section 10113 of Public Law 115-334 December 20, 2018, the Agriculture Improvement Act of 2018 (2018 Farm Bill). Section 10113 amended the Agricultural Marketing Act of 1946 (AMA) by adding Subtitle G (sections 297A through 297D of the AMA). Section 297B of the AMA requires the Secretary of Agriculture (Secretary) to evaluate and approve or disapprove State or Tribal plans regulating the production of hemp. Section 297C of the AMA requires the Secretary to establish a Federal plan for producers in States and territories of Indian Tribes not covered by plans approved under section 297B. Lastly, section 297D of the AMA requires the Secretary to promulgate regulations and guidelines relating to the production of hemp in consultation with the U.S. Attorney

General. USDA is committed to issuing the final rule expeditiously after reviewing public comments and obtaining additional information during the initial implementation.

BACKGROUND: The IFR established a domestic hemp production program pursuant to the Agriculture Improvement Act of 2018. The IFR outlines provisions for the U.S. Department of Agriculture (USDA) to approve plans submitted by States and Indian Tribes for the domestic production of hemp. It also establishes a Federal plan for producers in States or territories of Indian Tribes that do not have their own USDA-approved plan. The program includes provisions for maintaining information on the land where hemp is produced, testing the levels of total tetrahydrocannabinol, disposing of plants not meeting necessary requirements, licensing requirements, and ensuring compliance with the requirements of the new part. As a supplement to statutory and regulatory requirements, USDA made available additional guidance documents on sampling and laboratory testing. In addition, on February 27, 2020, USDA delayed requirements for hemp testing laboratories to obtain Drug Enforcement Administration (DEA) registration and clarified allowable cannabis disposal methods.

This document notifies the public of the reopening of the comment period from [Insert date of publication in the

FEDERAL REGISTER] to [insert date 30 days after date of publication in the FEDERAL REGISTER]. Comments previously submitted to USDA by stakeholders during the initial sixty day public comment period [October 31, 2019 - December 30, 2019] or during the thirty day extension period [December 31, 2019 - January 29, 2020] need not be resubmitted, as these comments are already incorporated into the public record and will be considered in the final rule.

Public Comment Requested:

AMS received approximately 4,600 comments from stakeholders during the initial ninety-day public comment period. These comments represent the perspectives of various organizations and individuals within the stakeholder community and provided AMS additional context for decision making. AMS is reopening the public comment period for the IFR to encourage additional input on several topics identified by commenters during the initial ninety-day comment period. The reopening of the public comment period allows stakeholders to provide AMS with further insight gained from the 2020 hemp growing season. AMS is interested in this additional input for all aspects of the U.S. domestic hemp production program, and particularly interested in comments on the following topics:

1: Measurement of Uncertainty for Sampling

The IFR addresses the measurement of uncertainty (MU) in laboratory activities by requiring labs to report the MU as part of any hemp test results. However, the IFR does not address or provide an MU to account for the variability that may occur prior to a sample arriving at a laboratory during cutting, bagging, sealing, transporting, handling, and other "pre-laboratory" activities. Multiple commenters suggested the establishment of an additional MU to account for this variability in addition to the MU provided in the IFR applicable to "in-laboratory" activities. Commenters said that sampling uncertainty arises from the processes related to the collection and handling of the actual plant material to be tested, and the omission of sampling uncertainty in the MU will certainly result in inaccurate, incomplete, and otherwise invalid test results due to the nature of the hemp sampling. One potential way to address this, as presented in a comment, would add an additional MU for pre-laboratory activities (a), in addition to the measurement of uncertainty for in-laboratory activities (b), such that a total measurement of uncertainty (c) can be calculated as the square root of the sum of those squared values ($a^2 + b^2 = c^2$). For example, if the in-laboratory measurement of uncertainty (b) is calculated as 0.0300 percent, and the pre-laboratory

measurement of uncertainty (a) is estimated to be 0.0400 percent, then the total measurement of uncertainty (c) would be 0.0500 percent. AMS seeks additional information on this topic and alternative proposals on how to compute the MU for sampling. Numerical valuations or calculation formulas submitted with comments should clearly demonstrate how sampling uncertainty might be incorporated into the current THC tolerance threshold established by the IFR.

2: Liquid Chromatography Factor, 0.877

The 2018 Farm Bill mandates that all cannabis be tested for THC concentration levels using ``postdecarboxylation`` or similar methods. As explained in the IFR, ``postdecarboxylation`` means testing methodologies for THC concentration levels in hemp, where the total potential delta-9-tetrahydrocannabinol content, derived from the sum of the THC and THCA content, is determined and reported on a dry weight basis. The postdecarboxylation value of THC can be calculated by using a chromatograph technique using heat, known as gas chromatography, through which THCA is converted from its acid form to its neutral form, THC. The result of this test calculates total potential THC. The postdecarboxylation value of THC can also be calculated by using a high-performance liquid chromatograph technique

("LC or "HPLC"), which keeps the THCA intact, and requires a conversion calculation of THCA to calculate total potential THC. As explained in the IFR, the decarboxylated value is calculated using a conversion formula that sums delta-9-THC (Δ^9 -THC) and (87.7) percent of THC-A. Several commenters claim that this formula is inaccurate since it is based on a 100 percent conversion factor, which is nearly impossible to achieve in a laboratory setting. In other words, commenters claim that since the conversion of the THCA to Δ^9 -THC is never perfectly complete without loss or degradation of starting material, the molar sum of Δ^9 -THC and THCA-A measured by LC is always higher than the total Δ^9 -THC measured by GC. To account for this, commenters presented several alternative computation methods, one of which would not multiply the THCA content by 87.7 percent, but rather by 52.62 percent, which is 60 percent of 87.7 percent. Based on comments questioning the accuracy of this figure, AMS seeks additional information from stakeholders regarding the use of this conversion formula. Any alternative factors provided should be clearly quantified and explained.

3: Disposal and Remediation of Non-Compliant Plants

The IFR requires non-compliant cannabis plants be disposed of through a DEA-registered reverse-distributor or

other law enforcement personnel. Under the IFR, no part of a non-compliant plant may be retained or "remediated" for non-ingestible uses like fiber, seed, or pulp. Many comments on the IFR expressed concern about these disposal requirements. Because of this, in February 2020, AMS issued guidance relaxing the requirements for law enforcement-supervised disposal of non-compliant plants and provided examples of how disposal of non-compliant plants may occur on a farm¹. AMS is now requesting additional comment on these disposal practices, including the potential for "remediation" of non-compliant plants. Commenters presented several ideas on how remediation might occur including separation of floral material, rendering plant material as "non-consumable", or "non-ingestible", removing THC from non-compliant plants using methods like filtering or other further processing, or allowing States and Tribes the option to establish their own allowable remediation practices. AMS is also requesting input on whether the on-farm disposal methods provided in the guidance issued on February 27, 2020, (plowing under, mulching, disking, mowing, burying, or burning) is adequate. AMS encourages the submission of quantitative

¹¹ <https://www.ams.usda.gov/rules-regulations/hemp/enforcement>

and qualitative data to identify and demonstrate alternative disposal and remediation activities that ensure non-compliant plant material does not enter the stream of commerce.

4: Negligence

The 2018 Farm Bill establishes criteria to define certain negligent acts, including failing to provide a legal description of land where hemp is produced, not obtaining a license to produce hemp, or growing non-compliant plants. With regard to the production of non-compliant cannabis plants, the IFR states that "hemp producers do not commit a negligent violation if they produce plants that exceed the acceptable hemp THC level and use reasonable efforts to grow hemp and the plant does not have a THC concentration of more than 0.5 percent on a dry weight basis." Commenters to the IFR suggested AMS increase the negligence threshold from 0.5 percent to 1.0 percent. AMS seeks additional stakeholder comments specific to this suggestion. Comments should include quantitative and qualitative data if available.

5: Interstate Commerce

The 2018 Farm Bill and IFR indicate that no State or Indian Tribe may prohibit the transportation or shipment of legally produced hemp across State or Tribal boundaries.

Based on comments to the IFR, we are seeking additional input on whether the IFR is sufficient, or if additional regulatory requirements are needed, to facilitate domestic interstate commerce and transactions, particularly the potential need for national, comprehensive, documentation requirements. Commenters presented several proposals on the kinds of documentation that should be required to accompany raw hemp during transport from a farm to a processing and/or a drying facility. For example, commenters suggested that producers be required to include certain documentation such as copies of the laboratory testing report(s), hemp grower license, invoice / bill of lading, and contact information of buyer and seller. AMS is requesting comments on whether documentation of this nature should be required to accompany all shipments of hemp throughout the U.S.

6: 15-day Harvest Window

The IFR requires that within 15 days prior to the anticipated harvest of cannabis plants, a producer shall have an approved Federal, State, or local law enforcement agency or other USDA-designated person collect samples from plants for the purpose of determining THC concentration. This requirement was established to ensure accuracy in THC testing, since THC concentration in cannabis increases the

longer the plant is left in the ground. AMS received a significant number of comments on the 15-day requirement during the initial comment period. Commenters to the IFR suggested AMS increase the 15-day window to 30 days. AMS is seeking additional comments on this suggestion as well as explanations on why a 30-day window may be more appropriate. Any quantitative and qualitative data provided by stakeholders should be specific and clarify alternative recommended time frames.

7: Hemp seedlings, microgreens, and clones

The 2018 Farm Bill and IFR established statutory and regulatory criteria for commercial hemp production, including sampling and testing of cannabis flower material from mature cannabis plants regardless of the intended final use of the plant. Based on comments submitted in response to the IFR, AMS now seeks additional information from stakeholders regarding agricultural operations that grow cannabis plants, but not to maturity, and without mature flowers. These facilities include seedling, seed, clone, microgreen, and other types of operations that do not grow hemp plants for harvesting mature hemp flowers, and are therefore unable to meet the sampling and testing requirements as described in the IFR. AMS is considering the inclusion of specific regulatory provisions to still

require licensing but not subject licensees to the same sampling and testing criteria as required of traditional hemp growers that sell mature hemp into the stream of commerce. AMS is also requesting additional input on research associated with the THC concentration of immature hemp plants, and any other additional justification on why these types of facilities should not be subject to sampling and testing requirements.

8: Hemp breeding and research

The 2018 Farm Bill and IFR identify the legal requirement to dispose of non-compliant cannabis plants produced at commercial hemp farming facilities. The IFR does not speak to the requirements for hemp breeding and research facilities, many of which are operated by States and land-grant research institutions. These types of facilities are engaged in a wide range of research efforts to develop new hemp cultivars. USDA encourages this type of research and wants to establish a regulatory framework for researchers that is flexible and not burdensome. Based on comments submitted to the IFR on the need for regulatory clarity for these types of facilities, AMS requests input on how the final rule might regulate breeding and/or research facilities. AMS is considering establishing certain regulatory provisions for researchers and research

facilities. Specifically, AMS is requesting input on whether employees of research facilities should be required to obtain a license, and whether these types of facilities should have certain disposal protocols for non-compliant plants. AMS is also considering an exemption for researchers and research facilities from the sampling and testing requirements required of traditional hemp growers who sell hemp into the stream of commerce.

9: Sampling Methodology - Flower vs. Whole Plant

Because THC is concentrated in the flower material of hemp plants, the IFR requires that hemp samples or "cuttings" be collected from the flowers of hemp plants. Comments received on this topic suggested that samples should be collected from not only the flower material of the plant, but from a composite sample of the entire hemp plant, including flowers, stems, stalks, and potentially seeds. AMS is considering the inclusion of sampling provisions that allow for "whole-plant" sampling, as well as a specific requirement for the length of a sample (ie. "two inches" or "20 centimeters"), and is requesting input on these specific topics. AMS is also requesting input on specific requirements for "milling" or preparation of a hemp sample prior to laboratory analysis. One comment suggested AMS revise regulations conform more closely to

the practices recommended by AOAC, particularly those methods pertaining to grinding specifications (2018.11²) and moisture content (930.04³), or consider the protocols developed by the Division of Regulatory Services within the University of Kentucky's College of Agriculture, Food and Environment, specifically SOP#HMP-LB-001⁴ (Procedures for Receiving, Preparing and Releasing Hemp Samples), and SOP#HMP-LB-002⁵ (Procedures for Measuring Delta-9 THC Content in Industrial Hemp by Gas Chromatography with Flame Ionization Detection).

10: Sampling Methodology - Homogenous Composition, Frequency, and Volume

The IFR requires that sampling be conducted to ensure a representative sample of each lot. As part of this requirement, the number of samples collected must be sufficient so that, at a confidence level of 95 percent, no more than one percent of the plants in the lot would exceed the acceptable hemp THC level. The sampling requirements in the IFR do not take into account differences between varieties or different end uses of hemp plants.

² AOAC Official Method of Analysis 2018.11

³ AOAC Official Method of Analysis 930.04

⁴ See <https://www.kyagr.com/marketing/hemp-law.html>

⁵ See: <https://www.kyagr.com/marketing/hemp-law.html>

Many commenters explained that the sampling requirements imposed by the IFR are expensive, burdensome, and nearly impossible to meet by State Departments of Agriculture and Tribal governments. Based on this input, AMS is considering several changes to the sampling requirements; these changes would modify the number of samples required to be collected, and/or provide for the States and Tribes to establish sampling requirements based on end-use.

AMS is considering establishing a specific number of plants to be sampled from every lot, regardless of the lot size, and is requesting input on how to establish these requirements. Specifically, AMS is requesting input on how to potentially establish a fixed sliding scale (for example, a lot of fewer than 10 acres requires a sample of five plants; a lot of between 10 and 20 acres requires six plants; etc.,) rather than leaving those calculations to each State and Tribe.

AMS is also considering establishment of different sampling and testing requirements for hemp based on end use (i.e. risk-based.) AMS further seeks stakeholder comment on potential risk-based methods for hemp lot sampling for differing varieties intended for fiber, grain, seed, or biomass for extract. Methodology discussed should show

quantitative and qualitative data and estimate potential risk levels (i.e., the expected likelihood of growing non-compliant hemp) for different varieties based on the plant's intended end use.

11: Sampling Agents

The IFR requires that all hemp production must be sampled and tested for THC concentration levels, and that samples must be collected by a USDA-approved sampling agent or a Federal, State, or local law enforcement agent authorized by USDA to collect samples. Currently, sampling agents are required to complete a basic training module offered by AMS. AMS is now soliciting comment on the potential need for more rigorous training and/or certification requirements for sampling agents. For example, AMS is interested in whether sampling agents should be required to complete an online training module administered by AMS and pass an examination. Or, alternatively, whether States and Tribes should be able to develop and require the completion of specific training programs for sampling agents under their respective State or Tribal hemp programs. AMS is specifically requesting input on the content of sampling agent training, the frequency with which training should occur, and whether AMS should maintain a national list of trained sampling agents

on the AMS website. The comments should clearly explain why additional requirements may be necessary and suggest what those additional requirements may entail.

12. DEA Laboratory Registration

The IFR requires that laboratory testing of hemp for the purpose of determining compliance under the U.S. Domestic Hemp Product Program be conducted by laboratories appropriately registered with the Drug Enforcement Administration (DEA).

On February 27, 2020, USDA announced guidance⁶ delaying the requirement to use laboratories registered with DEA for testing (7 CFR 990.3(a)(3)(i) and 990.26(e)). Under this guidance, testing can be conducted by labs that are not yet DEA-registered until the final rule is published, or Oct. 31, 2021, whichever comes first. This change was intended to allow additional time to increase DEA-registered analytical lab capacity. AMS is now requesting additional input on whether the DEA laboratory registration requirement should be permanently removed, and if so, how lab disposal requirements of non-compliant hemp samples will adhere to the requirements of the Controlled Substances Act.

⁶ <https://www.ams.usda.gov/rules-regulations/hemp/enforcement>

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