



Agricultural Marketing Service

7 CFR Part 990

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

Establishment of a Domestic Hemp Production Program

AGENCY: Agricultural Marketing Service, Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: This final rule supersedes the interim final rule that established the Domestic Hemp Production Program, as mandated by the Agriculture Improvement Act of 2018 (2018 Farm Bill). This rule includes regulations used by the Department of Agriculture (USDA) to approve plans submitted by States and Indian Tribes for the domestic production of hemp. This rule also includes regulations on the Federal hemp production plan for producers in States or territories of Indian Tribes that do not have their own USDA-approved plans. The program provides requirements for maintaining records about the land where hemp is produced, testing the levels of total delta-9 tetrahydrocannabinol, disposing of non-compliant plants, licensing hemp producers, and ensuring compliance under the new program.

DATES: This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION: This rule is issued under the authority of section 10113 of the 2018 Farm Bill (Pub. L. 115-334; December 20, 2018), which amended the Agricultural Marketing Act of 1946, as previously amended (7 U.S.C. 1621 *et seq.*) (AMA), by adding Subtitle G (sections 297A through 297E). 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. Section 297D of the AMA requires the Secretary to promulgate regulations and guidelines relating to the production of hemp under sections 297B and 297C in consultation with the U.S. Attorney General.

AMS issued an interim final rule (IFR) on October 31, 2019 (84 FR 58522), and began its initial implementation of the program. To date, USDA has approved approximately 45 State and Tribal hemp plans. However, not all of the States and Tribes have implemented their plans for various reasons, including the need to take additional steps to complete State legislative or rulemaking processes or to establish the regulatory scheme as well as the extension of the 2014 Farm Bill Program. Thus, as of November 2020, twenty States and nine Tribes have submitted reports on their respective programs. Based on the reports submitted by States and Tribes in 2020, producers have planted 6,166 acres under the 2018 Farm Bill hemp plans, of which approximately 730 acres were subject to disposal.

As of the effective date of this final rule, the interim final rule is superseded. This final rule replaces the IFR at 7 CFR part 990, effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The Agricultural Marketing Service (AMS), which has been delegated authority to administer the U.S. Domestic Hemp Production Program, provided multiple opportunities for public comment. AMS accepted comments during an initial comment period from October 31, 2019, through December 31, 2019. This initial comment period was extended for an additional 30 days on December 18, 2019 (84 FR 69295), ending January 29, 2020. AMS reopened the comment period for 30 additional days on September 8, 2020 (85 FR 55363), ending October 8, 2020. A total of approximately 5,900 comments were received during all comment periods from States; Indian Tribes; industry and agricultural organizations; private citizens; members of Congress, the scientific community; agencies; and

individuals involved in the growing, processing, transporting and marketing of hemp. A summary of the public comments received and AMS's responses appear under "Comment Analysis" in section IX of this document.

I. Introduction

Hemp is a commodity with numerous industrial and horticultural uses including fabric, paper, construction materials, food products, cosmetics, production of cannabinoids (such as cannabidiol or CBD), and other products.¹ While hemp was produced previously in the United States (U.S.) for hundreds of years, its use diminished in favor of alternatives. Hemp fiber, for instance, which had been used to make rope and clothing, was replaced by less expensive jute and abaca imported from Asia. Rope made from these materials was lighter, more buoyant, and more resistant to saltwater than hemp rope, which required tarring. Improvements in technology further contributed to the decline in hemp use. The cotton gin, for example, simplified the processing of cotton, which replaced hemp in the manufacture of textiles.

The hemp industry continued in the U.S. until the Marihuana Tax Act of 1938. This Act ended the legal production of hemp in the United States, and hemp was added to Schedule I of the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.* Prior to the 2018 Farm Bill, all *Cannabis sativa* L., regardless of delta-9 tetrahydrocannabinol (THC) concentration level, fell within the CSA definition of "marihuana" unless the product fell under a narrow range of exceptions (e.g., the "mature stalks" of the plant).² As a result, many aspects of domestic production of what is now defined as hemp was limited to persons registered under the CSA to do so.

¹ Section 297D(c) of the AMA explicitly preserved the authority of the U.S. Food and Drug Administration (FDA) to promulgate regulations and guidance related to the production of hemp under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) (FD&C Act) and section 351 of the Public Health Service Act (42 U.S.C. 262) (PHS Act). *See* section 297D(c)(1) ("Nothing in this subchapter shall affect or modify . . . the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*); section 351 of the Public Health Service Act (42 U.S.C. 262); or the authority of the Commissioner of Food and Drugs and the Secretary of Health and Human Services. . . ." under those Acts).

² Although the statutory spelling is "marihuana" in the Controlled Substances Act, this rule uses the more commonly used spelling of marijuana.

Under the Agricultural Act of 2014 (2014 Farm Bill), Pub. L. 113-79, State departments of agriculture and institutions of higher education were permitted to produce hemp as part of a pilot program for research purposes. The authority for hemp production provided in the 2014 Farm Bill was extended until January 1, 2022, by the Continuing Appropriations Act, 2021, and Other Extensions Act (Pub. L. 116-260) (2021 Continuing Appropriations Act).

Hemp production in the U.S. has seen a resurgence in the last several years.

Since importation of seed is covered under USDA's Animal and Plant Health Inspection Service (APHIS) regulations, this final rule does not regulate hemp seed imports. APHIS regulates the importation of all seeds for planting to ensure safe agricultural trade. Hemp seeds can be imported into the U.S. from Canada if accompanied by either: 1) a phytosanitary certification from Canada's national plant protection organization to verify the origin of the seed and confirm that no plant pests are detected; or 2) a Federal Seed Analysis Certificate (SAC, PPQ Form 925) for hemp seeds grown in Canada. Hemp seeds imported into the U.S. from countries other than Canada may be accompanied by a phytosanitary certificate from the exporting country's national plant protection organization to verify the origin of the seed and confirm that no plant pests are detected.

This final rule does not address the exportation of hemp. Should there be sufficient public interest in exporting hemp in the future, USDA will work with industry and other Federal agencies to help facilitate this process.

The 2018 Farm Bill requires USDA to promulgate regulations and guidelines to establish and administer a program for the production of hemp in the United States. Under this new authority, a State or Indian Tribe that wants to have primary regulatory authority over the production of hemp in that State or territory of that Indian Tribe may submit, for the approval of the Secretary, a plan concerning the monitoring and regulation of such hemp production. For States or Indian Tribes without an approved plan, the Secretary is directed to establish a Departmental plan to monitor and regulate hemp production in those areas.

The 2018 Farm Bill specifies requirements that all hemp producers must meet. These include licensing requirements; recordkeeping requirements for maintaining information about the land where hemp is produced; procedures for testing the THC concentration levels for hemp; procedures for disposing of non-compliant plants; compliance provisions; and procedures for handling violations.

For the purposes of 7 CFR part 990, and as defined in the 2018 Farm Bill, the term “hemp” means the plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Delta-9 tetrahydrocannabinol, or THC, is the primary intoxicating component of cannabis. Cannabis with a THC level exceeding 0.3 percent is considered marijuana, which remains classified as a Schedule I controlled substance regulated by the Drug Enforcement Administration (DEA) under the CSA.

The term “State” means any of one of the fifty States of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States. The term “Indian Tribe” or “Tribe” has the same definition as in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304). This final rule also includes the definition of “territory of an Indian Tribe” to provide clarity to the term because the AMA does not define it. The final rule defines “territory of the Indian Tribe” as (a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, including rights-of-way running through the reservation; (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state; (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same; and (d) any lands title to which is either held in trust by the United States for the benefit of any Indian Tribe or individual or held

by any Indian Tribe or individual subject to restriction by the United States against alienation and over which an Indian Tribe exercises jurisdiction. Under an approved Tribal plan, the Indian Tribe will have regulatory authority over hemp production within its Territory.³ A full list of terms and definitions relating to part 990 can be found under “Definitions” in section IV.

This rule is divided into several sections. The first section provides a general introduction to the rule. This section does not go into a detailed description of all parts of the rule or about the provisions of the rule that are discussed later on in other sections. Sections for State and Tribal plans as well as the USDA plan contain general information on land use, tribal jurisdiction authority, sampling, testing, disposal and remediation, compliance provisions, information sharing, certification of resources, and State and Tribal plan approvals. The USDA section also includes USDA hemp license provisions and suspension. These two sections provide general provisions that are discussed in more detail in the comment analysis section. Sections containing definitions, severability and the regulatory analysis are included before the regulatory language. The reader may be best served by reading the comment section to determine the changes made to this rule.

II. State and Tribal Plans

Section 297B (7 U.S.C. 1639p) of the AMA requires that States or Indian Tribes seeking primary regulatory authority over the production of hemp in that State or territory of that Indian Tribe, submit, for the approval of the Secretary, a plan concerning the monitoring and regulation of such hemp production. State or Tribal plans must be submitted to USDA and approved prior to their implementation. Nothing preempts or limits any law of a State or Tribe that regulates the production of hemp and is more stringent than the provisions in Subtitle G of the AMA.

³ We note that if an Alaskan Native Corporation wants to produce hemp on land it owns in fee simple, it would need to have a State or USDA license, whichever is applicable, because that land does not qualify as Indian Country and the Corporation does not have jurisdiction over that land.

AMS received extensive public input on the regulatory requirements for State and Tribal hemp plans. Incorporating the input received, the following sections explain the changes to the regulatory requirements for State and Tribal hemp plans.

A. Land used for production.

The 2018 Farm Bill and the IFR required that plans include a process by which relevant information regarding the land used for hemp production in their jurisdiction is collected and maintained. Certain information on mailing addresses and hemp production sites must be collected for each licensee covered by the State or Tribal plan.

The information required to be collected includes a legal description of the land and geospatial location for each field, greenhouse, or other site where hemp is produced. Geospatial location is necessary because many rural locations do not have specific addresses, and these coordinates will assist with the proper identification of hemp production locations.

In addition to the land information required to be collected by the appropriate State or Indian Tribe, AMS chose to require licensed producers, including those under the USDA plan, to report their hemp crop acreage to the Farm Service Agency (FSA). Although many commenters opposed this requirement based on costs around the time and travel expense necessary to physically visit the appropriate FSA County Office, AMS has determined that maintaining the FSA reporting requirement is essential for several reasons. AMS recognizes that in some cases producers may travel to FSA offices miles away incurring additional time and cost. These costs are incorporated in the expected burden of this program.

First, USDA is statutorily required to provide law enforcement with certain “real-time” information about who is growing hemp, whether their license is in good standing with the regulatory body issuing the license, and the location(s) where hemp is being grown. Having FSA collect the necessary information enables USDA to provide the most accurate and “real-time” information to law enforcement, as required by Subtitle G of the AMA. Second, FSA offices serve as useful resources to all farmers and, in collaboration with other USDA agencies,

can provide a wide range of insurance, risk management, and conservation program guidance and information. These offices currently serve the agricultural industry within their communities, where producers can establish farm and producer records, record their licensing information, and report crop acreage. The producer may also, with supporting documentation, update their FSA farm records for leases, sub-leases, or land ownership. Requiring farmers to visit the FSA office ensures that they receive information on the availability of these helpful tools and programs. This is particularly important for new farmers, who may not be aware of the wide range of programs and services offered by USDA.

Further, FSA maintains the technology necessary for data collection and geographical land identification. These tools will provide easy access to information needed for law enforcement and for other agricultural programs. AMS has determined, for these reasons, to continue to require the reporting of hemp crop acreage to FSA.

Based on input from commenters, USDA is also clarifying the distinction between the term “lot” as defined in the IFR, and the term “subfield” as it relates to FSA reporting. Although this final rule uses the term “lot” to discuss the land where hemp is grown, when a producer visits the FSA office to report hemp crop acreage, FSA staff will help producers determine the applicable FSA-specific term for designating the location(s) where hemp is being grown. The terminology used by FSA to denote land areas include terms like “farm,” “tract,” “field,” and “subfield,” which are equivalent to AMS’s term “lot.” FSA staff will not provide a “lot number” to producers as described in the IFR. FSA will use designations that they currently use such as track, field, or subfield, depending on the specific area. This designation does not change the requirements or the information submitted for law enforcement. AMS will amend the form to reflect these terms. When reporting to FSA, producers must provide their State or Tribe-issued license or authorization number. A link to FSA information on how to report hemp crop acreage to FSA is available at

<https://www.fsa.usda.gov/Assets/USDA-FSA-Public/usdfiles/FactSheets/2019/crop-acreage-reporting-19.pdf> and is available on the USDA hemp production program website.

As described in the IFR, certain State hemp pilot programs operating under the 2014 Farm Bill authority developed “seed certification” programs to help producers identify hemp strains with potentially lower THC concentrations. The term “certification” in this context means tested or verified, but it does not necessarily mean certified for varietal purity. USDA acknowledges that this remains a significant hurdle to the hemp industry and is committed to assisting with the research and development of compliant hemp varieties. Although AMS encourages States and Tribes to develop seed-certification programs if sufficient data is available, AMS has determined, at this time, that requiring the use of certain “compliant” varieties or establishing National rules for State-level certification programs is inappropriate. AMS will look at best practices from States and Tribes to evaluate if a program would be applicable to a USDA plan. If applicable, USDA may develop a performance-based sampling program. Such a program will require USDA to conduct rulemaking and comment procedures.

The term “seed certification,” as found in the Federal Seed Act and its Regulations, refers to a third-party verification process that assures seed customers that they are receiving pure varieties and high-quality seed for planting purposes. The Federal Seed Act grants authority to seed certifying agencies in each State to administer varietal seed certification standards for all major agricultural crops, including hemp. Recognized seed certifying agencies are members of the Association of Official Seed Certifying Agencies (AOSCA), and they administer uniform AOSCA standards and inspect crops being grown for seed throughout the production process to maintain varietal purity. These activities protect seed customers in both domestic and export markets. Seed produced under these types of certification programs ensure a distinct, recognized variety that is properly tested and legally labeled. Seed certification under the Federal Seed Act is concerned with many varietal characteristics, not solely THC concentration. This enables farmers to confidently purchase seed of a suitable variety, by purchasing seed certified as to

variety. Using certified seed, as described in the Federal Seed Act regulations and AOSCA standards, is an option for states and tribes if they have the data to support that the seed would work in their environment. While varietal certification does not absolutely ensure a specific THC content, the fact is that THC content (or at least a range) is a reliable varietal characteristic. Therefore, if the farmer is able to confidently purchase seed of a suitable variety by purchasing seed certified to variety, they at least know what to expect from the variety in their area.

For this reason, AMS recommends the use of hemp seed from varieties that have undergone varietal certification, following the process outlined in the Federal Seed Act Regulations, and produced following AOSCA standards. This recommendation will assist hemp farmers to purchase recognized hemp varieties that have been tested for purity and are properly labeled.

Additionally, AMS administers the Plant Variety Protection Office (PVPO) that is actively accepting applications of seed-propagated hemp for plant variety protection. The PVPO provides intellectual property protection to breeders of new varieties of seeds, tubers, and asexually reproduced plants. Under the U.S. Plant Variety Protection Act, PVPO examines new applications and grants certificates that protect varieties for 20 years (25 years for vines and trees). Certificate owners have rights to exclude others from marketing and selling their varieties, manage the use of their varieties by other breeders, and enjoy legal protection of their work. This work, however, does not certify seeds for THC content.

B. Tribal Jurisdictional Authority.

The final rule clarifies the extent of a Tribe's regulatory authority over hemp production within its Territory. Several commenters stated that language in the IFR raised uncertainty as to whether Indian Tribes could regulate hemp production by non-Indians operating on fee lands within a Tribe's Territory. To address this uncertainty, § 990.4(b)(4) of the final rule now provides that "[u]pon USDA approval of a Tribal plan, a Tribe may exercise jurisdiction and

therefore primary regulatory authority over all production of hemp in its Territory regardless of the extent of its inherent regulatory authority.” Thus, as long as the land at issue qualifies as land within the territory of an Indian Tribe under § 990.1 of the final rule, an Indian Tribe with a USDA-approved plan may regulate all hemp production on that land. USDA determined that this additional language is consistent with Congressional intent in the 2018 Farm Bill and best ensures that hemp production is managed consistently throughout the Territory of an Indian Tribe.

If an Indian Tribe desires to have primary regulatory authority over the production of hemp in its Territory, under the 2018 Farm Bill, the Tribe may submit a plan to USDA. Section 297C of the AMA provides that “In the case of a State or Indian Tribe for which a State or Tribal plan is not approved under section 297B, the production of hemp in that State or the territory of that Indian Tribe shall be subject to a plan established by the Secretary to monitor and regulate that production.” Hence if a Tribe does not regulate hemp production within its Tribal Territory, USDA, not a State with an approved plan, will regulate hemp production program within that Territory.

Sections 297B and C plainly show that Congress chose to take a territorial approach to the Tribal regulation of hemp production under the AMA. If Congress only wanted Indian Tribes to assume primary regulatory authority over hemp production in areas within their inherent jurisdictional authority it could have stated this. Instead, Congress opted for a land-based approach and delegated to Tribes the authority to assume hemp production regulatory authority throughout their territories. In consideration of the statutory language and the overall statutory scheme of the 2018 Farm Bill, USDA has determined that an Indian Tribe with an approved plan may regulate hemp production throughout its territory without regard to the Indian Tribe’s ability to demonstrate inherent regulatory authority under the factors set forth in *Montana v. United States*, 450 U.S. 544 (1981). Because Congress did not define Territory of the Indian Tribe in the AMA and did not include discussion in the legislative history of the

meaning of this term, USDA is exercising its authority to issue regulations to implement the provisions in the 2018 Farm Bill to define this term in this manner.

USDA's decision is in-line with agency determinations where the agency determined that Congress delegated a Tribe with authority to exercise regulatory authority over non-Tribal fee land within reservations. EPA Interpretive Rule: Revised Interpretation of Clean Water Act Tribal Provision, 81 FR 30183 (May 16, 2016); EPA Final Rule: Indian Tribes—Air Quality Planning and Management, 63 FR 7254 (Feb. 12, 1998); *Arizona Public Serv. Co. v. EPA*, 211 F.3d 1280 (D.C. Cir. 2000).

Moreover, USDA's decision is practicable and prevents piecemeal licensing by Tribes and USDA within a single Tribal Territory. If a Tribe was only able to exercise primary regulatory authority over hemp production within its Territory when it could demonstrate the inherent authority to do so, USDA could be required to regulate some hemp production within the Territory – for example, it could foreseeably be required to regulate hemp production by non-Indians operating on fee lands in certain cases. Such a system would be confusing for producers and regulators alike.

For the foregoing reasons, the final rule now clearly explains that upon USDA approval of a Tribal plan, a Tribe may exercise primary regulatory authority over all production of hemp in its Territory regardless of the extent of its inherent regulatory authority, as reflected in §§ 990.2 and 990.4 of the final rule.

C. Sampling for total THC.

AMS is changing certain aspects of the sampling requirements. This section addresses performance-based sampling, how to sample hemp plants, sampling agents, and the harvest window after sampling takes place.

Sampling Requirements

AMS received significant input from commenters on how hemp sampling procedures and requirements should be changed. When referring to “sampling,” we mean the process of collecting cuttings from hemp plants for purposes of compliance testing.

Performance Based Sampling

The IFR required State and Tribal hemp programs to collect samples from the flower material of the cannabis plant. The IFR also required State and Tribal hemp programs to collect enough samples to ensure at a confidence level of 95 percent that no more than one percent (1%) of the plants in the lot would exceed the acceptable hemp THC level. Guidance issued concurrently with the IFR explained these requirements in greater detail. The sampling requirements in the IFR did not consider geography, environmental factors, State or Tribal level seed certification programs, or other factors faced by States and Tribes when developing sampling requirements for their hemp programs. AMS is modifying the sampling provisions as presented in the IFR to allow States and Tribes to develop performance-based sampling requirements. Performance-based sampling achieves defined objectives and focuses on results. It differs significantly from a prescriptive action in which licensees are provided detailed direction on how those results are to be obtained. A performance-based approach would simply set a performance objective (e.g., reliability of 95 percent) and allow the States and Tribes considerable freedom in how to achieve that reliability objective with their sampling methodology.

Some State hemp regulators have successfully developed sampling requirements that ensure adherence to State and Federal regulations, while allowing for flexibilities due to limited State resources and State and Tribal differences. States expressed extensive concerns about the requirements in the IFR that all lots must be sampled and tested, due to significant logistical and fiscal impacts. They explained that, since most hemp in a given region is harvested at the same time, sampling must be completed within a very short time frame by only a few individuals. Several States also explained how sampling occurs under established State programs and

described the different ways that perceived risk determines State requirements. Some States utilize different sampling requirements for broad end-use categories like “fiber/grain” hemp versus “cannabinoid” hemp, while others base their requirements on historical THC concentrations of certain varieties or on the characteristics and growing history of a certain farm or producer. While these States’ plans have not been approved under the 2018 Farm Bill regulations, we believe that providing States and Tribes the flexibility to develop sampling plans based on data they gather during an extended period of time may be an effective method at ensuring the overall acceptable hemp THC level of hemp grown in the State or Tribe. AMS agrees that sampling requirements should allow States and Indian Tribes more flexibility in the management of their hemp regulatory programs.

AMS agrees that requiring sampling from every lot may be burdensome and expensive for State and Tribal regulatory entities and producers. AMS also finds compelling the arguments presented by States’ regulatory agencies and other commenters that there are different risk factors for hemp used for fiber and grain versus hemp used for cannabinoids. Data submitted with comments show that the THC levels of hemp used for cannabinoids are frequently higher than those of hemp for fiber and grain. The FDA authorizes the marketing of few types of cannabinoid products. This final rule does not cover cannabinoid products.

AMS also acknowledges that research institutions face special circumstances when conducting hemp research. Accordingly, this rule provides sampling and testing flexibility to these institutions and producers working with them to conduct hemp research. Producers that produce hemp for research, along with the research institution itself, must obtain a license from a State, Tribal Government, or USDA. However, the hemp that is produced for research is not subject to the same sampling requirements provided that the producer adopts and carries out an alternative sampling method that has the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to this alternative method will not test above the acceptable hemp THC level. Research institutions and producers growing

hemp for research purposes shall ensure the disposal of all non-compliant plants. Research institutions and producers growing hemp for research purposes shall also comply with the reporting requirements including reporting disposal of non-compliant plants. Research institutions that handle “hot” hemp must follow CSA requirements for handling marijuana.

States and Indian Tribes are allowed to develop performance-based requirements for these institutions. However, the alternative method must have the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to the alternative method will not test above the acceptable hemp THC level.

AMS views this flexibility as necessary to help support research and development as it relates to hemp production. This decision allows these types of research facilities and institutions to confidently oversee the study of hemp through trialing and genetics research, which AMS believes to be critical to the growth of industry, particularly in its infancy. Over time, the flexibility provided by this final rule will help to stabilize industry by providing greater understanding of hemp genetics and how certain varieties respond differently to growing conditions in various geographic locations. All producers are expected to benefit from such knowledge as they will be made aware of the more stable and consistently reliable hemp varieties. Any non-compliant plants produced by research institutions as a result of research and development will still need to be disposed and verified through documentation. Research and development facilities are still required to be licensed by States and Tribes. Research institutions must follow licensing and reporting requirements.

In performance-based approaches, measurable or calculable parameters are available to determine whether the performance standard is met. These performance parameters are identified to provide measures of performance and the opportunity to take corrective action if performance is lacking. In the case of hemp, the performance parameter is the 0.3 percent THC level and other measures are included in this final rule if the parameter is not achieved such as disposal and remediation.

USDA finds that in order to increase regulatory effectiveness, it makes sense to allow States and Indian Tribes to consider performance-based alternatives when developing sampling plans. If the objective or intended result can be achieved by setting a readily measurable standard that is enforceable, the proposed requirement should merely specify the objective or result to be obtained rather than prescribe to the licensee how the objective or result is to be attained. In other words, requirements should be performance-based, and highly prescriptive rules and requirements should be avoided absent good cause to the contrary.

The sampling requirements for State and Tribal plans allow for States and Indian Tribes to develop unique sampling protocols for hemp growing facilities under their jurisdiction. Sampling protocols must be sufficient at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level and ensure that a representative sample is collected that represents a homogeneous composition of the lot. Alternatively, the final rule allows States and Indian Tribes to adopt a performance-based sampling protocol. A performance-based protocol must have the potential to ensure, at a confidence level of 95 percent, that the cannabis plants will not test above the acceptable hemp THC level. USDA encourages the alternative protocol to consider seed certification processes or process that identifies varieties that have consistently demonstrated to result in compliant hemp plants in that State or territory of the Indian Tribe, whether the producer is conducting research on hemp at an institution of higher learning, whether a producer has consistently produced compliant hemp plants over an extended period of time, and other similar factors. AMS believes this will provide needed flexibility to States and Indian Tribes to develop logical and enforceable sampling requirements that take into consideration their unique circumstances. AMS will still require States and Indian Tribes to submit their individual sampling requirements for review as a component of the plan approval process. Sampling protocols submitted by States and Indian Tribes must comply with the thresholds established by the 2018 Farm Bill and this final rule. If performance-based sampling requirements are not included in a State or Tribal plan, the method

used for sampling must be sufficient at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level and ensure that a representative sample is collected. from every lot, and thereby every producer must be sampled and tested. When evaluating sampling protocols submitted by States and Indian Tribes, USDA will evaluate the risk of producing non-compliant material to determine approval or disapproval. In evaluating the risk, USDA will take into consideration whether the performance-based factors the State or Indian Tribe used have the potential to assure compliance at a 95 percent confidence level.

Since USDA cannot develop performance metrics that would be applicable independently from where the producer is located, producers licensed under the USDA plan are subject to the sampling requirements in the rule. USDA guidelines provided on the USDA website at <https://www.ams.usda.gov/rules-regulations/hemp/information-sampling> describe best practices for complying with those requirements.

USDA recognizes that several States and Tribes may include performance-based sampling in their plans and that their experience could demonstrate that their sampling procedures may be adaptable to the USDA plan. If USDA finds this to be the case, USDA will explore a performance-based sampling scheme for producers under the USDA plan in the future through notice and comment rulemaking.

Where to Take Samples on the Hemp Plant

AMS will retain the requirement that pre-harvest samples be taken from the flower material of hemp plants. However, this rule clarifies the number of inches of plant material needed for the sample and provides greater detail as to where exactly on the plant to make a cutting. The IFR required that samples be taken from the “flower material” of hemp plants. Further, in guidance material issued concurrently with the IFR, AMS explained in greater detail where exactly on the plant to make a cutting by recommending samples be taken from the top third of the plant, “just underneath a flowering material.” Many commenters argued that samples

should be taken from the “whole plant” or that a “homogenized” sample should be taken to include the stem, stalk, leaves, and seeds along with flower material. Alternatively, some commenters proposed that samples be taken post-harvest from shredded whole plant material, otherwise known as “biomass.” Advocates of these positions asserted that THC levels of the whole hemp plant are better represented by samples collected from the entire plant, and not just from floral material. Other commenters advocated for sampling of a certain size or length of cutting. Such commenters advocated adoption of the sampling methods they or others had used under pilot programs. Many State agriculture departments suggested AMS continue to require samples taken from flower material.

Even though many commenters felt that whole plant sampling should be allowed, AMS is of the opinion that since THC is concentrated in the flower material of the plant, the flower material is more appropriate to test than the entire plant. AMS will modify the sampling requirement to state that the sample shall be approximately five to eight inches from the “main stem” (that includes the leaves and flowers), “terminal bud” (that occurs at the end of a stem), or “central cola” (cut stem that could develop into a bud) of the flowering top of the plant. This change is consistent with the sampling practices in several States that established hemp programs pursuant to the 2014 Farm Bill authority. AMS determined that this standard strikes an appropriate balance between the need to collect a sufficiently large portion of the plant’s flower (where THC and other cannabinoids are at their most concentrated), and the need to avoid cutting a portion that is so large that it would be logistically difficult to transport, dry, and prepare for lab testing. Based on the information discussed above and the experience and expertise of States and other commenters already engaged in hemp production pursuant to the 2014 Farm Bill authority, AMS is including new requirements herein.

AMS is publishing updated sampling guidance concurrently with this final rule. This guidance describes how to comply with this requirement regarding where to take the sample from the plant as well as other sampling requirements in the final rule. While the sampling

guidance provides best practices for meeting the requirements, States, Indian Tribes, and USDA licensees may adopt sampling procedures that differ from the guidance so long as those procedures meet the standards in this final rule.

Sampling Agents

The IFR required a Federal, State, local, or Tribal law enforcement agency or other Federal, State, or Tribal designated person to collect hemp samples for the purposes of testing THC levels in hemp. Comments in response to the IFR presented several concepts concerning how sampling agents should be designated and/or trained. Comments mostly suggested the need for enhanced training requirements for sampling agents to promote consistency in the ways that samples are collected nationwide. Based on comments received regarding sampling agents, AMS will provide additional training resources for sampling agents. These training documents will explain how sampling agents can meet the sampling requirements of this regulation. States and Indian Tribes with an approved plan may require the sampling agents used in their jurisdiction to take the USDA training, or they may develop their own custom training incorporating USDA requirements with additional State or Tribal requirements. States and Tribes must maintain information, available to producers, about trained sampling agents.

Other comments on the topic of sampling agents spoke to the strain on State and Tribal resources of requiring agents to take samples instead of producers. Commenters presented two proposals to alleviate this strain – allowing producers to collect their own samples and reducing the volume of farms and plants from which samples are collected. AMS is retaining the requirement that only designated agents can collect samples. This ensures that there is consistency in sampling throughout the industry. The flexibilities provided to States and Indian Tribes with primary regulatory authority over hemp in their jurisdiction will likely reduce the number of samples required to be collected and thus reduce the burden on designated sampling agents.

Harvest Window

The IFR required harvest within 15 days of sampling. AMS received comments regarding the challenges presented by the 15-day harvest requirement, including the logistical challenges to State and Tribal agencies charged with overseeing the collection of samples in this short timeframe, the logistical challenges to producers in harvesting hemp crops in this short timeframe, and testing challenges faced by laboratories in having to conduct compliance analyses in this short timeframe. Commenters suggested lengthening the 15-day harvest requirement to a longer period of time—with some asking for up to 60 days.

AMS agrees with the arguments presented by commenters and recognizes the challenges imposed on the industry by the 15-day harvest requirement. AMS must also balance the logistical challenges of a harvest window requirement with the fact that THC concentration in hemp generally increases the longer the plant is in the ground. AMS now understands from data provided in comments that THC concentration does not increase linearly and is impacted by a myriad of environmental factors including moisture, wind, temperature, disease, sunlight, and soil, as discussed in the Comment Analysis section of this rule. The regulatory objective is to ensure, as best as possible, harmonization of the THC levels in the pre-harvest sample and that of the harvested material. Requiring that samples be taken prior to harvest is the best way to judge the THC concentration of the plant and the lot the sample represents. AMS recognizes that the most accurate measurement would be at time of harvest, but also understands the logistical practicalities discussed above and therefore has determined the most balanced approach is 30 days. For these reasons, AMS is expanding the window within hemp must be harvested after sampling to 30 days.

Under this final rule, no more than 30 days prior to the anticipated harvest of cannabis plants, a “sampling agent” must collect samples for compliance testing. If producers do not harvest within 30 days of sampling, the plant will likely have a higher THC level at harvest than the sample that is being tested. This requirement balances the need for accuracy with the logistical realities faced in the sampling and testing processes and will yield the most accurate

measurement of the THC level at the point of harvest. Increasing the window within hemp must be harvested after sampling from 15 to 30 days will better allow for variables such as testing, weather, agricultural practices, and equipment delays.

D. Testing laboratories.

The IFR introduced regulatory requirements for laboratories testing hemp for compliance purposes. AMS also issued guidance with the IFR to explain best practices for hemp testing laboratories (www.ams.usda.gov/rules-regulations/hemp). Based on comments to the IFR, AMS is changing certain parts of these regulations and updating the accompanying testing guideline. While the testing guidance provides best practices for meeting the regulatory requirements, States, Indian Tribes, and USDA licensees may use test procedures that differ from the guidance so long as those procedures meet the standards in the final rule.

Registration with DEA

The IFR required all hemp testing laboratories to be registered with the DEA in accordance with the CSA (21 U.S.C. 823(f)). On February 27, 2020, AMS announced a delay in enforcement of this requirement until October 31, 2020, or the publication of a final rule, whichever came first (USDA, DEA Provide Options for Labs, Disposal of Non-Compliant Hemp Plants. Thursday, Feb 27, 2020)⁴ AMS announced this enforcement delay to allow additional time to increase DEA registered analytical lab capacity and avoid potential delays to producers in receiving test results. Although AMS received comments in opposition to this requirement, AMS is retaining the requirement in this final rule that any laboratory testing hemp for purposes of regulatory compliance must be registered with DEA to conduct chemical analysis of controlled substances in accordance with 21 CFR 1301.13. This requirement also applies to any laboratory testing hemp throughout the growing season to informally monitor THC concentration. Registration is necessary because laboratories could potentially handle cannabis

⁴ www.ams.usda.gov/press-release/usda-dea-provide-options-labs-disposal-non-compliant-hemp-plants

that tests above 0.3 percent THC on a dry weight basis, which is, by definition, marijuana and a Schedule 1 controlled substance. Instructions for laboratories to obtain DEA registration, along with a list of approved laboratories, are available on the USDA Domestic Hemp Production Program website. AMS is aware that there are still not enough DEA-registered hemp testing facilities in some States or territories of Indian Tribes. However, since the IFR was published, numerous laboratories have applied for registration and DEA is working diligently to process these requests. Given the limited number of DEA-registered labs available to hemp producers, delay in enforcement of this requirement is continued until December 31, 2022. AMS anticipates this delay will provide adequate time for testing facilities to obtain DEA registration.

Laboratory Testing Requirements

Section 297B(a)(2)(A)(ii) of the AMA requires that State and Tribal plans for primary regulatory jurisdiction include a “procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp produced in the State or territory of the Indian Tribe.” Since not all testing methods include decarboxylation, AMS is requiring that the total THC, which includes the potential conversion of tetrahydrocannabinolic acid (THCA) into THC, be reported and used for purposes of determining the THC content of a hemp sample.

The IFR included requirements on how laboratories conduct hemp testing for the purposes of regulatory compliance to assure that total THC levels were measured. Commenters provided extensive input on testing requirements, particularly the requirement to test for “total” THC instead of only “delta-9” THC. AMS is retaining this requirement.

AMS looked at current testing methodologies that would meet the decarboxylation requirement set in the 2018 Farm Bill. In gas chromatography (GC) testing, heat is applied to the sample, which decarboxylates THCA, producing delta-9 THC, so that the final delta-9 THC result is actually a total THC result. GC is the more traditional technique used for THC testing

and was the technique used by Dr. Small⁵ in his research that derived the 0.3 percent threshold that was used as a basis for the 2018 Farm Bill requirement and is used by law enforcement as the threshold to differentiate hemp from marijuana. In his research papers, the 0.3 percent threshold is based on *total available* delta-9 THC, which is the sum of THCA and delta-9 THC in the plant material.

Liquid chromatography (LC) testing does not involve the use of significant heat, so that the THCA in a sample does not generally decarboxylate. Results can be reported for THCA and delta-9 THC separately. When LC is used, the total THC needs to be calculated post-testing in order to report results as a “post-decarboxylation” delta-9 THC value. The requirement to report the total THC value as the THC content regardless of testing methodology used ensures testing consistency across the program.

Samples must be tested using post-decarboxylation or other similarly reliable analytical methods by which the total THC concentration level reported accounts for the conversion of THCA into THC. Acceptable testing methodologies currently include gas or liquid chromatography with detection.

The total THC, derived from the sum of the THC and THCA content, shall be determined and reported on a dry weight basis. In order to provide flexibility to States and Tribes in administering their own hemp production programs, alternative testing protocols will be considered if they are comparable to and similarly reliable as the baseline mandated by section 297B(a)(2)(A)(ii) of the AMA and established under USDA regulations and procedures. Updated USDA procedures for sampling and testing will be issued concurrently with this rule and will be provided on the USDA website.

Reporting requirements for laboratories are discussed later in Section X (Regulatory Analysis) of this final rule. To clarify these requirements, laboratories conducting testing for

⁵ Small, E.; Beckstead, H. D.; Chan, A. The Evolution of Cannabinoid Phenotypes in Cannabis. *Economic Botany*, 29, 219-232, 1975.

purposes of monitoring THC concentration throughout the growing season are not subject to these reporting requirements. These tests are for the producer to monitor his or her production as it grows and not to comply with pre-harvest testing requirements in this rule. Only laboratories conducting the “final” test that will be used to determine whether a sample is compliant are subject to reporting requirements.

Measurement of Uncertainty

This final rule requires that laboratories calculate and include the Measurement of Uncertainty (MU) when they report THC test results. “Measurement of uncertainty” is defined as “the parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement.” This definition is based on the definition of “uncertainty (of measurement)” in section 2.2.3 of the Joint Committee for Guides in Metrology⁶ 100:800, Evaluation of measurement data — “Guide to the Expression of Uncertainty in Measurement” (JCGM Guide). The National Institute of Standards and Technology (NIST) Technical Note 1297, “Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results” (TN 1297), is based on the JCGM Guide. AMS also relied on the Eurachem/Co-Operation on International Traceability in Analytical Chemistry’s “Guide on Use of Uncertainty Information in Compliance Assessment, First Edition 2007”. Colloquially, the measurement of uncertainty is similar to a margin of error. When the measurement of uncertainty, normally expressed as a +/- with a number (e.g. +/- 0.05), is combined with the reported measurement, it produces a range, and the actual measurement has a known probability of falling within that range (typically 95%).

⁶ The Joint Committee for Guides in Metrology is composed of international organizations working in the field of metrology. Its membership includes the Bureau International des Poids et Mesures, the Organisation Internationale de Métrologie Légale, the International Organization for Standardization, the International Electrotechnical Commission, the International Union of Pure and Applied Chemistry, the International Union of Pure and Applied Physics, the International Federation of Clinical Chemistry and Laboratory Medicine, and the International Laboratory Accreditation Cooperation.

Laboratories should meet the AOAC International⁷ standard method performance requirements for selecting an appropriate method to determine the MU.

This final rule requires that laboratories report the MU as part of any hemp test results. The rule also includes a definition of “acceptable hemp THC level” to account for the uncertainty in the test results. The reported THC concentration of a sample may not be the actual concentration level in the sample. However, the actual THC concentration is expected to be within the distribution or range calculated when the reported THC concentration is combined with the measurement of uncertainty.

The use of MU for purposes of determining the acceptable hemp THC level does not alter Federal law with regard to the definition of hemp or marijuana. As stated above, the 2018 Farm Bill defines hemp as the plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 THC of not more than 0.3 percent on a dry weight basis. Likewise, the Federal (CSA) definition of marijuana continues to include those parts of the cannabis plant as specified in 21 U.S.C. 802(16) (and derivatives thereof) that contain more than 0.3 percent THC on a dry weight basis. The foregoing provisions of Federal law remain in effect for purposes of Federal criminal prosecutions, as well as Federal, civil, and administrative proceedings arising under the CSA.

The definition of “acceptable hemp THC level” is also retained in this final rule. States and Indian Tribes shall adopt this concept in their plans. This definition explains how to interpret test results that include the MU with an example. The application of the MU to the reported delta-9 tetrahydrocannabinol concentration on a dry weight basis produces a distribution, or range. If 0.3 percent or less is within the distribution or range, then the sample will be considered to be hemp for the purpose of compliance with the requirements of State,

⁷ USDA established the Association of Official Agricultural Chemists in 1884. In 1965, it changed its name to the Association of Official Analytical Chemists and became an independent organization in 1979. In 1991, it adopted its current, legal name as AOAC International.

Tribal, or USDA hemp plans. For example, if a laboratory reports a result as 0.35 percent with a measurement of uncertainty of +/- 0.06, the distribution or range is 0.29 percent to 0.41 percent. Because 0.3 percent is within that distribution or range, the sample, and the lot it represents, is considered hemp for the purpose of compliance with the requirements of State, Tribal, or USDA hemp plans. However, if the MU for that sample was 0.02 percent, the distribution or range is 0.33 percent to 0.37 percent. Because 0.3 percent or less is not within that distribution or range, the sample is not considered hemp for the purpose of plan compliance, and the lot it represents will be subject to disposal. Thus the “acceptable hemp THC level” is the application of the MU to the reported delta-9 tetrahydrocannabinol content on a dry weight basis producing a distribution or range that includes 0.3 percent or less. As such, the regulatory definition of “acceptable hemp THC level” describes how State, Tribal, and USDA plans must account for uncertainty in test results in their treatment of cannabis. This definition affects neither the statutory definition of hemp, 7 U.S.C. 1639o(1), in the 2018 Farm Bill nor the definition of “marihuana,” 21 U.S.C. 802(16), in the CSA.

Sections 297B(a)(2)(A)(iii) and 297C(a)(2)(C) of the AMA require that cannabis plants that have a THC concentration level of greater than 0.3 percent on a dry weight basis be disposed of in accordance with the applicable State, Tribal, or USDA plan. Because of this requirement, producers whose cannabis crop is not hemp will likely lose most of the economic value of their investment. Thus, AMS believes that there must be a high degree of certainty that the THC concentration level is accurately measured and is in fact above 0.3 percent on a dry weight basis before requiring disposal of the crop.

The NIST Reference on Constants, Units, and Uncertainty states that “measurement result is complete only when accompanied by a quantitative statement of its uncertainty. The uncertainty is required in order to decide if the result is adequate for its intended purpose and to

ascertain if it is consistent with other similar results.”⁸ Simply stated, knowing the measurement of uncertainty is necessary to evaluate the accuracy of test results.

Comments to the IFR generally expressed support for requiring that the measurement of uncertainty (MU) be accounted for when testing the THC concentration of hemp, due to the variability in laboratory testing equipment and complex mathematical principles involved. Comments also provided several suggestions on ways to improve the calculation of MU. Many comments advocated specifying an MU to create uniformity in testing across the nation.

USDA does not recommend establishing an MU upper limit (maximum) because 1) MU is typically not standardized, but is controlled using standard test methods, and 2) USDA does not have the data to set an upper limit so setting it would be arbitrary, not scientific. The hemp and scientific industries are just beginning to discuss standard test methods and the final rule does not establish an explicit test method. Setting an upper limit or maximum MU does not resolve the core issue and would not encourage or drive labs to improve accuracy and precision.

Setting an upper limit would in effect be setting a maximum or absolute MU. This may encourage labs to adopt the maximum MU as their MU, rather than drive for a smaller uncertainty. USDA may allow for establishing limits in the future, if needed, once methods are established and USDA has access to Proficiency Testing results and the reported MUs. We encourage States and Tribes to monitor, review and evaluate MU to evaluate trends and outliers, which may indicate “lab shopping” for higher MUs. The requirement for hemp testing laboratories to incorporate a MU is being retained in this regulation.

Laboratory Accreditation

In the IFR, AMS requested input on establishing a fee-for-service hemp laboratory approval process or a requirement for laboratories to obtain ISO 17025 accreditation for labs that wish to offer THC testing services. Comments reflected a range of views across the industry, both in support of and in opposition to additional laboratory certification requirements. In

⁸ <https://physics.nist.gov/cuu/Uncertainty/international1.html>

general, commenters preferred more regulatory flexibility to address the widespread concern of insufficient laboratory capacity as a result of laboratory certification/registration/accreditation requirements. Other commenters were opposed to accreditation requirements due to the cost. While AMS strongly encourages laboratories to be accredited to ISO/IEC 17025 (by an International Laboratory Accreditation Cooperation Mutual Recognition Agreement (ILAC MRA) signatory accreditation body), we also acknowledge that ISO 17025 accreditation requires significant time and financial commitment to pursue and maintain. The time and cost involved is most challenging for smaller and start-up labs. The initial accreditation can cost \$5,000-\$10,000 (and in some case more) and yearly ongoing costs are \$3,000-\$8,000. Smaller labs may not have the resources to pursue accreditation in a timely manner or they may have to spend additional time and money for consultants to assist them in setting up a quality management system and to navigate the application and audit processes.

Based on insufficient laboratory capacity at this time and the cost involved in adding this requirement, AMS will not provide an AMS administered lab approval program or require ISO 17025 accreditation. However, AMS remains committed to assisting the hemp laboratory testing community and is available to assist in the development of a laboratory approval program in the future. As explained in the IFR, if such hemp laboratory approval program is developed by AMS, such process will be conducted by USDA, AMS Laboratory Approval Service, which administers the Laboratory Approval Program (LAP). State and Tribal plans are free to include certain additional requirements for hemp testing laboratories, including ISO accreditation or other proficiency schemes.

E. Disposal and remediation of non-compliant plants.

State and Tribal plans are currently required to include procedures for ensuring effective disposal or remediation of plants produced in violation of part 990. Plants that are removed as a result of poor plant health, pests, disease, or weather events, along with removal of male or hermaphrodite plants as part of a cross-pollination prevention plan, are not subject to the disposal

requirements herein. This final rule retains the disposal requirements explained in the IFR but clarifies what “disposal” means and explains how the process must be conducted. This final rule also includes remediation as an option to remove non-compliant plants.

As explained in the IFR, if a producer grows cannabis exceeding the legal 0.3 percent THC level, the material must be disposed of in accordance with the CSA and DEA regulations because such material constitutes marijuana, a Schedule I controlled substance under the CSA. The material must be collected for disposal by a person authorized under the CSA to handle marijuana, such as a DEA-registered reverse distributor, or a duly authorized Federal, State, Tribal, or local law enforcement officer. In the final rule, AMS is incorporating flexibilities for disposal that were announced on February 27, 2020 (<https://www.ams.usda.gov/rules-regulations/hemp/enforcement>). Some of these new options include, but are not limited to, plowing under non-compliant plants, composting into “green manure” for use on the same land, tilling, disking, burial, or burning. These methods are intended to allow producers to apply common on-farm practices for the disposal of non-compliant plants. One of the top considerations in making this change was to minimize, to the extent possible, the resource impact to State, Tribal, and local law enforcement in handling hemp that is out of compliance. In addition, we are confident that any disposal options make the product unusable and therefore is not at risk for entering any streams of commerce. Based on comments received, AMS is permanently retaining these on-farm disposal flexibilities.

AMS received comments on this requirement describing the expense associated with destroying cannabis in accordance with the CSA, primarily the requirement that disposal be conducted offsite by a reverse distributor or other law enforcement officer. Based on this input, AMS, in coordination with DEA partners, delayed enforcement of the disposal requirements in the IFR. In the final rule, producers have several options on how to handle non-compliant plants. Producers do not need to use a DEA-registered reverse distributor or law enforcement to dispose of non-compliant plants. Producers may dispose of the plants using one or more of the means

described by AMS at <https://www.ams.usda.gov/rules-regulations/hemp/disposal-activities>. It is the Agency's intent that these methods allow producers to apply common on-farm practices as a means of disposal while rendering the controlled substance non-retrievable or non-ingestible. Under this final rule, State and Tribal plans must still include procedures to verify disposal. This may come in the form of in-person verification by State or Tribal representatives, or alternative requirements the direct growers to provide pictures, videos, or other proof that disposal occurred successfully. Producers under the USDA plan must document the disposal of all non-compliant plants. States and Indian Tribes operating under approved hemp production plans and producers under the USDA plan must notify USDA of any occurrence of non-conforming plants or plant material and provide the disposal record of those plants and materials monthly.

State and Tribal plans must include procedures to verify disposal, whether through the use of in-person verification by State or Tribal representatives, or requirements for producers to provide pictures, videos, or other proof that disposal did in fact occur. State and Tribal plans must also include requirements to submit to AMS the monthly disposal and remediation report documenting any on-farm disposals or remediations that occurred during the prior month. As of November 2020, twenty States and nine Tribes operating under the 2018 Farm Bill reported 4,192 licensed producers representing 6,166 acres planted. Of these acres planted, there were 231 disposals representing 730 acres disposed due to not meeting the 0.3 percent acceptable hemp THC level.

AMS did not provide additional remediation options in the IFR. The only remediation alternative was to completely dispose of the non-compliant material. AMS is adding remediation to this final rule based on comment. AMS received many comments suggesting the inclusion of procedures to allow for non-compliant cannabis to be "remediated." AMS agrees with this suggestion and is publishing remediation techniques concurrently with this rule that can be followed to remediate non-compliant plant material into compliant form. As described in the IFR, hemp exceeding the acceptable THC level may not be further handled, processed, or enter

the stream of commerce. AMS believes— that hemp producers should have the opportunity to remediate non-compliant crops in order to minimize financial risk associated with the loss of investment in their hemp crop. For this reason, this final rule allows remediation activities, either disposing of flower materials and salvaging the remainder of the plant or blending the entire plant into biomass plant material. Through both forms of remediation, producers may be able to minimize losses, and in some cases produce a return on investment while ensuring that non-compliant material does not enter commerce.

If a producer elects to perform remediation activities as allowable under this final rule’s provisions (referenced above), an additional sampling and testing of the post-remediated crop must occur to determine THC concentration levels. Only those successfully remediated crops will be allowed to enter the stream of commerce, and all other remaining non-compliant crops must then be disposed.

AMS believes the inclusion of remediation and post-harvest sampling into the final rule provides the additional flexibility requested by commenters that expressed the need for producers to have greater opportunity for success as established and beginning farmers entering hemp production.

F. Compliance with enforcement procedures, including determination of negligence and annual inspection of hemp producers.

The IFR required State and Tribal plans to include compliance procedures to ensure hemp was being produced in accordance with the requirements of this part. Comments to the IFR were generally opposed to the compliance requirements, particularly as they relate to the definition of negligence. Producers, along with State and Tribal regulatory agencies, found the negligence requirements in the IFR overly harsh and strict. This final rule changes these compliance procedures, particularly how “negligence” is determined. In the context of this regulation, negligence is defined as a failure to exercise the level of care that a reasonably prudent person would exercise in complying with the regulation. The definition employed in this

rule is derived from the definition of negligence in Black's Law Dictionary. *See* BLACK'S LAW DICTIONARY (10th ed. 2014) (defining *negligence* as "[t]he failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation").

This final rule increases the negligence threshold from 0.5 to 1.0 percent THC and clarifies how States and Indian Tribes determine when to suspend or revoke a producer's license. AMS believes that raising the negligence threshold from 0.5 percent to 1.0 percent THC will increase flexibility to farmers as they learn more about how to grow compliant hemp and as the availability of stable hemp genetics improves. In developing the compliance requirements for State and Tribal plans, AMS recognizes that there may be significant differences across States and Indian Tribes in how they will administer their respective hemp programs. This final rule provides that a producer shall not be subject to more than one negligent violation per calendar year.

State and Tribal hemp plans must still include requirements to conduct annual inspections of, at a minimum, a random sample of hemp producers to verify hemp is not being produced in violation of this rule, along with a procedure for handling violations.

In accordance with the 2018 Farm Bill, States and Indian Tribes with their own hemp production plans have certain flexibilities in determining whether hemp producers have violated their approved plans. However, there are certain compliance requirements that all State and Tribal plans must contain. This includes procedures to identify and attempt to correct certain negligent acts, such as failing to provide a legal description of the land on which the hemp is produced, not obtaining a license or other required authorizations from the State or Tribal government, or producing plants exceeding 0.3 percent total THC. States and Indian Tribes may include additional requirements in their plans.

This final rule specifies 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 1.0 percent on a dry weight

basis. AMS recognizes that hemp producers may take the necessary steps and precautions to produce hemp, such as using certified seed, using other seed that has reliably grown compliant plants in other parts of the country, or engaging in other best practices, yet still produce plants that exceed the acceptable hemp THC level. AMS believes that a hemp producer in that scenario has exercised a level of care that a reasonably prudent person would exercise if the plant does not have a THC concentration of more than 1.0 percent on a dry weight basis. AMS arrived at this increased tolerance based on input from commenters, particularly State agriculture departments that operated hemp research programs under the 2014 Farm Bill, along with data provided by laboratories testing hemp subject to 2018 Farm Bill requirements. The 0.5 percent was based on data from three states participating in the 2014 Farm Bill pilot program. AMS believes raising the negligent violation threshold from 0.5 percent to 1.0 percent in the final rule provides a greater buffer and reduces farmers' exposure to risk of violation accrual and license suspension.

AMS recognizes the violation threshold may incentivize (or disincentivize) innovation by research institutions and producers. AMS acknowledges more innovation and research across industry will bring more stability to stakeholders. AMS believes the 1.0 percent threshold incentivizes innovation across industry more so than a 0.5 percent violation threshold. Further, comments addressed the negative impact of the accrual of negligent violations on the financial stability of the individual business. They described how a hemp grower's access to credit and insurance is jeopardized when negligent violations accumulate and lead to a determination of culpable negligence. Comments explained that lending institutions and insurance providers look for risk factors. They also raised questions about how the accrual of negligent violations may be interpreted by lender or providers. Comments said that many insurers will not cover crop losses if losses are due to the growers' negligence.

AMS acknowledges institutional lenders view violations as risk factors in decision making. AMS also notes that not all culpable violations are derived from the accrual of negligent violations. Culpable violations may be the result of producers violating other parts of

the 2018 Farm Bill. However, the 2018 Farm Bill explicitly considers certain actions as constituting negligent violations. AMS's intention is to provide a threshold between 0.3 percent THC level and what would be considered a negligent violation so not all hemp that tests over the 0.3 percent be considered a negligent violation. Because a producer will not have committed a negligent violation every time he or she grows hemp with a concentration of hemp above the 0.3 percent level, this will assist producers when requesting loans or other financial assistance.

Several comments suggested that a 0.5 percent negligence threshold threatens the survival of farmers in an emerging industry. Comments suggested that the low threshold is a barrier to entry for new farmers or farmers with no experience growing hemp, who risk high initial capital investments to establish operations. Comments argued that the low threshold favors larger farms using industrialized hemp varieties and production practices, and that the low negligence threshold in the IFR would unnecessarily criminalize farmers working with a legal agricultural commodity. Increasing this threshold to 1.0 percent benefits producers, including small and new farmers, that intended to grow hemp but whose crops tested "hot" even though they made reasonable efforts to grow hemp.

In cases where a State or Indian Tribe determines a negligent violation has occurred, a corrective action plan shall be established. The corrective action plan must include a reasonable date by which the producer will correct the negligent violation. Producers operating under a corrective action plan must also periodically report to the State or Tribal government, as applicable, on their compliance with the plan for a period of not less than two calendar years following the violation. A producer who negligently violates a State or Tribal plan three times in a five-year period will be ineligible to produce hemp for a period of five years from the date of the third violation.

Several comments explained how these requirements as written in the IFR were confusing and difficult to administer. Particularly, commenters explained how a producer could easily receive three negligent violations during one growing season, which would lead to an

automatic licensing revocation for the following five years. For example, a producer may grow hemp in three different locations. If the hemp becomes non-compliant cannabis, all in one season, the producer would lose the license in one season. Commenters described this as too strict and too severe a penalty for honest mistakes that many first-year hemp producers will certainly make. AMS agrees and wishes to clarify that this is not the intent of the regulation. AMS acknowledges that producers may have more than one production area and that they may harvest at different times. Tests results may be over the allowable limit on those production areas but the planting was performed at the same time using the same seeds. Allowing for only one violation per season would help minimize duplication of enforcement. This final rule provides that a producer shall not be subject to more than one negligent violation per calendar year. As it is customary in agriculture, practices vary due to many factors such as weather, availability of labor, transportation and storage capacity and more. Due to many factors, producers make determinations about planting and harvest cycles. In certain circumstances, producers may plant before the first cycle has been harvested specially when they plant in multiple locations. Calendar year is easier to administer and will allow for various growing seasons.

Each geographical area has a growing season based on specific temperature, weather, soil or other factors in that region, therefore this rule is defining growing season as a calendar year. This will allow flexibility, including a year-round season if States and Indian Tribes have a warmer climate or greenhouse growing.

Negligent violations are still not subject to criminal enforcement action by local, Tribal, State, or Federal government authorities under this regulation.

State and Tribal plans also must contain provisions relating to producer violations made with a culpable mental state greater than negligence, meaning acts made intentionally, knowingly, or with recklessness. This definition is derived from the definition of negligence in Black's Law Dictionary. See BLACK'S LAW DICTIONARY (10th ed. 2014) (giving as a

definition of *negligence* “[t]he failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation”). If it is determined a violation was committed with a culpable mental state greater than negligence, the State agriculture department or Tribal government, as applicable, shall immediately report the producer to the Attorney General, USDA, and the chief law enforcement officer of the State or Indian Tribe.

State and Tribal plans also must prohibit any person convicted of a felony related to a controlled substance under State or Federal law from participating in the State or Tribal plan and from producing hemp for 10-years following the date of conviction. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date. This exemption language must be included in all State and Tribal hemp plans, whether they administered a 2014 Farm Bill research pilot program or not.

The 2018 Farm Bill does not define what it means to “participate in the [State or Tribal] program.” AMS is not requiring States and Indian Tribes to adopt a specific definition. Instead, they must define who those persons are in their plan. The definition must include one individual for whom a criminal history records check can be conducted for each license or authorization that the State or Indian Tribe issues. The final rule identifies and defines “key participants” as those participating in the USDA plan. State and Tribes may, but are not required, to adopt this definition for their plans.

The State or Indian Tribe will need to review criminal history reports for each individual identified as participating in its program. The final rules defines “criminal history report” as the Federal Bureau of Investigation’s Identity History Summary. The State or Indian Tribe may review additional reports or checks to determine whether an individual may participate in its plan. Finally, any person found by the USDA, State, or Tribal government to have materially falsified any information submitted to the program will be ineligible to participate.

G. Information sharing.

The IFR included requirements for State and Tribal plans to contain procedures for reporting specific information to USDA. Limited comments were received on these requirements. This information has been transmitted already by many States and Tribes to USDA. This information meets the requirements set in the 2018 Farm Bill. Therefore, the following requirements are the same as required under the IFR and are in subpart F of this final rule. This is separate from the requirement to report hemp crop acreage with FSA as discussed above.

The information required includes contact information for each hemp producer covered under the plan, including name, address, telephone number, and email address (if available). If the producer is a business entity, the information must include the full name of the business, address of the principal business location, full name and title of each employee for whom the entity is required to submit a criminal history report, and an email address if available, and Employee Identification Number (“EIN”) of the business entity. Producers must report the legal description and geospatial location for each hemp production area, including each field, greenhouse, or other site used by them, as stated in section A of this preamble. The report also shall include the status of the license or other required authorization from the State or Tribal government, as applicable, for each producer under a hemp production plan. States and Indian Tribes will submit this information to USDA not later than 30 days after the date it is received using the appropriate reporting requirements as determined by USDA.

These reporting requirements are found at § 990.70 in this final rule. Further explanation of the specific information to be submitted, the appropriate format, and the specific due dates for the information is discussed in Section X (Regulatory Analysis) of this final rule. This information submitted from each State and Tribal plan, along with the equivalent information collected from individuals participating under the USDA plan, will be assembled and maintained by USDA and made available in real time to Federal, State, Tribal, and local law enforcement, as required by the 2018 Farm Bill. All information supporting, verifying, or documenting the

information submitted to USDA must be maintained by the States and Indian Tribes for at least three years.

Under § 990.70(c), States and Indian Tribes must also submit annual reports regarding the total planted, harvested, and disposed acreage. Additionally, because the final rule provides for remediation of plants, the final rule requires all remediated acreage to be reported as well. Similarly, under § 990.71(c), all USDA hemp plan producers must submit annual reports to USDA detailing total planted acreage, total acreage disposed and remediated, and total harvested acreage.

H. Certification of resources.

All State and Tribal plans submitted for USDA approval must also have a certification stating the State or Indian Tribe has the resources and personnel necessary to carry out the practices and procedures described in their plan. Section 297B of the AMA requires this certification, and the information is important to USDA's approval of State and Tribal plans, in that all such plans must be supported by adequate resources to effectively administer them. This section has not changed from the IFR.

I. State and Tribal plan approval, technical assistance and USDA oversight.

Since the publication of the IFR, AMS has worked extensively with States and Indian Tribes in developing hemp production plans. As States and Indian Tribes begin the work of modifying their plans to incorporate the changes herein, we encourage States and Indian Tribes to continue working with and sharing information with AMS. States and Tribes may need to change plans based on changes in this final rule because their State or Tribal laws may no longer match the requirements in this final rule. Even though some of the changes in this final rule are less burdensome, State and Tribal plans must follow their own legislations. Accordingly. They must amend their plans. During the plan development and/or revision process, States and Indian Tribes are encouraged to contact USDA so we may provide technical assistance in developing plan specifics. Since the publication of the IFR, USDA approved over 60 State and Tribal plans

within the 60-day requirement. USDA approved plans that comply with the 2018 Farm Bill and with the provisions of the IFR. For the 2021 planting season, the 2018 Farm Bill, amended by the Continuing Resolution (CR) (Agriculture Improvement Act of 2018 (7 U.S.C. 5940 note; Public Law 116-260)), provided that States and institutions of higher education can continue operating under the authorities of the 2014 Farm Bill until January 1, 2022. AMS clarified the avenues for Tribal participation under authorities in the 2014 Farm Bill to grow industrial hemp for research purposes. This clarification is available on the AMS website:

<https://www.ams.usda.gov/content/usda-clarifies-industrial-hemp-production-indian-Tribes>.

Due to this extension, many States decided to remain under the 2014 Farm Bill provisions and rescinded their previously approved plans. All States are eligible to remain or start programs under the 2014 Farm Bill provisions. As a result, USDA will oversee 20 State and 20 Tribal plans under the 2018 Farm Bill until new States and Tribes submit more plans under the 2018 Farm Bill provisions.

As of November 2020, States and Tribes operating under the 2018 Farm Bill reported 4,192 licensed producers representing 6,166 acres planted. Of these acres planted, there were 231 disposals representing 730 acres disposed due to not meeting the 0.3 percent acceptable hemp THC level. This data is limited because even though many States and Tribes have approved plans, they have not all been fully implemented. USDA expects more data will be available as the 2021 season begins and States and Tribes implement their programs.

USDA will use the procedures in this rule, which are substantively similar to those in the IFR, to review and approve State and Tribal plans. If a plan does not comply with the requirements of the Act and this regulation, it will not be approved. However, USDA has worked with many States and Tribes submitting plans to assist them in meeting the requirements and obtaining approval for their plans.

If a plan is not approved, USDA provides a letter of notification outlining the deficiencies identified. The State or Tribal government may then submit an amended plan for review. If the

State or Tribe disagrees with the determination made by USDA regarding the plan, a request for reconsideration can be submitted to USDA using the appeal process as outlined in section V of this document. Plans submitted by States and Indian Tribes must be approved by USDA before they can be implemented.

States and Indian Tribes can submit their plans to USDA through electronic mail at farbill.hemp@usda.gov or by postal carrier to USDA. The specific mailing address is provided on the USDA Domestic Hemp Production Program website.

If the State or Tribal plan application is complete and meets the criteria of this part, USDA issues an approval letter. Approved State and Tribal plans, including their respective rules, regulations, and procedures, are posted on USDA's hemp program website.

A USDA-approved State or Tribal plan will remain in effect, unless approval is revoked by USDA pursuant to the revocation procedures discussed in this section or unless the State or Tribe makes substantive revisions to their plan or their laws that alter the way the plan meets the requirements of this regulation. Additionally, changes to the provisions or procedures under this rule or to the language in the 2018 Farm Bill may require plan revision and resubmission to USDA for approval. Changes to applicable Federal and State or Tribal statutes may also require plan revision and resubmission to USDA for approval and may lead to plan revocation if the plan is not amended. Should States or Indian Tribes have questions regarding the need to resubmit their plans, they should contact USDA for guidance.

A State or Tribal government may submit an amended plan to USDA for approval if: (1) the Secretary disapproves a State or Tribal plan; or (2) the State or Tribe makes substantive revisions to their plan or to their laws that alter the way the plan meets the requirements of this regulation, or as necessary to bring the plan into compliance with changes in other applicable law or regulations.

If the plan previously approved by USDA needs to be amended because of changes to the State's or Tribe's laws or regulations, such resubmissions should be provided to USDA within

60 days from when the new State or Tribal law or regulations are effective. Producers will be held to the requirements of the previous plan until such modifications are approved by USDA. If State or Tribal government regulations in effect under the USDA-approved plan change, but the State or Tribal government does not resubmit a modified plan within 60 days of the effective date of the change, USDA will issue a notification to the State or Tribal government that approval of its plan will be revoked. The revocation will be effective no earlier than the beginning of the next calendar year. If a plan is revoked, producers previously subject to an approved plan would be eligible to apply to USDA for a license. This is a change from the IFR that allowed for resubmission because of a change in State or Tribal law or regulations within a calendar year. This modification is due to USDA's need to know in a timelier manner, since such laws and regulations are the foundations of the hemp plans. The words of the plans do not have meaning if they are not aligned with current authorities.

USDA has the authority to audit States and Tribes to determine if they are in compliance with the terms and conditions of their approved plans. If a State or Indian Tribe is noncompliant with their plan, USDA will work with that State or Indian Tribe to develop a corrective action plan. However, if additional instances of noncompliance occur, USDA has the authority to revoke the approval of the State or Tribal plan for one year or until the State or Tribe become compliant. AMS still believes that one year is sufficient time for a noncompliant State or Indian Tribe to evaluate problems with their plan and make the necessary adjustments. Should USDA determine the approval of a State or Tribal plan should be revoked, such a revocation would begin after the end of the current calendar year, so producers will have the opportunity to adjust their operations as necessary. This will allow producers to apply for a license under the USDA plan so that their operations do not become disrupted due to the revocation of the State or Tribal plan.

III. Department of Agriculture Plan

The 2018 Farm Bill requires USDA to administer a hemp production plan for producers in jurisdictions where hemp production is legal but is not covered by an approved State or Tribal plan. The USDA licensing remains available to producers in States and Tribal territories without a USDA-approved hemp plan. All hemp produced in a jurisdiction without an approved State or Tribal plan must meet the requirements of the USDA plan. The requirements for producers operating under the USDA plan are similar to those operating under approved State and Tribal plans.

Regulatory requirements for producers licensed under the USDA plan in this final rule differ in some cases from corresponding requirements in the IFR and are explained in the following section. Comments submitted to the IFR generally did not address these requirements specifically; rather they focused on the broader requirements around sampling, testing, and disposal, to which all hemp producers are subject, whether licensed by a State, a Tribe, or USDA.

A. USDA hemp producer license and criminal history report.

To produce hemp under the USDA plan, producers must apply for and be issued a license from USDA. USDA has been accepting applications from producers since October 2019. Any license issued by USDA prior to publication of this final rule will remain in effect and subject to the original expiration date. As of the issuance of this final rule, USDA has issued 380 licenses under the USDA plan.

While a State or Tribal government has a draft hemp production plan pending for USDA approval, USDA will not issue USDA hemp production licenses to individual producers located within that State or Tribal territory. Once USDA approves a hemp production plan from a State or Tribe, it will deny any license applications from individuals located in the applicable State or Tribal territory. If USDA disapproves a State or Tribal hemp production plan, individual producers located in the State or Tribal territory may apply for a USDA hemp production license,

unless hemp production is illegal in the State or Tribal territory where they intend to produce hemp.

Comments to the IFR described confusion around the application window for when USDA would receive and process applications as described in the IFR. The IFR said that for the first year after USDA began to accept applications, applications could be submitted any time. For all subsequent years, license applications and license renewal applications would have to be submitted between August 1 and October 31. AMS requested input on this application window, and commenters were generally opposed. Under this final rule, USDA will accept applications for USDA hemp production licenses on a rolling basis to better accommodate the needs of producers. AMS continues to encourage the submission of applications well before the planting season so AMS has adequate time to process the applications. All applications must comply with the requirements as described below. The license application is available online at the USDA Domestic Hemp Production Program website at <https://www.ams.usda.gov/rules-regulations/hemp/information-producers>. Applications may be submitted electronically or by mail.

The producer license application requires contact information such as name, address, telephone number, and email address (if available). If the applicant represents a business entity, and that entity will be the producer, the application will require the full name of the business, address of the principal business location, full name and title of the key participants on behalf of the entity, an email address if available, and EIN of the business entity. All applications must be accompanied by a completed criminal history report. Several comments to the IFR expressed opposition to this requirement. AMS is retaining this requirement since verification of compliance with the felony restriction is a statutory requirement. If the application is for a business entity, a completed criminal history report must be provided for each key participant.

Some commenters expressed concern with the requirements pertaining to “key participants,” particularly with the requirement that all key participants undergo a background

check. To the extent the commenters equated a criminal history check with a background check, AMS is retaining this requirement, since key participants are those individuals responsible for ensuring compliance with the regulatory requirements contained herein. If key participants are not subject to criminal history checks, AMS cannot ensure statutory restrictions on individuals with felony convictions related to controlled substances are met per Section 297B(e)(3)(B)(i) of the AMA. AMS notes that it will not conduct any other checks into the background of key participants.

Key participants are a person or persons who have a direct or indirect financial interest in the entity producing hemp, such as an owner or partner in a partnership. A key participant also includes a person in a corporate entity at executive levels including the chief executive officer, chief operating officer, and chief financial officer. This does not include other management positions like farm, field, or shift managers. The final rule also specifies that the definition of key participant does not include a member of the leadership of a Tribal government who is acting in their capacity as a Tribal leader, except when that member exercises executive managerial control over hemp production. AMS added this specification to address concerns raised by Indian Tribes regarding issues that can arise when a Tribal leader is also involved in the production of hemp in their capacity as a Tribal leader. While AMS understands the issues that can arise when a Tribal leader is subject to the felony conviction restriction, AMS must also ensure that all required entities operating under a USDA plan comply with Section 297B(e)(3)(B) of the AMA. Therefore, the definition of key participants still encompasses Tribal leaders who exercise executive managerial control over hemp production.

USDA will not accept criminal history reports completed more than 60 days before the submission of an application, because the 60-day window provides USDA with an expectation that the findings of the report are reasonably current and accurate.

The criminal history report must indicate the applicant has not been convicted of a State or Federal felony related to a controlled substance for the 10 years prior to the date of when the

report was completed. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

In addition to providing the information specified, the application will also require license applicants to certify they will adhere to the provisions of the plan.

Once all the necessary information has been provided, applications will be reviewed by USDA for completeness and to determine an applicant's eligibility. USDA will approve or deny license applications unless the applicant is intending to produce hemp in a jurisdiction that has submitted a plan to USDA or has a plan approved by USDA, in which case the application for a USDA license will be denied. Applicants will be notified if they have been granted or denied a license either by mail or email.

If an application is denied, the applicant will receive a notification letter or email specifying why the application was denied. If an application is denied because it is incomplete, the applicant will have the option of resubmitting a revised application. If the application was denied for other reasons, the applicant will have the opportunity to appeal USDA's decision in accordance with the appeals process outlined in the regulation in subpart D.

Once a license application has been approved, USDA will issue the producer license. Licenses are not transferrable in any manner. An applicant whose application has been approved will not be considered a licensed producer under the USDA plan until the applicant receives their producer license. Licenses do not renew automatically and must be renewed every three years.

Applications for renewal will be subject to the same terms and approved under the same criteria as initial applications unless there has been an intervening change in the applicable law or regulations since approval of the initial or last application. In such a case, the subsequently enacted law or regulation shall govern renewal of the license. Licenses will be valid until December 31 of the year that is at least three years after the license is issued. This date is not tied to the harvest and planting season. For example, if a producer applies for a license on

August 1, 2021, and is granted a license on September 15, 2021, the license would expire December 31, 2024. A December 31 expiration date will allow licensed producers time to apply for a license renewal prior to their prior license's expiration and prevent a gap in licensing.

A producer licensed by USDA must report their hemp crop acreage to FSA. Producers must provide specific information to FSA, including, but not limited to, USDA license number, the specific location where hemp is produced and the acreage, greenhouse, building, or site where hemp is produced. The specific location where hemp is produced must be identified, to the extent practicable, by the geospatial location. FSA will provide assistance in identifying the hemp growing location. Please refer to the Section II of this document on State and Tribal hemp production program requirements for further discussion on FSA reporting requirements.

If at any time there is a change to the information submitted in the license application, a license modification is required. A license modification is required if, for example, the licensed business is sold to a new owner or hemp will be produced in a new location not described on the original application. Producers must notify USDA immediately should there be any change in the information provided on the license application.

B. Sampling for THC.

The IFR stated that all hemp production must be sampled and tested for THC concentration levels. It is the responsibility of the licensed producer to pay any fees associated with sampling. AMS issued guidance on sampling procedures that meet the sampling requirements to coincide with publication of the IFR and will update the guidance with this final rule. AMS is requiring that all samples tested for THC concentration levels be conducted in DEA-registered laboratories. However, this requirement will not be applicable until December 31, 2022.

Significant input was received on the IFR sampling requirements. Please refer to section B under State and Tribal plans above and the discussion of comments below for a summary of findings. Producers under the USDA plan are subject to the sampling and testing requirements

as outlined in the USDA guidelines for sampling and testing. Since USDA cannot develop a one size fits all performance-based sampling program, all producers licensed under the USDA plan must comply with the USDA sampling guidelines. USDA licensed producers are responsible for obtaining the services of sampling agents and hemp testing laboratories themselves. USDA is updating guidance on sampling procedures and training for sampling agents with this rule. USDA does not provide sampling or testing services and will not pay for those services.

State and Tribal hemp regulators have successfully developed sampling requirements that ensure adherence to State and Federal regulations, while allowing for flexibilities due to limited State resources and State and Tribal differences. They explained that, since most hemp in a given region is harvested at the same time, sampling must be completed within a very short time frame by only a few individuals. Several States also explained that perceived risk determines State requirements. Some States utilize different sampling requirements for broad end-use categories like “fiber/grain” hemp versus “cannabinoid” hemp, while others base their requirements on historical THC concentrations of certain varieties or on the characteristics and growing history of a certain farm or producer. AMS agrees that sampling requirements should allow States and Indian Tribes more flexibility in the management of their hemp regulatory programs.

AMS agrees that requiring sampling from every lot may be burdensome and expensive for State and Tribal regulatory entities and producers.

AMS finds that it makes sense to allow States and Indian Tribes to consider performance-based alternatives when developing sampling plans that take into account unique sampling protocols for hemp growing facilities under their jurisdiction. The sampling requirements for State and Tribal plans allow for States and Indian Tribes to develop unique sampling protocols for hemp growing facilities under their jurisdiction. Sampling protocols must be sufficient at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level and ensure that a representative sample is

collected that represents a homogeneous composition of the lot. Alternatively, States and Indian Tribes may adopt a performance-based sampling protocol. A performance-based protocol must have the potential to ensure, at a confidence level of 95 percent, that the cannabis plants will not test above the acceptable hemp THC level. USDA encourages that the alternative protocol consider seed certification processes or process that identifies varieties that have consistently demonstrated to result in compliant hemp plants in that State or territory of the Indian Tribe, whether the producer is conducting research on hemp at an institution of higher learning or that is funded by a Federal, State, or Tribal government, whether a producer has consistently produced compliant hemp plants over an extended period of time, and other similar factors. AMS believes this will provide needed flexibility to States and Indian Tribes to develop logical and enforceable sampling requirements that take into consideration their unique circumstances. AMS will still require States and Indian Tribes to submit their individual sampling requirements for review as a component of the plan approval process. If a State or Tribal plan lacks a sampling protocol, every lot, and thereby every producer must be sampled and tested.

When evaluating sampling protocols submitted by States and Indian Tribes, USDA will evaluate the risk of producing non-compliant material to determine approval or disapproval. In evaluating the risk, USDA will take into consideration whether the performance-based factors the State or Tribe used have the potential to ensure compliance at a 95 percent confidence level.

Since USDA cannot develop performance metrics that would be applicable independently from where the producer is located, producers licensed under the USDA plan are subject to the sampling requirements in the rule. USDA guidelines provided on the USDA website at <https://www.ams.usda.gov/rules-regulations/hemp/information-sampling> describe best practices for complying with those requirements. However, USDA would consider a performance-based sampling scheme for producers under the USDA plan, and amend the sampling requirements accordingly, if information collected by USDA in the future is sufficient to make this

determination. Data must be reliable and able to be applicable across the production areas in the U.S.

Samples must be collected by a USDA-approved sampling agent, or a Federal, State, Tribal, or local law enforcement agent authorized by USDA to collect samples. As explained above, USDA is expanding the training requirements for sampling agents and will provide a list of authorized sampling agents on the USDA website. It is the responsibility of the licensed producer to pay any fees associated with sampling and testing. Sampling and testing guideline documents are being updated as part of this proceeding and are available on the USDA website.

The sampling procedures are designed to produce a representative sample for testing. They describe procedures for entering a growing area and collecting the minimum number of plant specimens necessary to accurately represent the THC content, through laboratory testing, of the sample to be tested.

C. Testing laboratories.

The THC level in representative samples must be at or below the acceptable hemp THC level. Testing must be conducted using post-decarboxylation or other similarly reliable methods where the total THC concentration level measured includes the potential to convert THCA into THC. Further, test results should be determined and reported on a dry weight basis, meaning the percentage of THC, by weight, in a cannabis sample, after excluding moisture from the sample. The moisture content is expressed as the ratio of the amount of moisture in the sample to the amount of dry solid in the sample.

Based on AMS's review of scientific studies, internal research and information gathered from the *United Nations Office on Drugs and Crime: "Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products"* (ISBN 978-92-1-148242-3), AMS has determined that testing methodologies meeting these requirements include gas or liquid chromatography with detection. As discussed earlier and stated in § 990.25(g), if a testing

laboratory utilizes alternative testing methods, they must be reviewed and approved by USDA to assess their reliability, accuracy, and compliance with the requirements.

As explained earlier in this document, AMS is requiring that all testing of samples for THC concentration levels be conducted in DEA-registered laboratories. Enforcement of this requirement has been delayed until December 31, 2022. Non-DEA-registered labs can continue testing hemp for THC concentration until that time. Labs testing hemp for THC must meet standards of performance described in this regulation. Standards of performance ensure the validity and reliability of test results; that analytical method selection, validation, and verification are appropriate (fit for purpose); and that the laboratory can successfully perform the testing. Furthermore, the standards ensure consistent, accurate, analytical performance and that the analytical tests performed are sufficiently sensitive for the purposes of the detectability requirements under this final rule.

Laboratories conducting THC testing must also be registered with DEA to handle controlled substances under the CSA (21 U.S.C. 822 and 21 U.S.C. 844) and DEA regulations (21 CFR part 1301). USDA is adopting this requirement because of the potential for these laboratories to handle cannabis products testing above 0.3 percent THC. Such products are, by definition, marijuana, and a controlled substance. DEA registration requirements verify a laboratory's ability to properly handle controlled substances.

As previously explained in the requirements for State and Tribal plans, AMS is not adopting requirements that hemp testing laboratories be approved under a USDA Laboratory Approval Program or undergo ISO accreditation.

It is the responsibility of the licensed producer to select the DEA-registered laboratory that will conduct the testing and to pay any fees associated with testing. Laboratories performing THC testing for hemp produced under this program are required to share test results with the licensed producer and USDA. USDA will provide instructions to all approved labs on how to electronically submit test results to USDA. Laboratories may provide test results to licensed

producers in whatever manner best aligns with their business practices, but producers must be able to produce a copy of test results. For this reason, providing test results to producers through a web portal or through electronic mail, so the producer will have ready access to print the results when needed, is preferred.

Samples exceeding the acceptable hemp THC level are marijuana and will be handled in accordance with the procedures discussed in section C below.

Any licensee may request that the laboratory retest pre-harvest samples, if it is believed the original THC concentration level test results were in error. The licensee requesting the retest of the second sample would pay the cost of the test. The retest results would be issued to the licensee requesting the retest, and a copy would be provided to USDA or its agent.

Research Institutions sampling and testing

AMS also acknowledges that research institutions face special circumstances when conducting hemp research. Under the IFR, researchers and research institutions were required to comply with the same production requirements as commercial producers. Under this final rule, and as described in detail below, research institutions and the producers working with them are afforded greater sampling and testing flexibility to facilitate continued hemp research. Producers that produce hemp for research must obtain a USDA license. However, the hemp that is produced for research is not subject to the same sampling requirements provided that the producer adopts and carries out an alternative sampling method that has the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to this alternative method will not test above the acceptable hemp THC level. The rule includes a performance-based standard for sampling for all licensed producers in section 990.24: “at a confidence level of 95 percent that no more than one percent (1%) of the plants in the lot would exceed the acceptable hemp THC level.” The performance-based standard for research is a modification of that standard: “the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to this alternative method will

not test above the acceptable hemp THC level.” We are comfortable with this modification to recognize that researchers may need flexibility to conduct their research and because the research hemp cannot enter the stream of commerce. USDA will monitor researchers’ compliance with this standard as part of its normal oversight and compliance program.

USDA licensees shall ensure the disposal of all non-compliant plants. USDA licensees shall also comply with the reporting requirements including reporting disposal of non-compliant plants. Research institutions that handle “hot” hemp must follow CSA requirements for handling marijuana.

Performance based plans from research institutions where a State or Tribal plan is not in place will be reviewed by USDA. Notice and comment requirements under the PRA process will be followed before a final determination is made by USDA to move forward with approving performance-based plans for those producers under the USDA plan.

States and Indian Tribes are allowed to develop performance-based requirements for these institutions. However, the alternative method must have the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to the alternative method will not test above the acceptable hemp THC level.

The research institutions must follow reporting requirements. AMS believes this exception is necessary to help support research and development as it relates to hemp production. This decision allows these types of research facilities and institutions to confidently oversee the study of hemp plants through trialing and genetics research. AMS believes this exception to be critical to the growth of industry, particularly in its infancy. Over time, the exception provided by this final rule will help to stabilize the industry by providing greater understanding of hemp genetics and how certain varieties respond differently to growing conditions in various geographic locations. All producers are expected to benefit from such knowledge as they will be made aware of the more stable and consistently reliable hemp varieties. Any non-compliant plants produced by research institutions as a result of research and development will still need to

be disposed and verified through documentation. Research institutions must follow licensing and reporting requirements.

D. Disposal of non-compliant product.

Under the IFR, non-compliant product was required to be disposed of by persons authorized to do so under the CSA and had to be destroyed. As explained below, under this final rule, producers may handle non-compliant product disposal on the farm, and they have greater flexibility in remediating that product. USDA producers are required to follow procedures for ensuring effective disposal of cannabis plants produced in violation of this rule. Plants that are removed as a result of poor plant health, pests, disease, weather events, along with removal of male or hermaphrodite plants as part of a cross-pollination prevention plans, are not subject to the disposal requirements herein. This final rule retains the disposal requirements explained in the IFR, but clarifies what “disposal” means and explains how the process must be conducted. If a producer grew cannabis exceeding the acceptable hemp THC level, the IFR required that the material be disposed of in accordance with the CSA and DEA regulations because such material is marijuana, a Schedule I controlled substance under the CSA. The IFR required that material be collected for disposal by a person authorized under the CSA to handle marijuana, such as a DEA-registered reverse distributor, or a duly authorized Federal, State, Tribal, or local law enforcement officer.

As explained earlier, AMS is now allowing the flexibility to conduct on-farm disposals and also allowing for remediation options.

If the results of a test conclude that the THC levels exceed the acceptable hemp THC level, the laboratory will promptly notify the producer and USDA or its authorized agent. If a licensed producer is notified that they have produced cannabis exceeding the acceptable hemp THC level, the cannabis must be disposed of in accordance with the on-farm disposal options described herein.

Licensed producers notified they have produced cannabis plants exceeding the acceptable hemp THC level must arrange for disposal or remediation of the lot represented by the sample in accordance with the procedures as specified above and described on the USDA website at <https://www.ams.usda.gov/rules-regulations/hemp/disposal-activities>.

Producers must document the disposal or remediation of all non-compliant cannabis. This can be accomplished by providing USDA with a copy of the documentation of disposal or remediation using the reporting requirements established by USDA. These reports must be submitted to USDA following the completion of the disposal or remediation process.

E. Compliance.

As described below, this final rule changes the THC threshold for a negligent violation from 0.5 percent under the IFR to 1.0 percent. Further, rather than being liable for multiple negligent violations in each growing season as under the IFR, this final rule provides that producers can only incur one negligent violation in each growing season, which prevents producers from accumulating multiple negligent violations and losing program eligibility after a single growing season.

USDA will maintain oversight of USDA-licensed hemp producers by conducting audits of USDA licensees and working with licensees with negligent violations to establish corrective action plans. Negligent violations by a producer may lead to suspension or revocation of a producer's license.

While USDA has not yet conducted any random audits, the department may conduct random audits of licensees to verify hemp is being produced in accordance with Subtitle G of the AMA no more frequently than every three years, based on available resources. The format of the audit will vary and may include a "desk-audit" where USDA requests records from a licensee, or the audit may be a physical visit to a licensee's facility. When USDA visits a licensee's facility, the licensee must provide access to any fields, greenhouses, storage facilities, or other locations

where the licensee produces hemp. USDA may also request records from the licensee, to include production and planting data, testing results, and other information as determined by USDA.

USDA will issue a summary of the audit to the licensee after the completed audit. Licensees who are found to have a negligent violation will be subject to a corrective action plan. Negligent violations include: (1) failure to provide a legal description of the land on which the hemp is produced; (2) not obtaining a license before engaging in production; or (3) producing plants exceeding the acceptable hemp THC level. Similar to the requirements for State and Tribal plans, USDA will not consider hemp producers as committing a negligent violation if they produce plants exceeding the acceptable hemp THC level if they use reasonable efforts to grow hemp and the cannabis plant does not have a THC concentration of more than 1.0 percent on a dry weight basis. AMS believes that increasing the negligence threshold from 0.5 percent to 1.0 percent will increase flexibility to farmers as they learn more about how to grow compliant hemp and as the availability of stable hemp genetics improves. Further, producers may only receive one negligent violation per growing season, as determined by USDA based on a review of producer records. USDA will use a calendar year as a growing season.

When USDA determines that a negligent violation has occurred, USDA will issue a Notice of Violation. This Notice of Violation will include a corrective action plan. The corrective action plan will include a reasonable date by which the producer will correct the negligent violation or violations and will require the producer to periodically report to USDA on its compliance with the plan for a period of not less than the next two calendar years. A producer who has negligently violated the provisions of this rule three times in a five-year period is ineligible to produce hemp for a period of five years from the date of the third violation. Negligent violations are not subject to criminal enforcement.

Hemp found to be produced in violation of this regulation, such as hemp produced on a property not disclosed by the licensed producer or without a license, would be subject to the same disposal provisions as for cannabis testing above the acceptable hemp THC level. Further,

if it is determined a violation was committed with a culpable mental state greater than negligence, USDA will report the violation to law enforcement.

The 2018 Farm Bill limited the participation of certain convicted felons in hemp production. A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on producing hemp under the Act. An exception applies to a person who was lawfully growing hemp under the 2014 Farm Bill before December 20, 2018, and whose conviction also occurred before that date.

F. Suspension of a USDA license.

There are no changes to the IFR provisions related to suspension of USDA licenses in this final rule.

A USDA license may be suspended if USDA receives credible information that a USDA licensee has either: (1) engaged in conduct violating a provision of this regulation; or (2) failed to comply with a written order from the AMS Administrator related to a negligent violation of this regulation. Examples of credible information are information from local authorities of harvested plants without testing or planting of hemp in non-licensed locations.

Any person whose license has been suspended shall not produce hemp during the period of suspension. A suspended license may be restored after a waiting period of one year. A producer whose license has been suspended may be required to comply with a corrective action plan to fully restore their license.

A USDA license shall be immediately revoked if the USDA licensee: (1) pleads guilty to, or is convicted of, any felony related to a controlled substance;⁹ (2) made any materially false statement with regard to this regulation to USDA or its representatives with a culpable mental state greater than negligence; or (3) was found to be growing cannabis exceeding the acceptable

⁹ For a corporation, if a key participant has a disqualifying felony conviction, the corporation may remove that person from a key participant position. Failure to remove that person will result in a license revocation.

hemp THC level with a culpable mental state greater than negligence or negligently violated the provisions of this regulation three times in five years.

If the licensed producer wants to appeal any suspension or revocation decision made by USDA as described in this section, they can do so using the appeal process explained in section V of this document.

G. Reporting and recordkeeping.

The 2018 Farm Bill requires USDA to develop a process to maintain relevant information regarding the land where hemp is produced. Reporting requirements under this final rule, particularly the requirement to report hemp crop acreage to FSA, are discussed extensively in Section B of the State and Tribal plan requirements and the same requirements are applicable to USDA licensed producers.

In general, changes from the IFR allow producers more flexibility in defining for FSA the areas (instead of “lots”) they use for hemp production. USDA hemp production licensees can apply for licenses on a rolling basis under this final rule, in contrast to the limited period provided under the IFR. Reporting requirements under this final rule are revised slightly to allow producers to account for on-farm disposal of non-compliant product.

USDA’s FSA is well suited to collect this information for the domestic hemp production program. FSA has staff throughout the United States who are trained to work with farmers to verify land uses. Many hemp producers are likely to be familiar with the FSA since they already operate traditional farms, and therefore already provide data to FSA on acres and crops planted. Producers may benefit from information to participate in other USDA programs through FSA offices. Licensed producers will be required to report their hemp crop acreage with FSA, and to provide FSA with specific information regarding field acreage, greenhouse, or indoor square footage of hemp planted. This information must include street address, geospatial location or other comparable identification method specifying where the hemp will be produced, and the legal description of the land. Geospatial location or other methods of identifying the production

locations are necessary, as not all rural locations have specific addresses. This information is required for each field, greenhouse, building, or site where hemp will be grown. USDA will use this information to assemble and maintain the data USDA must make available in real time to Federal, State, Tribal and local law enforcement as required by the 2018 Farm Bill and as described in section G below.

Specific procedures for reporting hemp acreage to FSA will be posted on the USDA Domestic Hemp Production Program website. All information will be maintained by USDA for at least three calendar years. FSA will assist producers in identifying the hemp growing locations since they have maps that allow for better identification. This is a procedure that FSA employees are very familiar with since it is used for other USDA programs. This rule also revises the definition of “lot” to include other terms used by FSA with the same meaning. FSA uses terms like “farm,” “tract,” “field,” and “subfield.” FSA staff will not provide a “lot number” to producers as described in the IFR. Instead, FSA will assist producers to identify the area where hemp is grown. More details are provided under the States and Tribal plan Section B earlier in this final rule.

Licensed producers are required to maintain copies of all records and reports necessary to demonstrate compliance with the program. These records include those that support, document, or verify the information provided in the forms submitted to USDA. Records and reports must be kept for a minimum of three years. Because the final rule allows producers to remediate plants, the final rule also requires producers to maintain records on all remediated cannabis plants.

Under the USDA plan, there will be additional reporting requirements for licensed producers. These include information requested in the application for a license and the record and reporting requirements needed to document disposal or remediation of cannabis produced in violation of the provisions of this rule. Specific reporting requirements are detailed in § 990.71.

H. Information sharing with law enforcement.

USDA is working to develop and maintain a database of all relevant and required information regarding hemp as specified by the 2018 Farm Bill. This database will be accessible in real time to Federal, State, local, and Tribal law enforcement officers through a Federal government law enforcement system. USDA AMS will administer and populate this database, which will include information submitted by States, Tribes, laboratories, and USDA licensed producers and information submitted to FSA. States and Tribes must provide information to USDA in a format that is compatible with USDA's information sharing system. USDA will work with States and Indian Tribes on system format and other information necessary to share information.

USDA will use this information to create a comprehensive list of all domestic hemp producers. USDA will also gather the information related to the land used to produce domestic hemp. This information will be comprehensive and include data from both State and Tribal plans and will include a legal description of the land on which hemp is grown by each hemp producer and the corresponding geospatial location or other identifiable location. Finally, USDA will also gather information regarding the status of all licenses issued under State and Tribal government plans and under the USDA plan.

This information will be made available in real time to Federal, State, local and Tribal law enforcement as required by the 2018 Farm Bill.

IV. Definitions

The following terms are integral to implementing Subtitle G of the AMA and establish the scope and applicability of the regulations of this final rule.

The term "Act" refers to the Agricultural Marketing Act of 1946. The 2018 Farm Bill amended the Agricultural Marketing Act of 1946 by adding Subtitle G, which is a new authority for the Secretary of Agriculture to administer a national hemp production program. Section 297D of Subtitle G authorizes and directs USDA to promulgate regulations to implement this program.

The “Agricultural Marketing Service” or “AMS” is the Agricultural Marketing Service of the U.S. Department of Agriculture is the agency the Secretary of Agriculture has been charged with the responsibility to oversee the administration of this new program.

The term “applicant” means any State or Indian Tribe that has applied for USDA approval of a State or Tribal hemp production plan for the State or Indian Tribe they represent. This term also applies to any person or business in a State or territory of an Indian Tribe not subject to a State or Tribal plan, who applies for a hemp production license under the USDA plan established under this part.

The term “cannabis” is the Latin name of the plant that, depending on its THC concentration level, is further defined as either “hemp” or “marijuana.” *Cannabis* is a genus of flowering plants in the family Cannabaceae, of which *Cannabis sativa* is a species, and *Cannabis indica* and *Cannabis ruderalis* are subspecies thereof. For the purposes of this part, cannabis refers to any form of the plant where the delta-9 tetrahydrocannabinol concentration on a dry weight basis has not yet been determined. This term is important in describing regulations that apply to plant production, sampling, or handling prior to determining its THC content.

The “Controlled Substances Act” is the statute, codified in 21 U.S.C. 801-971, establishing Federal U.S. drug policy under which the manufacture, importation, exportation, possession, use, and distribution of certain substances are regulated. Because cannabis with THC content concentration levels of higher than 0.3 percent is deemed to be marijuana, a Schedule I controlled substance, its regulation falls under the CSA. Therefore, for compliance purposes, the requirements of the CSA are relied upon for the disposal of cannabis that contains THC concentrations above the stated limit of this final rule.

The rule includes a definition of “conviction” to explain what is considered a conviction and what is not. Specifically, a plea of guilty or nolo contendere or any finding of guilt is a conviction. However, if the finding of guilt is subsequently overturned on appeal, pardoned, or expunged, then it is not considered a conviction for purposes of part 990. This definition of

“conviction” is consistent with how some other agencies conducting criminal history record searches determine disqualifying crimes.

A “corrective action plan” is a plan agreed to by a State, Tribal government, or USDA for a licensed hemp producer, to correct a negligent violation or non-compliance with a hemp production plan, its terms, the applicable law(s) or this regulation. Corrective action plans may also be a plan set forth by a State or Tribal government with an approved hemp production plan to correct a non-compliance of their program with their USDA-approved plan. This term is defined in accordance with the 2018 Farm Bill, which mandates certain non-compliant actions to be addressed through corrective action plans.

“Culpable mental state greater than negligence” is a term used in the 2018 Farm Bill to determine when certain actions would be subject to specific consequences. This term means to act intentionally, knowingly, willfully, recklessly, or with criminal negligence.

The term “decarboxylated” refers to the completion of the chemical reaction that converts THCA into delta-9-THC, the intoxicating component of cannabis. The decarboxylated value is also calculated using a molecular mass conversion ratio that sums delta-9-THC and eighty-seven and seven tenths (87.7) percent of THC-acid ($(\text{delta-9 THC}) + (0.877 * \text{THCA})$).

“Delta-9 tetrahydrocannabinol,” also referred to as “Delta-9 THC” or “THC” is the primary psychoactive component of cannabis, and its regulation forms the basis for the regulatory action of this part. As mandated by the Act, legal hemp production must be verified as having THC concentration levels of 0.3 percent on a dry weight basis or below. For the purposes of this part, delta-9 THC and THC are interchangeable.

The term “disposal” means the action or process of getting rid of cannabis that is non-compliant.

“DEA” is an acronym for the “Drug Enforcement Administration,” a United States Federal law enforcement agency under the United States Department of Justice. The DEA is the lead agency for domestic enforcement of the Controlled Substances Act. The DEA plays an

important role in the oversight of the disposal of marijuana, a Schedule I controlled substance, under the regulations of this part. The DEA is also instrumental in registering laboratories to legally handle controlled substances, including cannabis samples that test above the 0.3 THC concentration level.

“Dry weight basis” refers to a method of determining the percentage of a chemical in a substance after removing the moisture from the substance. Percentage of THC on a dry weight basis means the percentage of THC, by weight, in a cannabis item (plant, extract, or other derivative), after excluding moisture from the item.

The “Farm Service Agency (FSA)” is an agency of the U.S. Department of Agriculture that provides services to farm operations including loans, commodity price supports, conservation payments, and disaster assistance. For the purposes of this program, FSA will assist in information collection of land being used for hemp production.

“Gas chromatography” or GC, is a scientific method (specifically, a type of chromatography technique) used in analytical chemistry to separate, detect, and quantify each component in a mixture. It relies on the use of heat for separating and analyzing compounds that can be vaporized without decomposition. Under the terms of this part, GC is one of the valid methods by which laboratories may test for THC concentration levels.

For the purposes of this part, the term “geospatial location” means a location designated through a global system of navigational satellites used to determine the precise ground position of a place or object.

The term “handle” is commonly understood by AMS and used across many of its administered programs. For the purposes of this part, “handle” refers to the actions of cultivating or storing hemp plants or hemp plant parts prior to the delivery of such plant or plant part for further processing. In cases where cannabis plants exceed the acceptable hemp THC level, handle may also refer to the disposal of those plants.

“Hemp” is defined by the 2018 Farm Bill as “the plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

“Liquid chromatography (LC)” is a scientific method (specifically, a type of chromatography) used in analytical chemistry used to separate, identify, and quantify each component in a mixture. It relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid adsorbent material to separate and analyze compounds. Under the terms of this part, LC is one of the valid methods by which laboratories may test for THC concentration levels. Ultra-Performance Liquid Chromatography (UPLC) is an additional method that may also be used as well as other liquid or gas chromatography with detection.

“Indian Tribe or Tribe” is defined in the 2018 Farm Bill by reference to section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304). The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

A “key participant” is a person or persons who have a direct or indirect financial interest in the entity producing hemp, such as an owner or partner in a partnership. A key participant also includes persons in a corporate entity, including tribally-owned corporation individuals, at executive levels, including chief executive officer, chief operating officer, and chief financial officer. This does not include such management personnel as farm, field, or shift managers. This definition also does not include a member of the leadership of a Tribal government who is acting in their capacity as a Tribal leader except when that member exercises executive managerial control over hemp production.

“Law enforcement agency” refers to all Federal, State, Tribal, or local law enforcement agencies. Under the 2018 Farm Bill, State and Tribal submissions of proposed hemp production plans to USDA must be made in consultation with their respective Governors and chief law enforcement officers. Moreover, the 2018 Farm Bill contemplates the involvement of law enforcement in compliance actions related to offenses identified as being made under a “culpable mental state greater than negligence.” To assist law enforcement in the fulfillment of these duties, the 2018 Farm Bill also mandates information sharing that provides law enforcement with real-time data.

The term “lot” refers to a contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of cannabis throughout. In addition, “lot” is a common term in agriculture that refers to the batch or contiguous, homogeneous whole of a product being sold to a single buyer at a single time. Under the terms of this part, “lot” is to be defined by the producer in terms of farm location, field acreage, and variety (i.e., cultivar) and to be reported as such to FSA. For FSA reporting purposes, FSA staff will determine the appropriate designation for the specific location(s) where hemp is being grown using FSA terminology such as “farm,” “tract,” “field,” and “subfield” to mean “lot” for the purpose of this rule.

“Marijuana,” or, as defined in the CSA, “marihuana,” means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; 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. The term “marihuana” does not include hemp, as defined in section 297A of the Agricultural Marketing Act of 1946, and does not include the mature stalks of such plant; fiber produced from such stalks; oil or cake made from the seeds of such plant; any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake; or the sterilized seed of such plant which is

incapable of germination (7 U.S.C. 1639o(1)). “Marihuana” also means all cannabis that tests as having a THC concentration level on a dry weight basis of higher than 0.3 percent.

“Negligence” is a term used in the 2018 Farm Bill to describe when certain actions are subject to specific compliance actions. For the purposes of this rule, the term means failure to exercise the level of care that a reasonably prudent person would exercise in complying with the regulations set forth under this final rule.

Used in relation to the other terms and regulations in this part, “phytocannabinoids” are cannabinoid chemical compounds found in the cannabis plant, two of which are Delta-9 tetrahydrocannabinol (delta-9 THC) and cannabidiol (CBD). Testing methodologies under this part will refer to the presence of “phytocannabinoids” as either THC or CBD.

Under the terms of this program, “plan” refers to a set of criteria or regulations under which a State or Tribal government, or USDA, monitors and regulates the production of hemp. “Plan” may refer to a State or Tribal plan, whether approved by USDA or not, or the USDA hemp production plan.

The 2018 Farm Bill mandates that all cannabis be tested for THC concentration levels using “post-decarboxylation” or similar methods. In the context of this part, “post-decarboxylation” 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 post-decarboxylation 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 post-decarboxylation value of THC, or total THC, can also be calculated by using a liquid chromatograph technique, which keeps the THCA intact, and requires a conversion calculation of that THCA to calculate total potential THC. See also the definitions for decarboxylation and total THC.

The term “produce,” when used as a verb, is a common agricultural term that is often used synonymously with “grow,” and means to propagate plants for market, or for cultivation for market, in the United States. In the context of this part, “produce” refers to the propagation of cannabis to produce hemp.

“Producer” means a producer as defined in 7 CFR 718.2 specifically of hemp. The 2018 Farm Bill mandates that USDA maintain a real-time informational database that identifies registered hemp production sites, whether under a State, Tribal, or USDA plan, for the purposes of compliance and tracking with law enforcement. AMS will maintain this system with the information collection assistance of FSA. In order to maintain consistency and uniformity of hemp production locations, USDA is using FSA to collect this information through their crop acreage reporting system. In this context, a common use of the term “producer” is essential to maintaining a substantive database. For this reason, the definition of “producer” incorporates the FSA definition of “producer” with the additional qualifier that they are a producer specifically of hemp. All producers are required to be licensed or authorized to produce hemp under the USDA Domestic Hemp Production Program.

“Remediation” refers to techniques utilized to transform non-compliant cannabis into something useful and compliant while disposing of non-compliant parts. Remediation can occur by removing and destroying flower material, while retaining stalk, stems, leaf material, and seeds. Remediation can also occur by shredding the entire plant into a bio-mass like material, then re-testing the shredded biomass material for compliance.

“Secretary” means the Secretary of Agriculture of the United States Department of Agriculture.

Section 297A of the Act defines “State” as any of one of the fifty States of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States. The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

The term “State department of agriculture” is defined by the 2018 Farm Bill as the agency, commission, or department of a State government responsible for agriculture in the State. The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

The term “store” is related to the term “handle” under this part and means to deposit hemp plants or hemp plant product in a storehouse, warehouse, or other identified location by a producer for safekeeping prior to delivery to a recipient for further processing.

The term “Territory of the Indian Tribe” means (a) all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, including rights-of-way running through the reservation, (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a State; (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same; and (d) any lands title to which is either held in trust by the United States for the benefit of any Indian Tribe or individual or held by any Indian Tribe or individual subject to restriction by the United States against alienation and over which an Indian Tribe exercises jurisdiction.

The IFR defined the Territory of the Indian Tribe as “Indian Country” in 18 U.S.C. 1151 because section 1151 is a commonly acceptable approach to determine a Tribal government’s jurisdiction. The final rule retains the language of section 1151, but adds item (d) to the definition of “Territory of the Indian Tribe.” This addition does not significantly expand the definition because many of the lands encompassed by item (d) were already considered as “Territory of the Indian Tribe” under the IFR. For example, off-reservation trust land, if not considered part of a reservation under section 1151(a), is generally considered within a dependent Indian community under section 1151(b). *See Club One Casino, Inc. v. Bernhardt*, 959 F.3d 1142, 1149–50 (9th Cir. 2020); Felix Cohen, COHEN’S HANDBOOK OF FEDERAL INDIAN

LAW, section 3.04 (Nell Jessup Newton ed. 2012). Also, restricted fee lands outside of a reservation are often considered part of a dependent Indian community, provided the lands satisfy the two requirements of a dependent Indian community—lands that are (1) set aside by the Federal Government for the use of the Indians and (2) under federal superintendence. *Citizens Against Casino Gambling in Erie Cty. v. Chaudhuri*, 802 F.3d 267, 281 (2d Cir. 2015).

However, because “dependent Indian communities” is an oft-litigated term that is interpreted varying among the courts, USDA decided to add item (d) to the definition of “Territory of the Indian Tribe” to add clarity and ensure nationwide consistency regarding the jurisdictional boundaries of regulatory authority over the production of hemp.

“Total THC” is the post-decarboxylation value of THC, either after testing with gas chromatography or LC after using a conversion factor. LC does not use decarboxylation as part of the process and this addition is to account for the conversion of THCA into THC if decarboxylation was part of the process. The addition of 87.7 percent of THCA is applicable if the testing laboratory uses LC with detection to measure the THC. Total THC is the measured THC plus 87.7 percent of THCA.

As defined by the 2018 Farm Bill, the term “Tribal government” means the governing body of an Indian Tribe. The statutory definition is self-explanatory, and USDA is adopting the same definition without change for part 990.

The “U.S. Attorney General” is the Attorney General of the United States.

“USDA” is an acronym that stands for the “United States Department of Agriculture.”

V. Appeals

The following paragraphs explain when and how to appeal a USDA decision. State or Tribal plans may include similar appeal procedures. No changes were made to this section based on comments.

An applicant for a USDA hemp production program license may appeal a license denial to the AMS Administrator. USDA licensees can appeal denials of license renewals, license

suspensions, or license revocations to the AMS Administrator. All appeals must be submitted in writing and received within 30 days of the denial. Appeals may be submitted by mail or electronic form. This submission deadline should provide adequate time to prepare the necessary information required for the appeal. The Administrator will take into account the applicant or USDA licensee's justification for why the license should not be denied, suspended, or revoked, and then issue a final determination. Determinations made by the Administrator under the appeals process will be final unless the applicant or USDA licensee requests a formal adjudicatory proceeding to review the decision, which will be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Formal Adjudicatory Proceedings, 7 CFR part 1, subpart H, which USDA will amend to add the Domestic Hemp Production Program. If the applicant or USDA licensee does not request that the Administrator initiate a formal adjudicatory proceeding within 30 days of the Administrator's adverse ruling, such ruling becomes final.

Appeals Under a State or Tribal Hemp Production Plan

A State or Tribe can appeal the denial of a proposed hemp production plan, or the proposed suspension or revocation of a plan by USDA. USDA will consult with States and Tribes to help ensure their draft plans meet statutory requirements, and that existing plan requirements are monitored and enforced by States and Indian Tribes. If, however, a proposed State or Tribal plan is not approved, or an existing plan is suspended or revoked the decision may be appealed.

If the AMS Administrator grants a State or Indian Tribe's appeal of a disapproval of its hemp plan, the proposed State or Tribal hemp production plan shall be approved as proposed. If the AMS Administrator denies an appeal, prospective producers located in the State or Tribal Territory can apply directly to USDA for a hemp license. Similarly, if an appeal of a denied proposed State or Tribal plan is denied, producers located in the impacted State or Tribal territory may apply for licenses under the USDA plan.

A State or Tribe appealing the suspension or revocation of their hemp production plan must explain the reasoning for the appeal and the appeal must be filed within the time-period provided in the letter of notification or within 30 business days from receipt of the notification, whichever occurs later. This timeframe should be adequate for the assembly of the information required to be submitted as part of the appeal.

VI. Interstate Commerce

Nothing in this rule prohibits the interstate commerce of hemp. No State or Indian Tribe may prohibit the transportation or shipment of hemp produced in accordance with this part and with section 7606 of the 2014 Farm Bill (expires January 1, 2022) through the State or the territory of the Indian Tribe, as applicable.¹⁰

VII. Outreach

As part of this rulemaking process, AMS held numerous meetings with State and Tribal governments and their representatives, industry organizations, groups and individuals with experience in the hemp industry, and representatives of law enforcement, as well as other Federal agencies.

In addition, USDA also conducted a listening session on March 13, 2019, that had more than 2,100 participants, and included comments from 46 separate speakers representing States, Tribes, producers, end-users, hemp organizations, and others. The recording of the listening session is available on the USDA website at <https://www.ams.usda.gov/rules-regulations/hemp>. On May 1 and 2, 2019, USDA also participated in Tribal consultation meetings for a total of 52 and 38 participants, respectively. On September 24, 2020, AMS conducted another Tribal Consultation with approximately 90 participants.

AMS published an interim final rule on October 31, 2019 (84 FR 58522), that established a temporary hemp production program and invited public comments on the program's

¹⁰ See section 10114 of the 2018 Farm Bill and the USDA General Counsel's Legal Opinion on the Authorities for Hemp Production at <https://www.ams.usda.gov/content/legal-opinion-authorities-hemp-production>.

provisions. The initial 60-day comment period was extended by 30 days on December 18, 2019 (84 FR 69295). The comment period was reopened for another 30 days on September 8, 2020 (85 FR 55363). A total of approximately 5,900 comments were submitted by States, Tribes, farmers, industry associations, and other interested groups and individuals during the combined comment periods expressing their views on the provisions of the IFR and suggesting modifications, many of which have been incorporated into this final rule.

Finally, in November 2019, AMS posted an informational webinar about the domestic hemp production program on its website (in English and Spanish) at <https://www.ams.usda.gov/rules-regulations/hemp>. AMS has also posted additional useful information for regulated entities and other interested persons on its website at <https://www.ams.usda.gov/rules-regulations/hemp>.

As required by the Farm Bill, the Secretary developed this final rule and related guidelines in consultation with the U.S. Attorney General. In addition, USDA has submitted information to, and consulted with, the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate regarding updates on the implementation of the hemp requirements in the Farm Bill.

VIII. Severability

This final rule includes a severability provision. This provision helps address the status of the regulations should a court vacate a particular provision. This section provides that if any provision of part 990 is found to be invalid, the remainder of the part shall not be affected.

IX. Comment Analysis

AMS accepted comments during an initial comment period from October 31, 2019 through December 31, 2019. On December 18, 2019 (84 FR 69295), this initial comment period was extended for an additional 30 days, ending January 29, 2020. AMS reopened the comment period for 30 additional days on September 8, 2020 (85 FR 55363), ending October 8, 2020.

Comments may be accessed through Regulations.gov.¹¹ Reopening the comment period gave interested persons an additional opportunity to comment on the IFR. Comments were solicited from all stakeholders, notably those who were subject to the regulatory requirements of the IFR during the 2020 production cycle.

AMS specifically requested comments on the 15-day sampling and harvest timeline; the possibility of establishing a fee-for-service hemp laboratory approval process for labs that wish to offer THC testing services; the possibility of requiring all laboratories testing hemp to have ISO 17025 accreditation; the number of labs already ISO 17025 accredited; additional examples of reasonable efforts to illustrate actions hemp producers can take in order to avoid committing a negligent violation under the program; the sufficiency of the hemp license application period; whether the information collection for the program is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; the ways to enhance the quality, utility, and clarity of the information to be collected; the ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; whether there is information or data that may inform whether or not the market will experience a significant shift, either positive or negative, in the developing hemp market and on consumers; any data or information on what impacts the regulation may have on current and future innovation in the areas of industrial hemp usages and how much such impacts on innovation may affect rural communities; the potential for innovation and the uncertainty and its impact on the hemp market vis a vis steady State; and additional reliable data sources on the annual receipts of industrial hemp producers.

¹¹ <https://www.regulations.gov/searchResults?rpp=25&po=0&s=AMS-SC-19-0042&fp=true&ns=true>

AMS received approximately 5,900 comments. Comments represented the views of States, Indian Tribes, hemp farmers and processors, universities, laboratories, trade associations, carriers, non-profit associations, other Federal government agencies, consumers, and other interested individuals. A summary of the comments and AMS's analysis and response follows.

EXTENSION OF COMMENT PERIOD

Several commenters urged AMS to extend the public comment period to allow for small businesses to meaningfully participate in this rulemaking process. One reason given was that the comment period fell in the middle of the harvest season for much of the mid-Atlantic and southern hemp growers, excluding those who grow indoors, and therefore were too busy to comment. Other reasons given were the ongoing global pandemic as well as many other ongoing natural disasters nation-wide that have presented additional strains and unique challenges to agricultural operations.

AMS Response: AMS provided an initial 60-day comment period and a 30-day extension and then reopened the comment period for 30 additional days in order to receive feedback from stakeholders thus giving ample time to interested parties to submit comments. In order to finalize the Domestic Hemp Promotion Program before the 2021 production cycle begins, AMS decided not to extend the comment period and to finalize this rule.

EXTENSION OF 2014 PILOT PROGRAM

Under the 2014 Farm Bill, State departments of agriculture and institutions of higher education were permitted to produce hemp as part of a pilot program for research purposes. Congress extended this authority under the 2021 Continuing Appropriations Act until January 1, 2022. After January 1, 2022, domestic hemp production must comply with Subtitle G of the AMA and this final rule.

Comments: Numerous comments praised the hemp production regulatory schemes established by States and Universities under the 2014 Farm Bill authority. Many comments reflected on the perceived increase in regulatory burden under the IFR, as opposed to the

regulatory scheme that has been applied to domestic hemp production until now. Many comments, while making recommendations with regards to specific aspects of the IFR provisions, also encouraged USDA to continue to regulate domestic hemp production under the 2014 Farm Bill until satisfactory resolution of industry concerns can be achieved. Further, several comments stated that the extension of the pilot programs under the 2014 Farm Bill for another two to three years would give the industry time to adjust to the new requirements and to develop hemp genetics to more easily comply with the regulations.

A few comments opposed extension of the 2014 Farm Bill pilot program, asserting that States now operating under the more restrictive 2018 Farm Bill provisions are placed at a disadvantage.

AMS response: The extension of the 2014 Farm Bill authority is not within the authority of USDA. Congress only extended this authority under the 2021 Continuing Appropriations Act (Pub. L. 116-260), until January 1, 2022.

THC LIMIT

The IFR adopts the 2018 Farm Bill definition of hemp as the plant species *Cannabis sativa* L. and any part of that plant with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Further, the IFR requires that THC levels in representative samples test at or below the acceptable hemp THC level. Testing must be conducted using post-decarboxylation or other similarly reliable methods, where the total THC concentration level measured includes the potential to convert THCA into THC. Finally, The IFR provides that hemp testing higher than the acceptable hemp THC level is considered a controlled substance and requires disposal.

Comments: Some comments supported the 2018 Farm Bill's hemp THC level of 0.3 percent, and some explained that States had successfully incorporated that limit into programs authorized under the 2014 Farm Bill. Some comments thanked USDA for clearly defining the

delta-9 THC standard in the IFR, which commenters said would foster uniformity across hemp production in all States.

However, a greater number of comments from various stakeholder groups, including producers, States, Indian Tribes, and hemp organizations, asserted that the 0.3 percent threshold is too low and impractical in a program intended for multiple end uses of hemp. Comments argued that individuals interested in obtaining cannabis for intoxication purposes are unlikely to be interested in material containing 1.0 percent THC – or perhaps higher, and that setting the threshold at even 1.0 percent THC would give farmers, breeders, and researchers a lot more flexibility and confidence in producing compliant crops. One commenter reported that their State recognizes hemp with THC concentrations of up to 0.39 percent, with most crops testing between 0.31 and 0.39 percent THC, and no end products testing higher than 0.3 percent THC. The comment suggested USDA should raise the THC limit to at least 0.39, if not up to 0.5 percent. Other comments recommended revising the threshold to a higher level, asserting that there is no scientific evidence that supports use of the 0.3 percent level. Some comments recommended increasing the threshold to 0.8 or 1.0 percent, while some suggested 2.0 percent and others as much as 5.0 percent. Comments explained that a THC concentration of 5 percent is not viable for recreational marijuana markets and that USDA should consider the end-use potential when determining a threshold. One comment recommending a THC threshold of at least 2.0 percent included a news story reporting that marijuana plants confiscated by law enforcement routinely have THC concentrations of 12 percent or higher.¹²

Several comments suggested that the IFR’s level of 0.3 percent delta-9 THC on a dry-weight basis is “more aspirational than practical.” Comments explained that THC levels vary with plant maturity and other factors. Comments urged USDA to build greater flexibility into the rule so producers don’t unwittingly become illegal marijuana farmers as a result of factors

¹² McCullough, Jolie. “Marijuana Prosecutions in Texas Have Dropped by More than Half Since Lawmakers Legalized Hemp.” *The Texas Tribune*, 3 January 2020; www.texastribune.org/2020/01/03/texas-marijuana-prosecution-drop-testing-hemp/.

beyond their control. One comment suggested USDA establish a wider gap between the THC levels that define controlled substances and agricultural commodities such as hemp to create an environment where hemp producers are presumed innocent until proven guilty of intentionally producing a controlled substance. Several comments recommended that university and other research programs be given more leeway as they work toward developing more compliant, regionally appropriate varieties through breeding.

Some comments noted that hemp containing more than 0.3 percent THC is not eligible for crop loss or replant payments under USDA Risk Management Agency regulations. Comments said further that if USDA is not certifying seed because of the regional effects of growing conditions on genetics, farmers are at risk and should be able to obtain comprehensive insurance coverage for crops with negligible overage above the acceptable THC level.

Comments explained that while the genetics of most U.S. crops have been developed over many years, hemp has not enjoyed that history, and it will take time to develop compliant but commercially viable crops with marketable CBD content for different regions. Comments asserted farmers will have fewer planting options because of the lack of a national hemp seed certification protocol and limited agronomic research on hemp varieties and production practices. Comments inferred that the 0.3 percent THC threshold would effectively demand that farmers plant a nationwide monoculture with little genetic diversity, which they said would leave U.S. hemp crops vulnerable to pests and diseases.

Many comments questioned the selection by Congress of the 0.3 percent THC threshold to legally distinguish hemp from marijuana.¹³ Comments frequently referenced a 1976 publication, *A Practical and Natural Taxonomy for Cannabis*, in which horticulturalists Dr. Ernest Small and Arthur Cronquist used 0.3 percent THC as a threshold to distinguish hemp from marijuana in their scientific study on cannabis.¹⁴ Comments highlighted statements made

¹³ Johnson, Renee. "Hemp as an agricultural commodity." Congressional Research Service (2014).

¹⁴ Small, Ernest, and Arthur Cronquist. "A practical and natural taxonomy for Cannabis." *Taxon* (1976): 405-435.

by Small and Cronquist, saying the researchers openly acknowledged that they “arbitrarily adopt a concentration of 0.3 percent delta-9 THC (dry weight basis) in young, vigorous leaves of relatively mature plants as a guide to discriminating two classes of plants,” and that the number was never intended to define hemp from a legal perspective. According to the comment, Small and Cronquist made no conclusionary statement on the use of the 0.3 percent THC threshold.

Several comments reported that countries determined to compete in the global marketplace, including Switzerland, Australia, Thailand, Uruguay, and Ecuador, recognize an acceptable hemp THC limit of 1.0 percent. According to comments, the international market settled on the 1.0 percent THC limit after numerous countries tested hemp over many years. Comments recommended the IFR incorporate the same standard.

Comments asserted that the rights of Indian Tribes and small Tribal farmers should be protected by allowing greater flexibility in the hemp production regulations overall, consistent with Tribal self-government. For example, comments said that Indian nations should be recognized to have authority to grow hemp with up to 1.5 percent THC and should not be restricted to 0.3 percent.

One comment explained that their company has focused on breeding efforts to develop genetics that produce CBD-rich hemp with the lowest possible THC concentrations. The commenter claimed their company has harvested millions of pounds of hemp compliant with the 0.3 percent total THC standard since 2017. The comment said they produced 25 million rooted cuttings this spring – enough, according to the comment, to produce biomass for the entire country, and the commenter assumed they were not the only ones who had done so. The comment asserted further that the global standard for THC concentration is 0.2 percent and that to be competitive, U.S. production must adhere to a similarly strict standard.

Although asserting that the IFR hemp THC level of 0.3 percent is not commercially reasonable, some comments acknowledged that only Congress could change the statute to allow

a higher limit, and some commenters offered to serve as resources in that effort. Other comments urged USDA to work with Congress to raise the THC threshold.

AMS response: Congress defined hemp in the 2018 Farm Bill as *Cannabis sativa* L. with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Any change to the statutorily established threshold of THC concentration requires an amendment to the statute. The CSA defines marijuana as cannabis that is over the 0.3 percent THC level. AMS has no discretion to change the THC level or to treat States and Tribes differently as the 2018 Farm Bill applies to all production of hemp in the U.S. Tribes do not have the authority to grow hemp with up to 1.5 percent THC as this would violate the 2018 Farm Bill and the CSA. Tribes' powers of self-government may be constrained by acts of Congress in accordance with Congress' constitutional authority to regulate commerce with Indian Tribes.

AMS notes that there seems to be confusion amongst some commenters on the THC level stated in the 2018 Farm Bill and the IFR's definition of acceptable hemp THC level. The acceptable hemp THC level in this final rule includes the 0.3 percent established in the Farm Bill plus any measure of uncertainty due to laboratory testing.

Regarding the comment citing the news story, AMS believes the commenter misconstrued the article's meaning. The article cited by the commenter explained that following passage of Texas's law that legalized hemp in early 2019, the number of marijuana prosecutions in the State plummeted, due in part to the lack of adequate and affordable criminal laboratory resources. According to the article, prosecutors were less likely to expend resources on low-level marijuana charges where the likelihood of conviction is low. The article described anticipated release of a new lab testing method that only determines whether THC concentration is above or below 2 percent for criminal testing purposes. According to the article, even though 2 percent is higher than the State's legal hemp limit of 0.3 percent, such testing would nevertheless be adequate for Texas law enforcement purposes, since nearly all marijuana plant prosecutions in the State involve THC concentrations of 12 percent or more. AMS believes

neither the article nor the State are advocating legalization of hemp THC concentrations of up to 2 percent, but that Texas law enforcement is merely using that limit as a convenient way to determine whether to pursue criminal prosecution.

In response to concerns that producers could unwittingly become illegal marijuana farmers without greater flexibility in the rule, AMS has modified the negligent violation threshold as explained in the section responding to comments on the negligent violation threshold. AMS also notes, however, that it does not have any authority over how the DEA chooses to enforce compliance with the CSA.

In the final rule, AMS is implementing a nation-wide domestic hemp production program as contemplated by the 2018 Farm Bill. It is not amending Risk Management Agency's regulations regarding crop loss or repayment payments. Thus, comments regarding those regulations are outside the scope of this rule.

TESTING FOR TOTAL THC

The IFR requires that when hemp THC levels are measured using post-decarboxylation or other similarly reliable methods, the total THC concentration level measured must include the potential to convert THCA into THC.

Comments: Some comments agreed that the measurement of delta-9 THCA should be added to the measurement of delta-9 THC and reported as total THC used for determining compliance with the hemp program requirements, as this is what many hemp producing States are already doing under State programs. A comment from an association of Departments of Agriculture reported that many States responding to their survey supported testing for total THC in this manner.

Other commenters disagreed. According to one comment, only 22 of 47 States with State-level hemp programs test for total THC. The comment said that 18 States do not currently test for total THC, and that 7 States' rules are ambiguous on this point. Other comments

reported that State programs currently testing for only delta-9 THC are confident that producers are not selling “hot” crops.

One comment said it is irrational to subject hemp biomass to decarboxylation when most biomass harvested for processing into increasingly popular consumer goods or industrial products will never even be decarboxylated.

Another comment explained how USDA cannot alter the definition of hemp as set forth in the 2018 Farm Bill. The comment said that there should not be a “total” THC mandate and, rather, the plain reading of the 2018 Farm Bill establishes that delta-9 THC is actually the determinative factor. The comment went on to explain how other State and Federal agencies also rely only on delta-9 THC when making critical distinctions with respect to hemp, such as the DEA and the FDA, to determine whether a substance is controlled and subject to criminal penalties. The comment presented an alternative testing methodology where testing methods must be able to determine the potential for THCA to convert into delta-9 THC, and the test result must reflect that ability as well as the aggregate computation, but the controlling factor whether a crop meets the definition of hemp and is within the “acceptable hemp THC level” relies only upon the delta-9 THC element. Thus, for compliance purposes, delta-9 THC is the standard, and the lab report must at least reflect THCA, delta-9 THC, and the Total THC results, but Total THC should not be determinative in whether a farmer has to destroy his crop.

Industry impacts. Commenters asserted that testing for THCA concentration, a component they argued which is not psychoactive, would vastly undermine the efficient production of hemp and the growth of the industry. Some comments supported the 0.3 percent THC standard, but said requiring testing for total THC goes beyond what is statutorily required, to the detriment of producers. Commenters argued that the difference between levels of delta-9 THC and total THC in hemp is significant, and that crops that would otherwise be compliant measuring only for delta-9 THC would not be compliant when measuring for Total THC.

Comments asserted that testing for total THC with a threshold of 0.3 percent effectively lowers the allowable hemp THC level to an even lower limit.

Comments also described the correlation between total CBD and total THC production and explained that producers trying to maximize CBD production will not be able to do so successfully if total THC levels are restricted to 0.3 percent. One comment claimed that a farmer can produce hemp plants with up to 25 percent cannabinoid content while staying under 0.3 percent delta-9 THC limit, but that the farmer would have to plant twice as many acres of a less potent hemp variety to produce the same amount of CBD end product and stay compliant under the IFR's Total THC limit.

Several comments reported that some CBD hemp processors reject product with CBD amounts of less than 8 percent. According to comments, breeders have worked years to develop cultivars that meet the 0.3 percent delta-9 THC threshold, but many cultivars would not be compliant under the total THC limit. Comments predicted that with a standard of 0.3 percent total THC, growers will stop growing hemp for CBD because the risk is too high that their hemp crops will exceed the limit and be destroyed, defeating the purpose for growing crops for the potential high returns related to CBD production. Comments further lamented that the industry would lose investments they've already made.

According to comments, many States that have only been measuring delta-9 THC under 2014 Farm Bill pilot programs have developed companion marketing programs that have been tailored to complement State hemp production programs. Comments asserted the total THC limit in the IFR would significantly impact these new and emerging markets and cripple the industry in those States, preventing them from selling their product.

Some comments claimed that common industry practice is to measure THC and THCA independently. Comments recommended USDA treat THC and THCA as two separate molecules and only be concerned with the amount of THC in a sample, rather than total available THC.

One comment recommended that if USDA wants to test for total THC, the limit should be raised to 0.694 percent, with negligence set at 1.094 percent, and that growers whose samples measure between the two limits should be allowed to retest samples with up to two certified labs of their choice at a cost of \$500 each. Another comment recommended that samples be tested for THC and THCA separately, with limits of 0.3 and 1.0 percent, respectively.

AMS response: The 2018 Farm Bill requires that State and Tribal plans provide a procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp. In order to use post-decarboxylation, the sample must be heated or a conversion made to account for the lack of heating process. This means that the total THC must account for THCA and delta-9 THC.

Currently, some States and Indian Tribes use gas chromatography (GC) to test hemp. In GC testing, heat is applied to the sample which THCA, producing delta-9 THC (a psychoactive compound), so that the final delta-9 THC result is actually a total THC result. GC is the more traditional technique used for THC testing and GC results are typically reported as “delta-9 THC” without distinguishing that the reported delta-9 THC is actually total THC.

Liquid chromatography (LC) testing typically does not involve the use of heat, so the THCA in a sample does not decarboxylate. In LC, results for THCA and delta-9 THC are obtained separately and can be reported separately. Cannabis naturally contains more THCA than delta-9 THC; if the THCA concentration is ignored while testing by LC, it is improbable to correctly distinguish hemp varieties from drug varieties. A total THC needs to be calculated post-testing in order to determine the “post-decarboxylation” delta-9 THC value as required by the 2018 Farm Bill. In this way, all testing methodologies report the same information.

AMS acknowledges that some States do not currently test for total THC and that switching to testing for total THC may have a negative impact on those State programs. Most laboratories that use LC obtain THCA results and delta-9 THC results in the same analysis, so the information should be readily available to incorporate a calculation for Total THC. The

opposite is also true. If USDA was to ignore the statutory requirement of using post-decarboxylation or other similarly reliable methods and allow for THC levels that do not account for decarboxylation, States and Tribes that currently require testing for total THC could experience a negative impact. When States or Tribes use different methods to measure THC, it impacts commerce because producers are not all on the same playing field. Also, since total THC at 0.3 percent is harder to obtain, those States and Tribes currently using total THC have been potentially selling less or destroying more hemp. Further, many in the industry have already made the switch to total THC since the IFR was published, diminishing the impact.

AMS consulted with the Departments of Justice and Health and Human Services to develop the IFR. The Drug Enforcement Administration's Analysis of Drugs Manual cites GC methodology, initially labeling results as delta-9 THC and then defining total THC and instructing how to determine compliance using total THC.

In order to provide flexibility to States and Indian Tribes administering their own hemp production programs, alternative testing protocols will be considered by AMS if they are comparable and similarly reliable to the baseline mandated by section 297B(a)(2)(ii) of the AMA and established under the USDA plan and procedures. Updated USDA procedures for sampling and testing will be issued concurrently with this rule and will be provided on the USDA website.

This final rule covers hemp production. Hemp products are regulated under the Food and Drug Administration and its various statutes¹⁵.

Statutory Compliance and Congressional Intent: Several comments expressed concern about regulatory inconsistency between the 2018 Farm Bill language testing methods and the IFR requirements. Commenters urged USDA to reconsider the legislative record and Congress's intent in passing the 2014 and 2018 Farm Bills. According to numerous comments, the plain

¹⁵ The 2018 Farm Bill explicitly preserved the authority of the U.S. Food and Drug Administration (FDA) to regulate hemp products under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act (PHS Act).

language of the 2018 Farm Bill statute does not support the IFR's requirement to test for total THC. Commenters asserted that if Congress had intended samples to be tested for total THC, they would have so specified, rather than making the specific reference to delta-9 THC in the statute. Comments concluded that concentrations of THCA in hemp should be irrelevant to its legal status under the regulations. One comment characterized "decarboxylated value" as a new legal term and questioned USDA's authority under the 2018 Farm Bill to create such a term. One comment went on to say that the term "potential conversion" as appearing in the IFR is offensive because Federal criminal law does not convert a legal substance into an illegal one simply because the substance has the "potential" to be converted.

Several comments cited a letter from Senators Merkley and Wyden,¹⁶ authors of the Hemp Farming Act of 2018 that was included in the 2018 Farm Bill, as evidence that the IFR wrongly requires testing of Total THC. In that letter, Senators Merkley and Wyden asserted that requiring hemp samples to be tested using methods by which the reported THC concentration accounts for the conversion of THCA to THC "is a complete reversal of the Congressional intent expressed in that law and requires testing that Congress specifically did not include." Comments also asserted that the Farm Bill definition of hemp is clear in that "all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not" of the hemp plant are expressly lawful so long as the plant does not contain a delta-9 THC concentration of above 0.3 percent. Thus, according to these comments, the IFR required measurement of a lawful plant-based acid when distinguishing between hemp and marijuana under the Controlled Substances Act, and such a requirement contradicts the plain language of the Farm Bill and the spirit of the law.

¹⁶ <https://www.merkley.senate.gov/news/press-releases/wyden-merkley-to-dea-interim-rule-on-hemp-contradicts-congressional-intent-by-criminalizing-intermediate-steps-in-hemp-processing-2020#:~:text=Authors%20of%20the%20provision%20in,by%20seriously%20misunderstanding%20hemp%20processing. See https://beta.regulations.gov/comment/AMS-SC-19-0042-0884.>

One comment asserted that requiring test reports of THC concentration to account for conversion of THCA into THC effectively mandates that only test methods relying on post-decarboxylation be used, nullifying Congressional intent that other similarly reliable methods that don't require conversion of THCA to THC should be authorized. The comment recommended revising the rule to comply with the Congressional mandate to allow testing through other similarly reliable methods.

AMS response: AMS is not making a determination of Congressional intent when passing the 2018 Farm Bill provision for hemp. Instead, AMS is following the plain statutory language that states that a State or Tribal plan shall be required to include “a procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp produced in the State or territory of the Indian Tribe”.

International Impact. Some comments asserted that the average global delta-9 THC limit is 1.0 percent. Others claimed that Europe has adopted a 0.3 percent THC limit, but that it applies only to delta-9 THC and not total THC. Comments contend that American hemp production required to comply with at 0.3 percent total THC limit will be disadvantaged in the international marketplace. Comments proposed that matching a global standard by establishing a higher delta-9 THC threshold or total THC limit would strengthen U.S. producers' market competitiveness. Other comments warned that reducing the domestic hemp supply by imposing the IFR's 0.3 percent total THC limit will incentivize importation of hemp biomass and hemp derivatives produced in countries with lower labor costs and less restrictive regulatory regimes, and that domestic hemp and hemp derivatives will be priced out of the market.

AMS response: The 2018 Farm Bill authorizes USDA to issue regulations to regulate the production of hemp and defines hemp in terms of the concentration of THC in a *Cannabis sativa* L. plant. A *Cannabis sativa* L. plant is considered hemp, and therefore not a controlled substance, if the THC concentration is not more than 0.3 percent on a dry weight basis. AMS

does not have the discretion to change this threshold in the definition of hemp even if this threshold could impact the global competitiveness of U.S.-produced hemp.

CALCULATING TOTAL THC

The 2018 Farm Bill and IFR identified and described the procedure for testing THC concentration using post-decarboxylation or other similarly reliable methods. The term decarboxylated was defined in the IFR as the completion of the chemical reaction that converts THC-acid (THCA) into delta-9-THC, the intoxicating component of cannabis. The decarboxylated value is also calculated using a conversion formula that sums delta-9-THC and eighty-seven and seven tenths (87.7) percent of THC-acid. The term decarboxylated is also commonly used in science and is the precursor to the term “post-decarboxylation,” which appears in the 2018 Farm Bill's mandate on the acceptable cannabis testing methodologies for identifying THC concentration levels. AMS adopted this definition in this final rule.

Conversion Efficiency: Many stakeholders opposed USDA's conversion formula described in the IFR. Comments claimed the IFR was based on 100 percent conversion efficiency, which is only achievable under controlled laboratory testing conditions and is not possible outside of a laboratory environment. One comment stated the IFR failed to account for the inefficiency of the decarboxylation process. Numerous other comments characterized the USDA formula as theoretical and explained that the realistic conversion efficiency is between 30 and 75 percent. For example, several commenters cited a peer reviewed study which found 72 percent to be a viable efficiency factor and provided the calculation formula: Total Potential THC = (0.72) x [(0.877 x THCA) x delta-9THC]. Additionally, a commenter suggested USDA utilize three different conversion factor tiers (0, 30, or 70 percent) depending on the end-use varietal because the THC concentration varies by varietal. The commenter argued that the conversion factors should reflect the different end-uses.

One comment said the calculation for “Total Potential THC” should be defined and incorporated into the final rule because the decarboxylation percentage definition is critical for

standardization and uniformity in the industry. Otherwise, according to the comment, States could adopt different decarboxylation percentages in their equations, causing confusion for growers. The comment gave the following formulas as examples: (Total potential THC = $0.877 \times \text{percent THCA} + \text{percent delta-9 THC}$) as compared to (Total Potential THC = $0.877 \times 0.70 \times \text{percent THCA} + \text{percent delta-9 THC}$), assuming a 70 percent THCA decarboxylation to delta-9 THC rate.

Another comment explained the need to include delta-8 THC into any calculation for the future state delta-9 THC.

AMS response: Delta-8 THC only exists in a trace amount in marijuana which has a high Delta-9 THC concentration. The Delta-9 THC amount is already low in hemp, so the concentration of Delta-8 THC would be basically undetectable in hemp. A quote from the “WHO Expert Committee on Drug Dependence Critical Review - Isomers of THC” regarding the relative amount of Delta-8 THC to Delta-9 THC that can be found at <https://www.who.int/medicines/access/controlled-substances/IsomersTHC.pdf?ua=1>.

The above range means that Delta-8 THC occurs at a level that is roughly 1000 times less than Delta-9 THC. So, if Delta-9 THC was observed at 0.3 percent in hemp, then the Delta-8 THC concentration would be roughly around 0.0003 percent. This contribution is completely negligible and contributes nothing significant to the total THC content. The trace amount of Delta-8 THC is about 100 times less than the uncertainty (MU) of the test method, further demonstrating that it is insignificant and not worthy of consideration in the final assessment of THC for hemp compliance.

AMS is adopting the calculation provided in the IFR for determining total THC. However, the calculation has been clarified to explain the use of the molar conversion ratio to mathematically convert THCA to delta-9 THC. As written in the IFR, the calculation may have been misunderstood as containing a conversion efficiency factor, which is not the case. THCA cannot be added to delta-9 THC without accounting for the difference in molecular mass. Using

stoichiometry, a molar conversion ratio (0.877) is used to mathematically convert THCA in terms of delta-9 THC. The molar mass of THCA is 358.47 g/mol and the molar mass of delta-9 THC is 314.45 g/mol. In other words, the mass of THCA has to be adjusted or multiplied by 0.877 to be comparable to the mass of delta-9 THC.

The 2018 Farm Bill requires that the THC content be expressed post-decarboxylation, which means that the conversion of THCA into delta-9-THC to account for the potential total THC in a sample must be taken into account. The term “potential” is used because it is not possible to readily, consistently, and reliably calculate the precise extent of the conversion of THCA to THC under *any and all* circumstances. Therefore, the calculation for total THC assumes 100 percent conversion efficiency and is hereby retained in this regulation. The calculation for total THC [total THC = (0.877 x THCA) + (delta-9 THC)] assumes that 100 percent of the THCA is decarboxylated, producing to delta-9 THC, meaning that it gives the maximum (or potential, or theoretical) total THC. The final rule includes a definition for total THC to provide more specificity on this issue. This is standard procedure for how theoretical yield is calculated in chemistry. The issue is that theoretical yield does not always equal actual yield. Just because a maximum total THC can be calculated does not mean that the maximum is always obtained; however, there is potential for this maximum to be obtained. The amount of THCA that actually decarboxylates, producing delta-9 THC, is dependent on multiple variables; primarily, the amount of heat it is exposed to and the amount of time it is exposed to that heat. These variables, in turn, depend on what is being done to a cannabis sample (tested via LC, tested via GC, used for smoking, used for extraction, etc.).

Incorporating the use of a conversion efficiency factor into the calculation is problematic due to these variables. Designating different conversion efficiency factors based on intended end use is not practical as the factors can still vary. For example, if an end-use of extraction is intended, there are many different types of extraction processes and even within one specific process there are still many different variables that will affect the conversion efficiency.

Ultimately, there is no way to standardize a conversion efficiency factor based on end-use, methodology, or processing. The infrastructure does not currently exist to measure and monitor conversion efficiency.

In terms of conversion during instrumental analysis, many commenters referenced a study conducted by Dussy¹⁷ that determined a conversion efficiency factor for a specific GC setup. The author of the study recommends determining THCA and delta-9 THC separately and calculating total THC (using the equation the IFR stated to use). The author says that “every total Δ 9-THC value determined after decarboxylation [by using GC] gives a minimal content rather than an exact value”. Therefore, the author proposes that labs using GC should calculate their own method’s conversion efficiency and then apply their efficiency to their result to increase their total THC value to make it comparable to LC. This is the opposite of what many commenters are proposing in that they wanted LC methods to incorporate conversion efficiency into their LC results to make total THC lower. The further complication of this “opposite” approach is that it is impossible without having a single conversion efficiency which, as stated previously, cannot be agreed upon and can vary widely. Furthermore, no matter how the conversion efficiency was to be applied, requiring each lab to determine their own method’s efficiency would require significant effort.

Delta-8 THC is a cannabinoid that can be formed from delta-9 THC. It is typically only found in very small quantities in plants, if it is found at all, and is more often obtained by growing a plant with high delta-9 THC and then converting the delta-9 THC into delta-8 THC through an extraction and conversion process in a lab to make a distillate product. It is rarely included in total THC calculations and many labs do not test for it. Delta-8 THC is unrelated to

¹⁷ Dussy F.E.; Hamberg, C.; Luginbühl, M.; Schwerzmann, T.; Briellmann, T.A. Isolation of Δ 9-THCA-A from hemp and analytical aspects concerning the determination of Δ 9-THC in cannabis products. *Forensic Science International*, 149, 3-10, 2005.

the 0.3 percent delta-9 THC limit or the “post-decarboxylation delta-9 THC” that are defined and required in this final rule.

SIMILARLY RELIABLE TESTING METHODS

The 2018 Farm Bill states that State, Tribal, or USDA plans shall include “a procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp.”

The IFR included two examples of standard industry post-decarboxylation testing methods that meet 2018 Farm Bill requirements: gas and liquid chromatography with detection. AMS selected these standard methods of chromatography as the best options for testing but also provided flexibility for alternative sampling and testing protocols if they are comparable and similarly reliable to the baseline mandated by the 2018 Farm Bill and established under the USDA plan and procedures.

Comments: Some comments expressed support for the use of post-decarboxylation. One comment described liquid chromatography as a preferable testing method over gas chromatography because there are no published methods for gas chromatography that show 100 percent conversion of THCA to THC. Comments suggested liquid chromatography is more accurate and representative than gas chromatography. USDA received a comment that because Tribes often do not have ready access to gas chromatography and may only be able to access liquid chromatography, the rules need to allow for a more lenient formula.

Many more comments opposed the IFR requirement to use post-decarboxylation testing methods on the grounds that the IFR too strictly interpreted or unnecessarily developed regulatory requirements that are not consistent with the statutory language of the 2018 Farm Bill. Comments stated that USDA should be flexible and allow for measuring THC levels with “similarly reliable methods,” as provided in the statute. Comments claimed that the IFR’s exclusive endorsement of gas or liquid chromatography methods ignores this statutory flexibility. Comments further asserted that these two methods may overstate THC levels in hemp samples

and that USDA should approve alternative reliable methods that may produce more accurate results.

According to some comments, reliable testing methods have emerged that do not necessitate decarboxylation to accurately measure THC concentrations. For example, comments claimed that some States recognize genetic testing that measures the ratio of cannabidiol to THC in a sample or that confirms a stable cultivar's taxonomic determination in lieu of post-decarboxylation testing to verify compliance with THC limits. Comments explained that genetic testing could include testing seed or testing during early plant growth stages, instead of depending on chemical analyses to measure THC levels in mature plants, which may be inconsistent under unpredictable growing conditions or dependent upon the time of sampling or the specific part of the plant that is sampled.

Comments advocated removing the Total THC testing requirement and recommended USDA work with scientific and agricultural communities to ensure testing standards are established and similarly reliable methods are developed that will accurately identify and measure THC without the forced conversion of other cannabinoids, isomers, and /or acids.

States Operating under 2014 Farm Bill Authority: Comments said that USDA should recognize that States have been effectively regulating hemp production using approved testing methods under 2014 Farm Bill pilot programs. Comments argued that by applying the IFR's new testing standard, certain hemp plants that are legally grown under one or more of the existing pilot programs are converted into plants that violate the 2018 Farm Bill. Comments contended that while USDA will argue that States and Tribes can propose a testing method other than post decarboxylation, the alternative method still has to measure potential conversion of THCA into THC.

Comments said further that the IFR must consider that hemp testing is an evolving science and that THC testing methods are likely to change over time. They stated that imposing new testing requirements is adding costs for growers, marketers, and regulators, and is limiting

the number of labs that can perform these tests, for unnecessary and possibly impermissible reasons. Finally, comments questioned whether USDA has the authority to impose new testing requirements when the statute spells out the testing standards to be applied in granting approval to State and Tribal plans.

A comment cited case law that held that under the Administrative Procedure Act (APA), agency decisions must be reasonable and based on factors and evidence that support the decision, divergent views notwithstanding. It suggested the IFR is arbitrary and capricious under the APA because USDA (1) “has relied on factors which Congress has not intended it to consider, “ (2) “entirely failed to consider an important aspect of the problem,” (3) “offered an explanation for its decision that runs counter to the evidence before the agency,” and (4) has made a decision that “is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” It further claimed that a court must sustain an agency’s action unless it determines that the agency committed a “clear error in judgment.” The commenter asked that their comment be considered within the context of these legal standards, and argued that THCA is not psychoactive; but can be converted into delta-9 THC through a chemical reaction, and that such a reaction may cause otherwise lawful hemp plants to test “hot.” The comment projected further that such “hot” plants will require disposal, causing a significant and unnecessary loss of hemp production, which will in turn reduce economic development and job growth in many rural communities.

The comment said post-decarboxylation testing was not required under the 2014 Farm Bill pilot program and the same plants that are legal under 2014 Farm Bill could be illegal under the IFR. The comment recognized that the pilot program will not be authorized after 2021 but said current disparate treatment under the two laws is problematic.

AMS response: The 2014 Farm Bill included a 0.3 percent THC level but did not include the requirement for this measurement to account for decarboxylation. Thus States have the flexibility to determine testing methodologies. The 2018 Farm Bill states that procedures for

testing use post-decarboxylation or other similarly reliable methods to determine delta-9 tetrahydrocannabinol concentration levels in hemp. AMS stated in the IFR and further adopts the language in this final rule that at this time two methods meet this requirement for decarboxylation. The current acceptable testing methods include gas and liquid chromatography, including LC with UV detection. As other testing methods and alternatives are developed by industry, AMS will review and evaluate their compliance with the 2018 Farm Bill. At this time, genetic testing has not been determined to be a similarly reliable testing methodology.

This final rule provides States and Indian Tribes the option to develop different sampling methodologies based on end use, including grain and fiber, to better account for differences in these plants. Biomass only needs to be tested after remediation to ensure that the sample that represented the plant that once tested above the acceptable THC level did not result in the plant being a controlled substance. This final rule does not set requirements for testing final products—but hemp plants, regardless of their end use, must still use the same testing procedures.

Although the USDA plan does not allow for sampling based on end use, AMS will study the experience of States and Tribes that adopt methodologies based on end use. If it appears that the data and experience of those States and Tribe suggest that their methodologies may be adaptable to the USDA plan, AMS may explore a sampling scheme based on end use for producers under the USDA plan in the future through notice and comment rulemaking

LICENSE APPLICATION PERIOD

AMS received comments on the timeframe established in the IFR for submitting applications for a USDA license. The application period extends between August 1 and October 31.

Comments: Several comments opposed the August-through-October window for USDA license applications and renewals. They explained that many outdoor hemp crops are harvested in September and October and that farmers are busy with harvest activities related to other crops

as well during that time of year. Comments noted that farmers typically finalize decisions about the coming crop year during the winter, after having time to attend industry and trade conferences, enter into production contracts, and obtain crop loans and insurance. Thus, according to comments, a longer application window or a later application window would give farmers time to plan for the coming year and submit hemp production license applications as appropriate. Comments also noted that a longer application period would give producers time to complete the mandatory background check. Some comments recommended the application period be extended to December 31. Others recommended a winter application period of January 1 to March 15.

Other comments recommended even greater flexibility in application periods. Comments explained that harvest cycles for hemp growers may vary regionally and by operation type. They said a significant number of hemp operations involve year-round cultivation, maintenance of mother clones, clone propagation, indoor cultivation, and/or tissue culture. Time and resources to gather and submit paperwork would not coincide with the down-cycles in productivity and would strain these types of operations. Some recommended USDA adopt a year-round, rolling application period with different deadlines for different operation types or sizes. One comment said it was unclear in the IFR whether State and Tribal plans were required to adhere to the same window provided for under USDA's plan. Several comments urged USDA to provide greater regulatory flexibility at the State and Tribal levels to determine the appropriate application and renewal timeframes for their jurisdictions. An example was given of a State's agriculture department transitioned enrollment from a restricted to an unrestricted timeframe to better manage the logistical challenges related to the enrollment period.

AMS response: AMS agrees with the commenters opposed to a limited USDA license application window and will allow for applications to be submitted for a USDA license year-round. This will provide greater flexibility to hemp producers to determine when to apply for a license or renew their license. This decision recognizes the different regional harvest timetables

and production types used by hemp producers, and how flexible timetables may allow producers to prepare applications during lower level periods of production activity thereby reducing some of producers' burden on time and resources when the producer is planning the next planting cycle(s). States and Tribes can determine their license application window as it best meets their programs.

FSA REPORTING AND INFORMATION SHARING

AMS received comments on the IFR requirement that hemp producers report acreage and provide licensing information to USDA's Farm Service Agency (FSA). Hemp producers must provide FSA information about their hemp crop acreage, such as its location and size, and must provide the producer license or authorization number issued under the hemp production plan under which they operate. States, Indian Tribes, and USDA must collect the same information, as well as other producer information, under their respective plans. USDA then assembles and maintains FSA and plan information and makes it available to law enforcement agencies, as required under the 2018 Farm Bill.

Comments: Several comments expressed strong support for FSA programs generally, acknowledging that FSA programs provide farmers valuable access to Federal programs and funding, and that registering crop acreage with FSA would help mainstream hemp production within agricultural communities. Comments noted that requiring hemp growers to register with FSA is similar to registration requirements for growers of other commodities and that FSA already compiles reports about other crops. However, many commenters opposed the requirement to register with FSA when they are already required to provide the same information to their licensing authority. Comments argued that the duplicative reporting requirement is unnecessarily burdensome to farmers, could be confusing, and could discourage farmers from seeking hemp production licenses or from growing hemp. One comment speculated that confusion about the duplicative requirement could lead to unintended violations by growers who don't comply. Other comments speculated that lower program participation would inhibit

industry growth and deprive States and Indian Tribes of licensing fees that enable them to fund their respective production plans.

Comments noted that the statute does not specify dual reporting of crop acreage to both FSA and the plan authorities under which they operate

Several comments took exception with the IFR's assumption that most hemp farmers are already registered and familiar with FSA and its programs. Comments from some State agriculture departments asserted that within their jurisdictions most farmers in general do not already work with FSA.

One comment asserted that participation in FSA programs is voluntary and that hemp growers should not be precluded from participating in the commenter's State program because they forego FSA registration. Other comments suggested that farmers growing hemp for personal use and hemp farmers also growing medical marijuana may be hesitant to register crop acreage with Federal agencies.

One comment expressed concern about FSA staffing in rural areas and asked USDA to increase funding to support additional reporting obligations. Another comment suggested USDA develop and fund one standardized reporting program for all plans and growers that would decrease program reporting burdens for all entities. Some comments encouraged streamlining collection of crop acreage information by allowing the use of open-source GIS mapping instead of FSA data and reporting tools. Comments also suggested USDA could rely on States and Tribes to provide grower crop acreage and registration information since they already collect it. Several comments recommended eliminating the FSA registration requirement altogether.

AMS response: AMS acknowledges the FSA reporting requirement may present a hurdle for certain hemp producers, particularly new and beginning farmers, farmers in rural locations, and farmers located in Tribal territories. However, AMS determined that the FSA reporting requirement is essential for two key reasons: real-time data collection and field-based resources.

First, USDA is required under the 2018 Farm Bill to provide law enforcement with certain “real-time” information about who is growing hemp, whether their license is in good standing with the regulatory body issuing the license, and the location(s) of where hemp is being grown. The daily collection of this information through FSA county offices enables USDA to easily transmit the required information to law enforcement. FSA maintains the technology necessary for data collection and geographical land identification. These tools will provide easy access to information needed for law enforcement and for other agricultural programs. This information is compiled in one system, using an information sharing mechanisms currently used by law enforcement and which they are familiar with, and transmitted to law enforcement in a safe manner, which otherwise would not be as readily available through State and Tribal reporting. States and Tribes must provide information to USDA in a format that is compatible with USDA’s information sharing system. USDA will work with States and Tribes on system format and other information necessary to share information.

Secondly, FSA’s county network is expansive with over 2,000 field office locations. FSA offices provide services both in person and virtually to accommodate the needs of producers.

Its mission runs parallel to other USDA agencies including Risk Management Agency, Natural Resources and Conservation Service, and Rural Development, each of which provide a wide range of benefits and services to local communities. AMS noted that in many cases, FSA is co-located with other Federal, State and county-level government offices which means a variety of services are provided through one central location. These services frequently include information on insurance and risk management programs, conservation and irrigation technical expertise, agricultural credit for operating or marketing, and rural housing loans. As such, the requirement is considered by AMS to be particularly important to new and beginning farmers who traditionally are not familiar with the wide range of programs and services offered by Farm Service Agency and the other USDA agencies.

DEFINITION OF “LOT”

AMS received comments on the definition of “lot” for providing geographical determination of hemp production and for sampling purposes. One comment explained that nursery operators and their field operating counterparts may need to file hundreds of permits for a single greenhouse under the IFR. The comment described as an example one greenhouse at a nursery, which may have upwards of 36 benches, in which each bench could have 20 different hemp varieties growing at any one time. The comment said that the IFR would require that single greenhouse to have 720 “lots,” and based on most States’ current rules, 720 containment plans, destruction plans, and transportation notices when any plants are moved – all possibly requiring agency approval prior to any action being taken. It further explained that the growing cycle for nursery stock could be as short as five to six weeks, and different varieties could take their place. The comment said a nursery with five or six greenhouses on a relatively small acreage may have to register thousands of lots and submit thousands of associated plans. It recommended that such a nursery should only be required to designate the actual greenhouse or indoor growing structure itself as used for the cultivation of hemp generally, and the term “lot” should not be defined to include any restriction or limitation to the same hemp varietal. The comment proposed revising the definition of “lot” to mean a contiguous area in a field, greenhouse, or indoor growing structure used for the cultivation of hemp.

AMS response: In this final rule, AMS is clarifying that the term “lot” has the same meaning as other terms used by FSA, as found in 7 CFR 718.2, to mean the same production area, such as “farm,” “tract,” “field,” and “subfield.” AMS uses the term “lot” to help growers and oversight officials identify farm locations, field acreage, and variety (i.e., cultivar).

Although a hemp producer must report their “lot” information to FSA, when a producer visits the FSA office to report hemp crop acreage, FSA staff will determine the appropriate designation for the specific location(s) where hemp is being grown. FSA staff will not provide a “lot number” to producers as described in the IFR, but instead designate either a “field” or “subfield” as the unique identifying number. This number is considered equivalent to a “lot number.”

A lot must always contain the same variety or strain of cannabis throughout the area because the final rule requires lot-based testing.

CERTIFIED SEED

The IFR explains that under the 2014 Farm Bill, various States developed seed certification programs to help producers identify hemp seed that would work well in their specific geographic areas.

Comments: Some comments concurred with USDA's decision not to introduce a hemp seed certification program with the IFR. Numerous commenters said that such a program would not be appropriate, that it would be too difficult to regulate, or that it would be premature now. Other comments said a federal hemp seed certification program is not necessary because some States and Indian Tribes had already developed such programs for their jurisdictions or are capable of doing so. Numerous comments said they recognized the difficulty of developing a hemp seed certification program but nonetheless urged USDA to pursue what they characterized as an important effort to allow for consistency among hemp producers when resources permit.

One comment asserted that seed certification is key to a regulated hemp industry and explained that certification is a common practice in the international seed industry. Several comments contended that USDA must develop a seed certification program to prevent hemp growers from purchasing and planting seed of unproven quality – or of the wrong varieties for their purposes – and risking unnecessary financial loss and regulatory violations. Comments claimed that hemp farmers already have difficulty verifying the origin, genetics, and reliability of hemp varieties currently on the market, and that a seed certification program would help farmers know whether seed they purchase is appropriate for their growing conditions or intended hemp product end-use. Numerous comments inferred that a seed certification program would identify hemp varieties that had been tested and proven to reliably produce compliant hemp plants in specific geographic areas.

Some comments argued USDA should not engage in hemp seed certification because plant genetic expression is influenced by environmental conditions and seed certifiers cannot guarantee plants will have THC concentrations within the acceptable range. Other comments countered that assertion and referenced a comment that reported on the analysis of cannabis genome trials and concluded that cannabinoid concentration is 80 percent or more controlled by genetics rather than environmental conditions.

Comments claimed that hemp varieties developed under proper breeding programs and certified in the European Union and Canada had been proven to have stable cannabinoid profiles across multiple regions. They suggest that comparable results could be achieved under a USDA seed certification program.

A comment claimed that the lists of acceptable/approved varieties provided by the processor and/or the governing authority in the State in which the hemp is grown needs to be updated soon and regularly. The policy language may be acceptable, but these lists need attention quickly so that ill-suited varieties are not planted and insured when planted outside of the area and not likely to perform as well.

Some comments asserted it is not necessary for USDA to develop a seed certification program now because the Association of Official Seed Certifying Agencies (AOSCA) has already established national standards for hemp field crop cultivars and is reviewing issues related to the development of certification standards for feminized seed and clones of CBD hemp. Other comments recommended USDA adopt AOSCA standards in the development of a Federal seed certification system, and several comments said that some States have already adopted AOSCA protocols for production of certified seed for commercial sale to farmers. For example, a comment stated that a state currently recognizes 17 hemp seed varieties that have been certified for use in that state in accordance with AOSCA standards. The comment said the state encourages farmers to use certified seed when possible and the state intends to rely on certified seed to streamline the hemp testing program in the future.

A comment clarified that there is a difference between seed that has been certified according to AOSCA standards (or an international equivalent standard) for varietal purity, and seed that has been tested for THC or other compounds. It asserted that some State programs have confused the terminology and urged USDA to clarify the difference and promote use of certified seed for varietal purity. The comment said the hemp industry has access to numerous proven varieties and that plant breeders are making strides to develop more varieties with specific characteristics.

Numerous other comments reinforced the need for seed certification programs that ensure hemp seed meets high standards for proper labeling, reliable germination rates, purity, and the ability to produce healthy plants. Some comments supported seed certification under State or Tribal programs, claiming such localized programs have proven successful in areas where they've been developed and used, and saying that such programs promote crop predictability and reduce uncertainty for farmers. One comment asserted that not only seed, but clone certification is a must, to ensure that growers are getting what they think they are when they purchase clones from nurseries. Some comments asserted confidence in certified seed could be extended to crop insurers, who could provide coverage at prices that reflect reduced risk. Some comments suggested growers using seed certified under a Federal certification program should be indemnified against legal liability or financial losses related to production of hemp that tests higher than the acceptable THC level. Some comments suggested States and Tribes that adopt seed certification programs for cultivars reliably producing compliant plants should be authorized to exempt such cultivars from hemp sampling and testing requirements or to employ random, risk-based sampling schemes supported by data about those cultivars.

AMS Responses: AMS is not establishing a seed certification program for hemp. The IFR explained USDA's decision to not establish a seed certification program was due to a lack of accurate data and the advanced technology necessary to develop such a program. The term "certification," as used here, means tested or verified and does not necessarily mean certified for

seed varietal purity or genetics. AMS understands that some seed certification-related studies are already under way in different locations and that results of these studies are helpful in production risk mitigation. AMS recommends the use of hemp seed from varieties that have undergone a variety review, following the process outlined in the Federal Seed Act and associated regulations, (7 U.S.C. 1551-1611 and 7 CFR part 201), and produced according to AOSCA standards. These types of seed have been screened and tested for purity and are properly labeled. This final rule maintains flexibility for stakeholders to continue with trials of seed varieties and does not prohibit the use of any hemp varieties by industry. Updating the varieties list is a State and Tribal issue, as they developed them. This final rule does not address seed certification. However, USDA will consider such a program in the future if enough information is available. If there is sufficient data to support a program, USDA will explore adopting one through rulemaking under the APA.

Separately from this hemp production regulation, AMS administers the Plant Variety Protection Office (PVPO). This office actively accepts applications of seed-propagated hemp for plant variety protection. Under the U.S. Plant Variety Protection Act, PVPO examines new applications and grants certificates that protect varieties for 20 years (25 years for vines and trees). PVPO provides intellectual property protection to breeders of new varieties of seeds and tubers. Certificate owners have rights to exclude others from marketing and selling their varieties, manage the use of their varieties by other breeders, and enjoy legal protection of their work.

REGULATIONS FOR DIFFERENT OPERATIONS

The 2018 Farm Bill requires any producer growing hemp to be licensed either by their applicable State or Tribal authority or USDA. The IFR further required that an authorized sampling agent collect samples from floral material for THC concentration testing in order to determine compliance with the Federally established THC threshold. Some operations growing

hemp do not grow to the stage where flower material is present and as such cannot test the floral material.

Clones and Cloning: Comments noted there are a significant number of grower operations that cultivate and produce hemp plants year-round. Some of these operations grow hemp varieties and maintain mother clones and/or grow plants for clonal propagation or tissue culture propagation purposes. Comments explained that hemp varieties grown in these types of production systems do not usually reach full maturity. According to comments, before achieving the floral stage of development, many of these hemp varieties are sold and enter the stream of commerce as starter plants that other licensed hemp growers may transplant to a field or greenhouse to be raised to full maturity and harvest. Comments questioned how immature or juvenile hemp plants with no floral material to test can demonstrate regulatory compliance under the IFR.

Microgreens: Comments raised similar concerns about hemp raised and marketed as microgreens or other types of immature plants intended for human consumption, noting that these plants cannot be tested for regulatory compliance because they have no floral material to test. Comments encouraged USDA to develop a regulatory process in which THC concentration testing may occur for immature, non-flowering hemp varieties so that operations like those producing clones or microgreens can support the development of the hemp industry.

One comment representing a hemp cultivation and distribution corporation in several states provided a pre harvest test on a microgreen variety grown in two different States. One State test reported 0.17 percent total cannabinoids and the other test reported 0.0193 percent total cannabinoids. Based on these tests, commenter indicated that hemp leaf greens/microgreens and related crops are not in danger of excess THC.

Hemp Research: Numerous comments stated the need for a separate regulatory scheme to support hemp research. Comments explained that the plant breeding process by its nature requires breeders to bring multiple varieties of plants to maturity in order to evaluate their

characteristics and potential use in ongoing hybridization projects. They said, for example, that plants with desirable characteristics such as frost and drought tolerance or pest resistance must be identified and preserved, while plants with unwanted genetic traits or diseases must be separated and destroyed in order to stabilize the genetics for THC expression and other desirable traits and understand how environmental factors, disease, and insect pressure affect the expression of those traits. According to comments, the THC concentration in such plants could exceed the acceptable THC level in the IFR and plant breeders could find themselves in violation of the law. As well, they explained that the IFR's disposal requirement could force breeders to destroy valuable plant material and waste years of work, as well as funding.

Other comments asked USDA to support research into hemp pollination and drift. Comments reported industry concern that cross pollination could reduce the value of neighboring CBD flower crops. They asked USDA to focus on grain producing geographic areas and varieties to provide the science to support large acreage growers.

Comments explained that the IFR's THC threshold of 0.3 percent reduces the incentive to conduct hemp variety research because of the likelihood that many plants will exceed that threshold. For example, comments suggested the THC limit for hemp plants in licensed breeding programs could be raised to 0.6 percent or 1.0 percent or higher. They suggested breeders be allowed to raise plants to maturity, collect data and save seed for further research, and be required to destroy noncompliant plant material at the end of the growing season. Other comments suggested that breeders and researchers should not have to wait for hemp plants to flower and undergo testing before they can remove and destroy those plants with undesirable traits.

Comments asserted that hemp strains used in genetic studies authorized by the 2014 Farm Bill and compliant with other program regulations may now be in jeopardy due to the uniform application of the IFR's 0.3 percent THC threshold and plant disposal requirements. They noted how a regulation that requires the disposal of what was previously compliant hemp will

undermine the efforts and millions of dollars invested by farmers and researchers. Other comments indicated that not having the ability to replicate certain genetic traits from a plant that is noncompliant can slow the development of industry.

Comments from and about university research programs suggested that USDA make land grant universities eligible for special research carve-outs or regulatory exemptions to allow them to continue research efforts. Other comments suggested USDA define criteria under which researchers and other plant breeders could be eligible for special research program exemptions. They suggested USDA develop criteria for certification or qualification of hemp researchers and breeders, and some suggested those meeting specified criteria could be exempt from the IFR's crop destruction and reporting requirements, provided they adhere to other restrictions, such as prohibiting research material from entering the chain of commerce, disposing of non-compliant plant material, and limiting plot size. Some commenters noted that without such allowances their university administrators would not allow them to continue research with any form of cannabis, including hemp, due to concerns about Federal grant disqualification.

One commenter requested an exemption for Tribal research facilities so that they will not have to destroy all non-compliant plants.

Comments noted that USDA's National Institute of Food and Agriculture had not issued requests for applications on hemp research and that hemp was not listed for funding under the Specialty Crop Research Initiative. Comments suggested more agronomic research is needed to address current gaps in knowledge related to hemp production and management and to standardize seed.

AMS response: Due to the variability in immature plants across producers, States, and Tribes, and the lack of consistency across varieties, USDA is unable to establish or standardize an approach to dealing with immature plants for USDA licensees. However, AMS acknowledges operations that grow hemp for certain purposes that do not bring plants to their flowering stage like clones and microgreens, may not need to meet the same sampling and testing requirements

as operations that grow flowering hemp. The final rule provides States and Tribes the flexibility to consider performance-based sampling protocols to address these concerns. As allowed under the AMA, States and Indian Tribes can be more restrictive and may impose sampling and testing requirements on these producers.

USDA also acknowledges that research institutions face special circumstances when conducting hemp research. Accordingly, this rule provides sampling and testing flexibility to these institutions and producers working with them to conduct hemp research under the USDA plan. Producers that produce hemp for research must obtain a USDA license or a State or Tribal license. However, the hemp that is produced for research is not subject to the same sampling requirements or the requirements pertaining to non-compliant plants, provided that the producer adopts and carries out an alternative sampling method that has the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to this alternative method will not test above the acceptable hemp THC level. USDA licensees will need to submit an alternative sampling method to USDA for approval and shall ensure the disposal of all non-compliant plants. USDA licensees shall also comply with the reporting requirements including reporting disposal of non-compliant plants.

AMS views this flexibility as necessary to help support research and development as it relates to hemp production by industry, particularly in its infancy. This decision allows these types of research facilities and institutions to oversee the study of hemp plants through trialing and genetics research. Over time, the flexibility provided by this final rule will help to stabilize industry by providing greater understanding of hemp genetics and how certain varieties respond differently to growing conditions in various geographic locations. All producers are expected to benefit from such knowledge as information about more stable and consistently reliable hemp varieties becomes available. Any non-compliant plants produced by research institutions as a result of research and development will still need to be disposed and disposal will need to be

verified with documentation. Research institutions that handle “hot” hemp must follow CSA requirements for handling marijuana.

SAMPLING AGENTS

This final rule reiterates that samples of hemp collected for purposes of testing THC must be collected by sampling agents, or by Federal, State, Tribal or local law enforcement agents authorized by USDA to collect samples. Requirements and training materials for sampling agents are provided on USDA’s website.

Third-party Sampling Agents: Some comments supported the use of third-party sampling agents to help offset the cyclical demand for hemp sample collection and to ensure integrity in the sampling process. Comments noted that some State agriculture departments have relied on in-house personnel to perform sampling activities and that these States did not use or require third-party sampling agents during piloting.

One comment reported use of third-party certified samplers for the 2020 season, and as of the date of their comment, had employed 74 certified sampling agents. The commenter said the State recommends producers make appointments with sampling agents 30 days in advance prior to intended harvests, and that they had not received any feedback regarding unavailability of sampling agents based on the 15-day window. The comment went on to report that the State had received numerous anecdotes of next-day availability for sampling, which the comment suggested would not be possible without the use of third-party sampling agents.

Resources: Several commenters worried that there would be insufficient numbers of appropriately trained, USDA-approved sampling agents available during harvest periods to ensure that all crops could be sampled, tested, and harvested within the 15-day window specified in the IFR. They asserted that sampling backlogs and delayed testing and harvesting would cause crops to mature beyond the acceptable hemp THC content concentration, resulting in crop disposals and financial losses for farmers. Several comments said producers in rural and remote

mountainous areas would be particularly impacted, since sampling agent travel into those areas would require extra time and expense.

Comments described how some States developed sustainable hemp oversight programs using risk-based sampling methodology to support regulatory monitoring of hemp growers. They asserted these same States would find it difficult to meet the IFR's sampling requirement because of a limited budget to hire and train additional personnel for sampling all hemp production. Comments reported having to make appointments for sample collection a week in advance under risk-based sampling plans and predicted it would be even harder to arrange for sample collection on a timely basis under the IFR's requirement that all hemp lots be sampled and tested.

Commenters presented two proposals to alleviate this strain – allowing producers to collect their own samples and reducing the volume of farms and plants from which samples are collected.

Some commenters requested that USDA compile a publicly available national list of sampling agents.

Sampling Agent Training: Comments highlighted the importance of providing robust training for sampling agents and recommended subsequent annual, documented refresher training be required. Some comments recommended USDA develop and implement a sampling agent certification scheme, while others suggested States and Tribes retain the authority to develop sampling agent training. Other comments suggested including a sampling agent training application on the USDA website.

Other Comments on Sampling Agents: Other comments objected to the IFR's provision that sampling agents be given unlimited access to all areas listed in the producer's license. Comments claimed that this provision, in addition to the fact that default sampling agents may also be law enforcement representatives, seems to associate the now legal hemp industry with potential illegal activity. Comments stated further that while State, Tribal, and USDA personnel

may require such access for audits or other purposes, broad access is not necessary for sampling hemp, and that sampling access should be limited to cannabis plant material being cultivated as hemp.

Other commenters suggested that sampling agents should be agricultural specialists rather than law enforcement specialists in order to alleviate possible tension between Indian Tribes and law enforcement, and would ensure that the sampling agents have an understanding of the agricultural product they are working with.

AMS response: AMS agrees with the many commenters that sampling agent training should be enhanced. Standardized training for sampling agents will help achieve regulatory consistency. As such, AMS will provide training documents for sampling concurrently with publication of this final rule. The revised sampling agent training will establish uniform and standardized criteria, including sampling processes and procedures, to ensure the sampling agents understand regulatory provisions of this final rule and the appropriate processes associated with sampling activities. This will help ensure that sampling done by different agents will be conducted similarly. AMS anticipates this will minimize variances in sampling practices that may affect the samples and ultimately the test results.

Training documents will explain how sampling agents can meet the sampling requirements of this final rule. States and Indian Tribes with an approved plan may require the sampling agents used by their licensed producers to take the USDA training, or they may develop their own custom training. This decision does not change the requirement that designated agents collect samples. We are retaining the requirement from the IFR that the use of third-party agents is acceptable. Requiring sample collection by trained agents ensures that samples are collected consistently throughout the industry and no conflict of interest exists between the sampler and grower.

Further, AMS has addressed commenters' concerns about adequate resources by allowing for States and Indian Tribes to design a sampling plan in accordance with the AMA and this final

rule that suits their needs and resources. Additional discussion of sampling methodologies and flexibilities is included elsewhere in this final rule.

AMS agrees with the concerns that sampling agents be given unlimited access to all areas listed in the producer's license and is clarifying that sampling agents need access only to areas where the hemp is grown and stored so they can perform their sampling work.

AMS agrees with comments that allowing third-party individuals to become certified hemp sampling agents creates jobs, gives producers greater flexibility during the harvest season, and allows the States and Tribes to reallocate resources. The final rule does not limit sampling agents to law enforcement officers and does not prevent agricultural specialists operating as sampling agents. Because States and Indian Tribes with approved plans may approve their own sampling agents, USDA encourages States and Tribes to maintain their own lists of sampling agents.

SAMPLING METHODOLOGY

AMS posted supplemental Sampling Guidelines for Hemp Growing Facilities on its website. The guidelines describe sampling procedures, including the number of cuttings to take for sampling each lot and how to pace a hemp field when sampling. A few comments addressed the Sampling Guidelines and recommended alternative sample volumes and field sampling patterns.

End-use / risk-based sampling: Comments asserted that hemp sampling requirements should differ based on the crop's end-use, primarily whether the crop is used for grain and fiber production or for cannabinoid extraction. They contended that the IFR requirement to sample every hemp lot, regardless of the crop's end-use, is expensive and burdensome for States, Indian Tribes, and individual growers. Comments generally discouraged requiring sampling and testing every lot for THC since THC concentration is significantly lower in male plants and grain/fiber varieties. Comments from State agriculture departments that administer pilot programs under the 2014 Farm Bill also explained how risk-based sampling requirements under their programs

function. Comments emphasized that a “one-size-fits-all” regulation is inappropriate and discourages innovation as there are different risk-profiles for hemp based on its end-use.

Comments maintained that grain and fiber varieties are less likely than cannabinoid crops to exceed the THC threshold and argued that assessing all hemp by the same standard may result in strained oversight resources and inefficiencies. One comment asserted that THC concentration in varieties grown for grain is reduced dramatically by the production of seeds in the flower and, therefore, hemp grown for grain is at lower risk of exceeding the THC limit. Comments also noted that the flower parts, where a majority of the THC is concentrated, do not fairly represent the THC content of the entire plant, which is used in biomass and fiber production.

One State agriculture department noted that many of the seed and fiber varieties being grown in their State were originally bred in Canada and have been selected for low THC content as part of Canada’s hemp program for many years. Several trade association comments noted that hemp grain/seed is not a source of cannabinoids, and that grain and fiber varieties are largely developed from certified, pedigreed seed that meets all THC testing standards. Commenters contrasted that with hemp crops grown for cannabinoids, and that the latter show higher phenotypic variability and lack of uniformity in the field because they have received less focus in breeding programs. One comment stated that hemp varieties grown for cannabinoid production often have questionable origins and are at a greater risk of producing higher THC than varieties grown for grain or fiber. Another comment claimed there are currently no certified varieties of hemp for CBD production.

Many comments agreed that hemp grown for cannabinoid production is more likely to exceed acceptable THC limits. Data from 2019 submitted with a comment showed that 13 percent of hemp samples tested exceeded 0.3 percent THC, and all were CBD varieties. The comment further recommends that certified seed varieties should be sampled and tested from a random selection of hemp grain and fiber fields 30 days prior to harvest. For uncertified

varieties, it recommends requiring a post-harvest test, as well as a pre-harvest test of a random selection of fields within 30 days of harvest. According to comments, those hemp crops being grown for cannabinoids should be subject to higher scrutiny and more frequent testing.

Another commenter cited data from the Midwestern Hemp Database¹⁸ showing that many publicly available varieties are exhibiting a linear (or curvilinear) relationship between Total CBD (%) and Total THC (%). Given this presumed relationship, Total CBD percentages are often not able to exceed 8 percent without exceeding the regulatory threshold of 0.3 percent THC. The commenter said these moderate levels of CBD production can have significant impacts on profitability as growers and therefore a whole plant testing methodology would help to mitigate this linear relationship.

Comments identified States and other institutions where they think risk-based oversight modeling works to ensure hemp is at 0.3% acceptable hemp THC level. For example, the Kentucky Department of Agriculture publishes a “Varieties List” to track THC content across hemp varieties. Comments characterized this as a useful tool for hemp farmers when planning production cycles and selecting hemp varieties. Several comments also described how, at the State level, other measures support risk-based oversight, like randomized sampling crops of a percentage of the total grower population or the use of risk criteria to identify “high risk” growers. Commenters credited these types of practices and activities with allowing states to efficiently oversee hemp production under pilot programs. Other comments described how financial institutions routinely incorporate risk-based modeling into the risk assessment of lending decisions, and that similar modeling should be adopted by USDA for sampling and testing.

Comments argued that subjecting all varieties to the same regulatory requirements under the final rule will compound logistical challenges to oversight bodies, strain resources, and

¹⁸ <https://farmdoc.illinois.edu/field-crop-production/hemp/midwestern-hemp-database-a-new-tool-for-hemp-growers.html>

increase costs for low-risk farmers. They said testing based on hemp's end-use created a more flexible approach to oversight while benefiting the farmer.

Two state department of agriculture comments supported end use or risk-based sampling methods in order to account for producers using certified seed, producing hemp for industrial use purposes, fiber, grain, seed, extraction of biomass, and indoor producers growing plants only in vegetative state for research or resale that pose a low risk for detectable THC content.

Several other comments suggested ways USDA could incorporate risk-based sampling into the domestic hemp production program. Comments recommended USDA evaluate and consider allowing greater regulatory flexibility for States and Tribes to develop and use risk-based modeling to guide their sampling and testing activities. According to comments, this approach would help offset the anticipated strain on resources during peak sampling that would otherwise result under the IFR requirements.

Two State agriculture departments recommended that crops produced from AOSCA-certified seed, which they said currently only include grain and fiber varieties, be considered low-risk for testing and compliance purposes. Comments said that as more CBD hemp varieties are developed and certified, they could also be subject to less stringent testing protocols.

A few comments suggested the adoption of a random risk-based sampling and testing scheme to reduce grower costs and relieve pressure on approved labs by reducing the number and volume of required tests. One comment indicated State hemp regulators have successfully developed sampling requirements for end-use that ensure adherence to State and Federal regulations, while allowing for flexibilities around State resources. Other comments sought requirements establishing a minimum number of cuttings per lot (e.g., "5" cuttings per lot regardless of size.) For example, one comment suggested that when sampling lots of less than 1 acre, taking cuttings of one plant will not allow for a representative sample, so a minimum of 5 plants be identified for cuttings. Another comment said that the sampling requirements in the IFR, as applied to a 170-acre field, could require the sampling of as many as 110 plants from that

field which would be impossible for a state department of agriculture to meet. As an alternative, USDA might provide a fixed sliding scale (for example, a lot of less than 10 acres requires 5 plants; a lot between 10 acres and 20 acres requires 6 plants; and so on) rather than leaving those calculations to each state. Alternatively, another comment explained how their state sampling protocol currently utilizes the parameters of a minimum of 6 cuttings per lot or acre, whichever is smaller, with the option for producers to increase the quantity of cuttings collected as they see fit (up to 150 cuttings per lot). Another comment described how contracted labs for their state have requested at least 40 grams of wet material and up to 60 grams if the licensee is also needing additional testing such as heavy metals, pesticides and mycotoxins.

One comment reported the results of a 2019 controlled study where the top 12 inches of the plant and the top 2 inches of flowering material were collected from each of 83 plants, for a total of 166 samples. The samples were tested using gas chromatography with flame ionization detection. Test results showing total delta-9 THC of the 2-inch cuttings were, on average, 0.0273 percent higher than results for the 12-inch cuttings. The comment interpreted the results to suggest that including vegetation from the entire plant yields lower THC results, and that all parts of hemp plants should be sampled because producers generally harvest the entire plant.

One comment reported that their State requires samples for any size lot to include 30 buds (subsamples) to insure there is large enough volume of material to provide for adequate sample testing. Another comment reported that State staff are directed to look at a cultivar and evaluate it for uniformity with respect to maturation, height, color, and basic plant architecture. According to the comment, uniformity within a cultivar results in fewer plants sampled than a cultivar exhibiting greater phenotypic diversity for the same acreage. The comment supported providing States with authority to establish sampling protocols, given the significant variation in plant counts between fields (on a per acre basis) and phenotypic diversity within and between cultivars. The comment also recommended that AMS provide guidance on a

recommended number of plants to be sampled per unit area, including the plant density for each sample number recommendation.

One comment advocated revisions to USDA's sampling guidelines. The commenter said the State has had to deviate from USDA's sampling table, specifically for smaller lots. According to the comment, taking a sample from one plant does not provide enough material for lab testing, and the State has had to bear the cost of taking a second sample. The comment mentioned that some of the State-contracted labs have requested at least 40 grams of wet material and up to 60 grams, if the licensee is also requesting additional testing, such as for heavy metals, pesticides, and mycotoxins. The comment also explained that to keep from delivering excess material from large lots to labs, inspectors take the required number of cuttings, then homogenize the sample, keep the required 40 to 60 grams, and leave the remaining sample material in the field. The comment supported a sampling protocol that would provide adequate testing material without unnecessarily overcutting plants material.

One comment reported results of a poll they conducted among States after the end of the 2018 growing season. According to the comment, three States – New York, Pennsylvania, and Minnesota – reported they had analyzed the THC content in microgreens, and none were found to be above 0.3 percent total THC.

One comment reported that their State has tested every hemp lot produced in Minnesota in the past five years, and that hemp grown for grain and fiber has never tested above the 0.3 percent total THC limit. According to the comment, varieties grown in Minnesota are certified varieties found either on the Health Canada List of Approved Cultivars or the European Union's Organization for Economic Co-operation and Development List of Varieties Eligible for Seed Certification.

One comment reported their State has implemented a risk-based sampling frequency schedule, under authorities provided for in the 2014 Farm Bill, using end-use and certified seed as guidance. According to the comment, official total THC results collected from regulatory

samples and formal research samples showed that hemp grown from certified seed have a low risk of testing above 0.3 percent. Additionally, the grain or stalk components of hemp have zero to negligible levels of total THC. The comment recognizes that more research is needed in this area but is confident that the utilization of hemp variety categories to determine the department's sampling frequency has been successful to date.

AMS response: AMS agrees that States and Indian Tribes need more flexibility in developing sampling methodologies. For States and Indian Tribes with primary regulatory authority, USDA is altering the sampling requirements in this final rule to allow performance-based sampling methodologies. Information submitted by States that participated in the 2014 pilot program show various ways these States are already using performance-based sampling. Some States are using a list of varieties that work in their geographical area while others rely on evaluation on what they consider high risk producers. USDA finds the data submitted by commenters to be reliable because these States have been growing hemp since the 2014 pilot program started and they have sufficient data to develop their sampling plans. AMS agrees with commenters that the performance-based concept is the same method that financial institutions use. Further, performance-based programs are also used by other scientific and Federal agencies such as USDA's Food Safety and Inspection Service and FDA.

AMS finds that it makes sense to encourage States and Indian Tribes to consider performance-based alternatives when developing sampling plans. The final rule provides the standard; however, States and Indian Tribes have the flexibility to determine how to achieve that standard tailored to their specific needs.

The sampling requirements for State and Tribal plans allow for States and Indian Tribes to develop unique sampling protocols for hemp licensees under their jurisdiction. State and Tribal plans must include a procedure for accurate and effective sampling of hemp that meets the requirements of the final rule. The method used for sampling must be sufficient at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the

acceptable hemp THC level. Alternatively, States and Indian Tribes may design a sampling method that is performance-based that ensures, at a confidence level of 95 percent, that plants will not test above the acceptable hemp THC level. This plan must be part of the State or Tribal plan. A performance-based method may consider: (1) a seed certification process or process that identifies varieties that have consistently demonstrated to result in compliant hemp plants in that State or territory of the Indian Tribe; (2) whether a producer is conducting research at an institution of higher learning or that is funded by a Federal, State, or Tribal government; (3) whether a producer has consistently produced compliant hemp plants over several years or several seasons; and other similar factors. USDA believes this will provide needed flexibility to States and Indian Tribes to develop logical and enforceable sampling requirements that take into consideration their unique circumstances. AMS will still require States and Indian Tribes to submit their individual sampling requirements for review as a component of the plan approval process. Sampling protocols submitted by States and Indian Tribes must comply with the thresholds established by the 2018 Farm Bill and this final rule. If performance-based sampling requirements are not included in a State or Tribal plan, every lot, and thereby every producer must be sampled and tested.

When evaluating sampling protocols submitted by States and Indian Tribes, USDA will take into consideration whether the performance-based factors the State or Indian Tribe used have the potential to ensure compliance at a 95 percent confidence level. USDA licensed producers are required to comply with the sampling requirements in this final rule. Additional guidance on sampling for USDA licensees or States and Indian Tribes that decide to use these guidelines is available on the USDA website at <https://www.ams.usda.gov/rules-regulations/hemp/information-sampling>. USDA may develop a performance-based sampling in the future if data is available and if it deems appropriate. Separate rulemaking and comment process will be necessary to establish a performance-based sampling plan by USDA.

USDA plans to audit State and Tribal activities to assess program compliance with all Federal requirements, which includes review of the performance-based sampling implemented by States and Indian Tribes.

Sampling Guidance: A comment noted that although the sampling protocol was issued as a guideline, it appears to be binding with regard to how hemp must be sampled. The comment said AMS should clarify that there may be other acceptable sampling procedures that would meet the IFR's sampling requirement. The comment explained further that some States operating hemp programs under the 2014 Farm Bill have established detailed hemp sampling protocols that producers are used to and should be allowed to continue.

Another comment appreciated the IFR's provision that the AMS Sampling Guidelines may need continual updating and refinement as industry, academia, and government discover new evidence, science, products, and innovations.

A comment described the hemp field sampling plan they adopted from Florida's nematode sampling plan. The plan recognizes that nematodes are unlikely to be evenly distributed throughout an orchard or field, which would also allow for accurate detection of THC fluctuation within a hemp field. The comment said Florida's sampling plan is accepted by every State and country to whom they send citrus plant material that has been screened for nematodes and recommended AMS revise the hemp Sampling Guidelines to incorporate Florida's sampling plan.

A comment said Kentucky requires cuttings from five plants per lot, believing this standard provides a reasonably representative sampling of the plants in each lot. It opposed the sliding scale in AMS's Sampling Guidelines, saying the sliding-scale calculation relies upon a decades-old pesticide residue sampling regime that may or may not be appropriate for calculating confidence levels in a hemp plant's THC levels. The comment asserted the sliding scale formula, which depends on a variable factor based on historical data, is likely to create state-to-state variations in the number of samples that must be collected, and would require

States with historically lower rates of non-compliant THC test results to take more samples per lot than those States with historically higher rates of non-compliance, which the comment found to be illogical. The comment explained that applying the Sampling Guidelines' sliding scale calculation to a 170-acre field could require the sampling of as many as 110 plants from that field. It went on to say that sampling a single field under that scenario would overburden available sampling and laboratory staff, make transporting sample material difficult, and make grinding sample material an impossible workload. The comment recommended AMS specify a single number of plants to be sampled from every lot, regardless of the lot's size, or publish a fixed sliding scale for industry-wide use, rather than leaving those calculations to each State. This comment was supported by several state departments of agriculture.

A comment noted the importance of moisture content consistency in compliance sampling and recommends 8-12 percent moisture content standardization. They also noted the need for best practices to be identified for drying sample material.

Several comments said USDA's sliding scale sampling protocol results in too little a sample for small acreages and too large a sample for large acreages. Comments asserted, for example, that one cutting for four acres or less would not be suitable to collect a representative sample and could put small acreage farmers at a higher risk of being violative or not might be sufficient to capture uncertainty related to population variability in a newly established crop. Another comment said that a true representative sample needs to entail multiple subsamples collected spatially across a field and pooled into an average sample. Further, according to the comment, since cannabinoids tend to increase along the height of the plant, floral material should be sampled at random heights from plants rather than all from the tops of plants to be representative.

Another comment recommended revisions to the Sampling Guidelines to provide that sampling agents should sample fields in a zig-zag pattern. The comment further recommended that AMS revise the Sampling Guidelines to provide that three cuttings should be taken from

every plant sampled, and that the three cuttings should be taken of floral, stem, leaf and stalk material at three different points on the plant. It argued that floral material makes up only 25 to 30 percent of hemp plants and that, to be truly representative of the sampled plant, the sample should consist of cuttings of all plant materials from throughout the plant.

One comment recommended requiring that samples consist of a minimum of 4 ounces of material to provide an adequate amount for testing. Another comment suggested USDA research and review multiple sampling protocols and select the best among them.

AMS response: AMS agrees that establishing clear and standardized Sampling Guidelines is important for all hemp producers and States and Indian Tribes with primary regulatory authority over hemp. AMS issued Sampling Guidelines and is updating that guidance to reflect the changes from the IFR to this final rule. States and Indian Tribes with USDA-approved hemp production plans may develop their own sampling procedures that take into account regional and other differences and are performance-based, so long as those procedures meet the requirements in the regulations at § 990.3. The entirety of the State or Tribal sampling plan, including any guidelines, must be included in the State or Tribal plan submitted to USDA for approval. When developing such plans the State or Indian Tribe must follow the requirements of this final rule that relate to where the cutting takes place including only flower material, and the number of inches necessary for sampling. Specific to sample size or weight of a cutting, AMS does not agree that establishing a specific volume is prudent given the variances in flower size and densities, and different scales of hemp production. It would be difficult to consistently sample at an exact weight of plant material across the spectrum of producers and therefore is not included in this final rule. Rather, AMS specifies a length (approximately five to eight inches) from the “main stem” (that includes the leaves and flowers), “terminal bud” (that occurs at the end of a stem), ”or “central cola” (cut stem that could develop into a bud) of the flowering top of the plant.

This is considered appropriate and fair to balance the collection of sufficient plant material necessary for compliance laboratory testing while avoiding the need to cut excessive and unreasonable amounts of plant material.

Further, AMS determined this final rule must provide some additional degree of flexibility for States and Indian Tribes in the development of their sampling plans, which is why as an alternative, this final rule allows for performance-based sampling methodologies in State and Tribal plans.

Flexibilities afforded to States and Indian Tribes developing their own hemp production plans will allow them to incorporate best practices, as those change and develop over time. For example, States and Indian Tribes can adapt field-walking patterns to various sized and shaped hemp grower operations. AMS believes that a national standard would be difficult to consistently apply given the various grower operations and that standard “zig-zag,” or letters “M” or “Z” walk patterns may not be feasible for sample collection of micro-acreage producers, very large scale producers or those with polygonal hemp lots.

As an alternative option, AMS has updated the Sampling Guidelines and Protocols in conjunction with the publication of this final rule. This resource document is available online and offers guidance States or Indian Tribes can adopt and incorporate into their own USDA-approved sampling procedures.

FLOWER VERSUS WHOLE PLANT SAMPLING

The IFR requires the collection of samples from the flower material of hemp plants for laboratory testing.

Comments: Several comments expressed support for sampling only hemp flowers, as provided in the IFR, although many recommended changes to the overall flower material sampling requirements. Those recommendations and commenters’ explanations for them are addressed in another section of the comment analysis. Numerous comments opposed the IFR’s floral material sampling requirement, preferring instead composite sampling of the flowers,

stems, stalks, and seeds, and asserting such samples would be more truly representative of the entire plant and lot. Numerous comments agreed that cannabinoid concentrations are higher in the flower than in other parts of the plant, and many comments argued that sampling only floral material would cause more samples to inappropriately and unfairly test “hot” and lead to unwarranted and costly crop disposals.

Several comments said that sampling only the flowering material of the hemp plant is inconsistent with the definition of industrial hemp, as amended by the 2018 Farm Bill, which refers to the whole hemp plant. Comments asserted that the statute did not limit sampling to floral material and challenged USDA’s interpretation of the statutory sampling requirement. As well, comments argued that requiring sampling of only flowering material could lead to legal challenges from producers who would be forced to destroy hemp that may be statutorily compliant, but not compliant with the IFR. They recommended that the regulations provide for sampling the whole plant and that USDA define the term “whole plant” to include the flower, stalk, and leaves.

Some comments stated that sampling only flower material ignores the hemp grown for seed and stalk end-uses, and not for cannabinoids. Comments claimed that sampling and testing only flowering material would limit industry diversification in terms of producing hemp for biomass intended for uses other than THC production. To address this, several recommendations for revisions to the IFR’s sampling requirements were offered. Some comments recommended taking larger samples from prescribed parts of hemp plants that would include other than flowering material. For example, both State departments of agriculture and Indian Tribes recommended taking branch samples from two or more specified parts of plants that would include flowers, stems, stalks, and seeds, and proposed a range of sample lengths they considered appropriate, from 4 to 18 inches. Some recommended taking samples of the lower part of branches as well as flowering tips from the same plant. Several comments urged USDA to adopt risk-based sampling requirements that would better align with the intended end-use of hemp

crops, like grain and fiber. Other comments recommended revising the IFR to allow States and Indian Tribes to design sampling requirements to meet the particular needs of producers in their jurisdictions, like producers who are well experienced with growing hemp and understand the potential to grow a non-compliant crop.

Commenters expressed the widely shared view that cuttings for hemp samples must come from various locations on the plant, not just the top third as indicated by the Sampling Guidelines. They explained that marketable hemp product comes from a composite of the entire plant, not just the top, and asserted that flower material samples should likewise come from the entire plant to ensure the sample accurately reflects the lot from which it is taken. Comments also voiced the need for greater regulatory clarity on the size of the floral cuttings due to concerns that no regulatory requirements address floral collection by authorized sampling agents, and variances in types of materials collected may affect test results.

Cannabinoid Concentrations: Comments described phytochemical characteristics of *Cannabis sativa* L and argued that samples taken from only one part of the plant are not representative of the whole plant. Some comments contended that flowers at the top of the plant have higher concentrations of THC and other cannabinoids – by as much as 30 percent, according to some – than flowers elsewhere on the plant. One comment cited a study¹⁹ that found that top-only sampling, as prescribed in many State testing programs, leads to an overestimation of THC content by nearly 37 percent. The study stated that to better represent total crop THC levels, samples should be taken from the top, middle, and bottom of plants in equal quantities. Commenters asserted that sampling flowers from only the top of the plant could lead to incorrect conclusions about the lot’s compliance and lead to inappropriate and costly lot disposals.

¹⁹ “THC Distribution in Field Grown Hemp Prior to Harvest,” J. Scott Lowman, Jack He, Mike Clark, and Mark Gignac; The Institute for Advanced Learning and Research (IALR), Danville, Virginia.

Other comments contended that THC concentrations are not necessarily higher at the top of the hemp plant. One comment used data to show that the distribution of THC concentrations throughout hemp plants is not consistent between varieties. It cited a 2019 comparison study in which 4-inch cuttings of floral material from two hemp varieties were taken from the top, middle, and bottom sections of plants. In one variety, total THC was highest in samples taken at the top, and lowest in samples taken from the bottom of plants. In the other variety, total THC varied little between samples from plant top, middle, and bottom positions. The comment said the data refutes the belief that THC levels are highest at the top of the plant and supports sampling from all parts of the plant to obtain an accurate representation of each lot's composite marketable hemp product.

Sampling technique: Some comments cautioned that inconsistent potency measurements may be the result of divergent sampling approaches and recommended that USDA provide regulatory clarity as to the proper sampling process.

A comment encouraged USDA to establish clear numeric designations of how much floral material is taken from each plant. Comments varied in their suggestions on sample cut including: 12 inches per plant; cuts from the top and bottom 18 inches of a terminal branch of the plant to achieve a more representative sample; cutting from the top twenty centimeters from the main stem of the female plant; eight to ten inches of the plant's primary stem; whole plant sampling whereby the top 1/3rd, middle 1/3rd and bottom 1/3rd are each sampled; and to ground the whole plant—not only the top 1/3rd—as that is not representative of the delta-9 THC level of the plant.

AMS response: The IFR required the collection of samples from the flower material of hemp plants for laboratory testing. Following the publication of the IFR, AMS made available at www.ams.usda.gov/rules-regulations/hemp a supplemental document addressing Sample Guidelines as a reference resource to industry. This resource document indicates that hemp samples are comprised of cuttings from just underneath a flower material located at the top one-

third of the plant. Following review of public comment from various stakeholders, AMS determined this final rule will allow for additional sampling methodologies for determining the sample size from the lot as described previously under the “Sample Size” discussion. However, since THC is concentrated in the flower material of the plant, the flower material is more appropriate to test than the entire plant. The final rule specified pre-harvest samples shall be approximately five to eight inches from the “main stem” (that includes the leaves and flowers), “terminal bud” (that occurs at the end of a stem), or “central cola” (cut stem that could develop into a bud) of the flowering top of the plant. This aligns provisions of this final rule with the common practices of several States that significantly participated in the 2014 Farm Bill hemp pilot programs. This decision further balances the need to collect a sufficiently large portion of the plant’s flower, where THC and other cannabinoids are at their most concentrated, and the need to avoid cutting a portion of the hemp plant that poses logistical challenges to shipment, drying and preparing for laboratory tests. AMS believes this provision will help standardize sampling across the nation.

AMS considered the differences of pre-harvest vs. post-harvest sampling and determined the most practicable way to identify THC concentrations of the plant is through pre-harvest sampling since the floral material is still intact. Floral material must be intact to assure the material submitted for testing is in fact the flower part of a hemp plant and it has not been compromised or mixed with other plant parts. AMS also considered the many commenters who endorsed “whole plant” sampling. AMS concluded that measuring THC concentration through floral material testing is more appropriate and practicable than testing the entire plant because testing the entire plant will dilute the THC concentration in the sample, except as allowable under remediation, as discussed elsewhere in this final rule. Further, the study cited by a commenter that shows THC concentrations throughout hemp plants are not consistent between varieties does not support the use of whole plant sampling because it compares different plant

varieties, not the THC level on different parts of the same plant variety where the sample is taken. Accordingly, sampling the top part of the plant will provide the most accurate results.

Since THC is concentrated in the flower material of the plant, the flower material is more appropriate to test than the entire plant. AMS will modify the sampling requirement to state that the sample shall be approximately five to eight inches from the “main stem” that includes the leaves and flowers, “terminal bud” that occurs at the end of a stem, ”or “central cola” (cut stem that could develop into a bud) of the flowering top of the plant. AMS believes this consistency will help establish a level playing field for all U.S. hemp producers. The Sampling Guidelines issued concurrently with this rule includes additional details.

AMS also includes additional flexibilities for disposal and remediation of “hot” hemp that would reduce the costs to producers. These are discussed later in this final rule and in separate guidelines published concurrently.

MEASUREMENT OF UNCERTAINTY (MU) – FIELD SAMPLING

The IFR did not address the subject of uncertainty when conducting field samples and only speaks to the measurement of uncertainty in performing laboratory tests for regulatory compliance.

Comments: Several comments noted that not accounting for MU in sampling is a potential oversight that should be addressed in the final rule. Several comments note that field sampling is the largest source of variability in any testing process, due to the choices individual sampling agents make and field condition variability. Comments argued that there is a wide degree of variability among individual plants in a hemp crop and that this contributes to further uncertainty in field sampling. Due to this uncertainty in the field during sample collection, commenters suggested that an MU for field sampling be included in the final rule.

Several State agriculture departments argued that the MU value should account for variability in the steps that occur before a sample reaches the laboratory. Comments noted the various steps in the field sampling process, such as cutting, bagging, sealing, transporting, and

handling, and explained that each increases uncertainty in the THC testing results before the sample even arrives at the laboratory for compliance testing. Commenters asserted that uncertainty related to each step in the field sampling collection process should be accounted for in the MU.

Several comments argued that, without a standardized MU for field sampling, some hemp crops with specific end-uses would be disproportionately impacted. According to comments, hemp crops grown for cannabinoids show the most phenotypic variability and lack of uniformity in the field. Comments said this variability should be accounted for before the sample reaches the laboratory.

One comment suggested following the ISO 15189 standards that take into account uncertainty sources during the analytical phase where the measurement actually occurs. Several comments requested that USDA establish a standardized method of calculating uncertainty resulting from sample collection procedures and for uncertainty in laboratory testing methods. One comment noted that USDA's Sampling Guidelines do not require the USDA-approved sampling agent to communicate to the laboratory anything related to crop variations or the agent's sampling methodologies that may contribute to uncertainty in testing the hemp crop for compliance.

A comment suggested a method for calculating MU that would include pre- and post-laboratory activities: MU would be calculated as the square root of the sum of squared values for pre- and post-laboratory activities, or, $(a)^2 + (b)^2 = (c)^2$, where (a) is field sampling activities and (b) is laboratory MU. The comment offered this example: *If the in-laboratory measurement of uncertainty (b) is calculated as 0.0300 percent, and the field sampling measurement of uncertainty (a) is estimated to be 0.0400 percent, then the total measurement of uncertainty (c) would be 0.0500 percent.*

An institute that commented discussed research which found that sampling from the whole plant more accurately reflected what was observed in a field. The comment explained

how the current USDA method, which analyzes only the top 1/3 of the plant, generates data that is error-prone and results that likely do not represent the actual THC levels that are present in the hemp plants in the field as a whole. It said, for example, in one research field, THC levels ranged from 0.06 percent to 2.46 percent in the top 1/3 plant samples when individual plants were evaluated separately.

The research also found significant variation in THC concentration across plants, which the commenter attributed to the lack of ability of the sampling procedure to generate a consistent, reproducible sample from any given hemp field. The research found if the field contains plants that are not completely uniform in their THC levels relative to each other, it is possible that this small subsample in any given analysis could over-represent plants that have higher levels of THC, thereby leading to failure of the field. On the other hand, equally possible, that analysis could over-represent plants that have lower levels of THC, leading to passing the field. The research stated that the most likely result of a sampling test is an inaccurate assessment of the total THC levels based on the method used to sample the plants in the field and then prepare them for extraction.

A comment from a private laboratory noted that when field sampling and pre-analysis handling and processing is done properly and uniformly, the pre-analysis measurement uncertainty can be reduced to 5-10 percent. The comment suggested that test results might be more consistent and uniform when collecting samples in a “W” pattern with a minimum of 10 – 15 individual cuttings taken from the top and middle third of the plant.

Some comments recommended USDA conduct or fund a study to determine appropriate requirements for calculating sampling uncertainty.

AMS response: AMS appreciates the different suggestions submitted by commenters on ways to handle potential variability and uncertainty associated with sampling. AMS recognizes that a variability in sampling may contribute to the overall uncertainty of the final result. For reasons explained below, AMS is unable to adopt a national standard for calculating the MU for

sampling. However, States and Indian Tribes, may include one in their State or Tribal plan as part of their performance-based alternative method for sampling under § 990.3(a)(2)(iii).

In order to develop a standardized approach to sampling MU, a sampling plan must first be well-established, standardized, and studied to accurately account for uncertainty differences in sampling methodologies. To measure uncertainty of the complete process, from primary sampling through analytical determination, all steps in the process must be included. There are many intermediary steps that must be measured, such as sampling conditions, sample preparation, sample preservation, and transportation, all of which are not always present and/or completed the same each time sampling occurs. States producing hemp under the 2014 Farm Bill have developed sampling plans that vary widely; sampling MU is not something that can be easily studied, calculated, or broadly standardized. Due to the variability in sampling across producers, States, and Indian Tribes, and the lack of available data, USDA is unable to establish or standardize a specific MU value or boundaries (upper or lower) for general use.

In the future, standards organizations, such as ASTM International through their Committee (D37) on Cannabis, will be establishing sampling standards that States, Indian Tribes, and producers could use to improve or help control sampling uncertainty. USDA also recognizes that States and Indian Tribes may have or will conduct their own study of the sampling uncertainty within their States or territories taking into account the conditions that may affect sampling. Those States and Indian Tribes may be able to calculate or standardize the MU for sampling within their States and territories. For those reasons, States and Indian Tribes may incorporate a sampling MU as part of an alternative method for sampling under § 990.3(a)(2)(iii).

POST-SAMPLE HARVEST WINDOW

The IFR required testing for total delta-9 tetrahydrocannabinol concentration levels and sampling for such testing was required to occur within 15 days prior to the anticipated harvest of

cannabis plants. The IFR required sampling to be conducted by a Federal, State, local, or Tribal law enforcement agency or their designee.

Comments: Numerous comments expressed opposition to the 15-day post-sample harvest window. Comments argued that a 15-day window is too short and urged AMS to make it longer, providing several examples of anticipated difficulties with the 15-day window.

According to comments, the 15-day sampling window in the IFR did not allow enough flexibility to reckon with adverse weather conditions that could delay or preempt field sampling and harvest activities. Comments said that isolated producers and others with limited access to harvest machinery might not be able to complete harvests within 15 days of sampling if weather prevents them from getting into the fields. Comments also noted that in some hemp production areas, climate changes are trending toward wetter harvest seasons, with frequent and catastrophic flooding in recent years. Other comments provided examples of climate variations across the U.S. and explained that the 15-day window is not uniformly suitable for all regions, some of which may be more prone to early freezes and other conditions that could forestall a timely harvest or force producers to harvest before receiving test results in order to save their crops.

Comments also pointed out that a 15-day window does not adequately accommodate a commonly employed two-phase harvest technique, wherein farmers first harvest the seeds and flowers and then the plant's stalks.

Comments additionally stated logistical challenges related to sampling on larger hemp farms or farms with several varieties. They asserted that the number of required samples greatly increased under the IFR from what was required under most State administered pilot programs, and that collecting, drying, and submitting samples for those additional lots will be very difficult within the 15-day window. A commenter stated that, in 2019, Colorado sampled only 23 percent of all registered hemp lots within a 30-day sampling window under the pilot program, while under the IFR requirements, they would need to collect more than four times as many samples in half the time.

Many commenters—from producers, state departments of agriculture, and Tribal governments—anticipated bottlenecks at laboratory testing facilities due to the limited number of DEA-registered laboratories available to provide testing. Comments from laboratories agreed that the increased demand for hemp testing would strain existing resources and make it difficult to return results to farmers in time to complete harvesting within the 15-day window. One commenter from a private laboratory also noted the strain on human resources this would create to oversight activities because laboratory employees are required to accompany sampling agents through the sampling process within the window. Other comments noted a possible shortage of available farm workers during a tight harvest window.

Comments from Indian Tribes stated that the requirement to test within 15 days prior to harvest by DEA registered laboratories is not practical for Indian Tribes, explaining that many Indian Tribes were moved to desolate lands where growing crops is hampered by location, quality of the land, available water and infrastructure, and access to ready transportation. Further, Indian Tribes said growers are hampered by the economies of size. Comments suggested that in much of the Indian Tribe territories, Tribes will not be able to develop large farms that reduce risk.

Many comments recommended increasing the sampling window to 30 days. Some suggested that producers be allowed to harvest before the return of laboratory results, but not be allowed to release product until test results are obtained. One comment added that allowing post-harvest testing would incentivize farmers to monitor their crops prior to harvest in order to minimize the need to destroy crops. Another comment recommended that all hemp testing labs be required to return results to growers within 15 days of receiving samples. Other comments proposed revising the regulations to require only that harvest commence, rather than be completed, within the specified period following sampling.

Data on compliance testing from North Carolina²⁰ cited a recent study showed an average of 12.65 days taken to receive test results, with a range of between 2 days and 41 days. It estimates that 50 percent of growers would begin to harvest before receiving the results of their THC compliance test and 22.5 percent would complete their harvest without receiving their results.

Another State department of agriculture said it has been operating their pilot program utilizing a 25-day harvest window but noted that 25 days has proved an insufficient amount of time in their experience managing their pilot program. They recommend the final rule utilize, at minimum, a 30-day sampling window.

A State extension service cited data from the Midwestern Hemp Database and reports from Rock River Laboratory which shows that 68 percent of the requests for THC compliance testing were submitted during the period of September 8th - October 1st and note this will create a tight peak window during which samples will be submitted. Due to this peak timeframe of compliance testing needs, several State departments of agriculture note that during these peak times there will be staffing shortages, delays in sampling, delays in analyzing material, delays in the reporting of results and delays due to unsuitable harvest conditions.

Another State department of agriculture recommends that certified seed varieties should be sampled and tested from a random selection of hemp grain and fiber fields 30 days prior to harvest. For uncertified varieties, it recommends requiring a post-harvest test, as well as a pre-harvest test of a random selection of fields within 30 days of harvest.

One commenter discussed data showing that different cultivars accumulate cannabinoids at different rates and at different times. Given the rapid changes in cannabinoid levels, the comment said its data highlights the challenges of scheduling pre-harvest regulatory samples and harvest dates.

²⁰ <https://beta.regulations.gov/comment/AMS-SC-19-0042-5294>

Finally, a few comments asked for clarification about the 15-day window. Some said it was unclear whether harvest must commence or be completed within the window. Others asked whether a producer is prohibited from harvesting before testing is completed. One comment stated that the 2018 Farm Bill does not contain a timing requirement.

One comment reported that their current sample-to-harvest window is 25 days, and that it does not appear to be long enough to sample all the State's outdoor hemp crops maturing concurrently.

One comment reported that the IFR's 15-day harvest window is not feasible to implement and puts incredible stress on the developing State's hemp industry. According to the comment, the State applied a 30-day sample-to-harvest window during the four years it participated under the 2014 pilot program. During the 2020 growing season, the State reported it has struggled to sample and test the 5,809 acres and 1.46 million indoor square feet that comprise the fields and facilities of the State's 700 licensed growers within 20 days. The comment claims that the State does not have the financial capability or staff resources to ensure sampling can be achieved at every field within the optimal and correct time.

Data analysis provided by North Carolina State University²¹ evaluated the 2018-2020 turnaround times for labs reporting THC test results to growers on 3,317 lots. The analysis found that in 22.5 percent of cases, growers would have had to commence harvest with no knowledge of their test results to meet the 15-day harvest window requirement in the IFR. The comment asserted that in reality, growers would need lab results in 10 days or less in order to make informed harvest decisions, in which case they assumed approximately 50 percent of the state growers would have had to start harvesting without knowing their test results. The comment referenced NCSU farm cost studies that showed farmers with some equipment at their disposal will spend approximately \$14,000 per acre on hemp cultivation. Noting that of those costs, seed/plant acquisition and labor are the greatest expenses, the comment asserted that

²¹ Ibid.

harvest is the most labor-intensive activity, and that requiring farmers to harvest without knowing whether their hemp crop is compliant or marketable puts them at great financial risk. The comment recommended extending the post sampling harvest window to 30 days to reduce financial risk for farmers.

A comment from another state noted that given the State's size and geography, distances between hemp production sites could be greater than 2000 miles, making the 15-day sample-to-harvest window impractical for them. The comment recommended allowing States and Tribes, who are better aware of their geographies and resources, to determine their own windows, up to 30 days.

One comment reported the State has three inspectors geographically dispersed throughout the State, servicing approximately 200 farms harvesting within the same 8-week time period. The comment advocated extending the harvest window to 30 days to cope with unforeseen weather events, extended travel, lab turnaround, resampling and testing, and other delays.

One comment contained preliminary findings from an ongoing 2020 study²² conducted by a state and a state university that showed different cultivars of hemp accumulate cannabinoids at different rates and at different times in plant maturity. Study data showed that some cultivars can rapidly accumulate THC and CBD, with weekly changes of as much as 0.1 percent THC and 1.5 percent CBD in some cases. The study found that the rates of THC and CBD accumulation were parallel in the four cultivars studied, with the CBD:THC ratio staying consistent around 24:1. The study concluded that given the rapid rate of change in cannabinoid levels, samples taken 2, 3, or 4 weeks prior to harvest may not accurately reflect the cannabinoid profile of the harvested material. The study further concluded that a larger harvest window increases the

²² Pearce, Bob et al. Sequential Sampling of Four Hemp Cultivars for Cannabinoids – 2020; University of Kentucky, College of Agriculture, Food, and Environment and Kentucky Department of Agriculture. <https://beta.regulations.gov/comment/AMS-SC-19-0042-5762>.

likelihood that non-compliant plant material will be harvested and potentially rejected at market, costing the grower the additional expense of harvesting.

AMS response: AMS recognizes weather and climate-related factors affect all cycles of agricultural production including pre-planting, planting, management, and harvest. AMS also understands these factors may vary by region from year to year, and that certain conditions might cause some farmers to alter their normal harvest timeframe as a result of factors beyond their control as mentioned in several comments. It is common agricultural practice to harvest crops taking into consideration weather patterns such as rain, wind or freezes. Producers also harvest crops based on the availability of labor and transportation, crop rotation and market demand among many factors. A 15-day harvest window may not allow producers the flexibility needed to take all these factors into consideration.

AMS considered the impact of the 15-day window on resources needed for sampling and testing activities. We acknowledge that sample collection may require an authorized sampling agent to visit multiple farms of varying sizes over a very short period of time. AMS further understands that in some places, the sampling agent may visit a farm on multiple occasions due to the size and harvest cycle of the farm. AMS also considered the turnaround time for producers to receive results from laboratory testing.

This final rule allows farmers to commence harvests before receiving test results, as did the IFR. However, crops may not be released in commerce or further processed until tests confirm that the lots in question are compliant with the regulations. Harvests must be completed within the 30-day timeframe provided by the final rule. AMS does not believe harvests should occur after that time because, generally, total THC levels continue to increase with time and there is too great a risk that the levels would increase after 30 days and thus the sample that was tested would not be an accurate reflection of the total THC of the harvested crop.

Regarding comments on laboratory resources, AMS considered input from our Science and Technology Program, which conducts laboratory testing for numerous agricultural

commodities and oversees our third-party laboratory approval program. AMS assessed testing activities, which include the receiving, selection, drying, processing (through liquid or gas chromatography), analysis, storage, and reporting of hemp test results. AMS considered the time necessary to ship samples to the laboratory and to issue test results back to the grower, recognizing that not all farms have readily available internet to expedite receipt of electronic laboratory notifications. Standard mail may be the primary means of communication for rural populations in certain regions and Tribal lands. AMS also considered the level of routine work at testing facilities across the nation and their capacity to efficiently process hemp samples while continuing unrelated, non-hemp laboratory activities. AMS agrees that it may be difficult at the peak of the season for high-volume laboratories to consistently issue timely results to growers, as producers experienced and DEA acknowledged, impacting growers' ability to make harvest decisions.

Based on comments received and knowledge of agricultural practices, AMS determined that the post-sampling harvest window should be extended to allow hemp harvests to be completed within 30 days after sampling. AMS believes allowing the additional time will provide flexibility for dealing with unforeseen weather events and other agricultural factors, and better accommodate complicated harvest processes. AMS also believes this will reduce strain on testing resources and ensure test results can be returned to growers on a timely basis.

LABORATORY ACCREDITATION – LABORATORY APPROVAL PROGRAM (LAP) and INTERNATIONAL STANDARDS ORGANIZATION (ISO)

The IFR required hemp growers to obtain testing from DEA-registered laboratories to ensure proper handling, disposal, and reporting of samples that exceed allowable THC limits for hemp and may therefore be controlled substances. As part of the IFR, AMS asked stakeholders whether laboratory accreditation should also be required for hemp testing labs. Specifically, AMS asked about accreditation through AMS's LAP, through the ISO standards (ISO 17025), or through both, and if so, which would be preferable.

Comment: Comments reflected a range of views across the industry, both in support of and opposition to additional laboratory certification requirements. In general, commenters preferred more regulatory flexibility to address the widespread concern of insufficient laboratory capacity as a result of laboratory certification/registration/accreditation requirements imposed by USDA regulation.

Supportive of LAP and ISO: Some comments supported requiring additional accreditation through both LAP and ISO. Comments explained that LAP accreditation imposes analytical standards and limits that ensure reliable and consistent results across hemp labs, while ISO 17025 accreditation ensures that labs adhere to their own established protocols. Comments asserted that additional accreditation is essential to ensure that laboratories, government entities, and farmers comply with regulations. One comment that supported requiring both accreditations said the scope of the ISO 17025 standards should include hemp testing methods.

One comment said requiring LAP and/or ISO accreditation in conjunction with DEA registration is a step in the right direction because current standards are subpar and do the industry a disservice, while adding LAP and/or ISO accreditation would provide a baseline standard that benefits all stakeholders, including consumers.

Either LAP or ISO: Other comments advocated requiring additional accreditation through either LAP or ISO, but not both. Comments said that requiring one or the other would be adequate to provide testing integrity, but that requiring both would unnecessarily overburden labs and create a testing bottleneck as labs worked toward accreditation. One comment said that since hemp products are consumable, public health and safety should be of paramount concern when choosing a lab accreditation program.

Comments supporting LAP accreditation specifically said such accreditation would improve grower access to qualified labs and would improve the efficiencies and protect the competitive interests of non-DEA labs. Comments favoring LAP accreditation pointed out that LAP already incorporates ISO 17025 standards and includes regular audits and records

management requirements. Comments added that incorporating ISO standards into LAP accreditation lends confidence in testing procedures and results, which in turn creates a fair marketplace for hemp. They asserted that the benefits of LAP accreditation outweigh the costs because they emphasize quality controls and accurate analytical performance by knowledgeable and trained staff. One comment suggested that using LAP-approved labs would facilitate USDA's hemp program oversight and the development of an evidence-based data tracking system. Another comment pointed out that LAP offers growers a complete online listing of qualified labs from which to choose.

Some comments argued against adopting LAP accreditation, saying the accreditation process is expensive and burdensome for laboratories, and that the user-fee program benefits only USDA. One comment said that it is unclear from the IFR how LAP differs from ISO and whether LAP accreditation offers more confidence in test results than ISO accreditation. Another comment said that LAP accreditation would be redundant to ISO accreditation and is not necessary.

Some comments favored the use of laboratories with ISO 17025 accreditation in addition to or instead of DEA-registration. Comments noted that hemp laboratories in many States already have ISO accreditation, although some are not DEA-registered. They suggested use of those labs should be grandfathered into approved hemp production plans. Some comments asserted that between LAP- and ISO-accreditation, ISO is the best alternative for the hemp industry because it meets the needs of the hemp industry, and at a reported cost of \$25,000, it reduces unnecessary expense and regulatory burden for labs and growers. One comment recommended that USDA specify that the most current ISO 17025 standard be required for accreditation – the 2017 version.

Neither LAP nor ISO: Several comments opposed requiring additional laboratory accreditation on top of DEA-registration. Some comments called it “overkill,” and said

requiring additional accreditation would put an undue strain on laboratories and delay testing and reporting results for growers.

None of the Above: Several comments opposed specifying any particular laboratory registration or accreditation and recommended instead that States and Indian Tribes be authorized to determine appropriate standards for hemp testing laboratories under their respective production plans. Comments said that allowing States and Indian Tribes to determine their own lab certification schemes would allow them to maintain appropriate testing capability while finding the best fit for the economic profile of their regulated jurisdictions. One comment suggested USDA encourage laboratories to participate in the Hemp Proficiency Testing Program established by the University of Kentucky, rather than building an accreditation program from scratch through LAP.

Other Alternatives: One comment asked USDA to clarify why any additional accreditation should be required. Another comment suggested that if laboratory accreditation is necessary, AMS should explore the most cost-effective choice from among LAP, ISO, or other commercial accreditations to minimize costs for growers. A comment suggested that DEA-registered labs not be required by the rule but be allowed as backups for labs with other accreditations. Another comment speculated that if only LAP or ISO accreditation were required, and DEA registration was not, growers would test their crops more frequently. Some comments recommended that no specific accreditation be required because the process is too costly and time consuming and would discourage labs from participating in the program. One comment suggested that USDA encourage labs to adhere to ISO 17025 standards, but not require accreditation.

Some comments suggested that LAP accreditation would be beneficial to the industry, but that such a program should be developed incorporating the expertise of former DEA or other chemists with experience testing cannabis. Other comments supported using ISO-accredited labs until LAP accreditation can be fully developed and used on a trial basis to gather adequate

experience and data. One comment suggested allowing States, Tribes, and USDA to contract with commercial labs or use private labs that adhere to ISO standards.

AMS response: AMS noted that commenters generally preferred more regulatory flexibility to address the widespread concern of insufficient laboratory capacity as a result of laboratory registration requirements outlined in DEA regulations. Adding ISO 17025 or other accreditation requirement to laboratories would decrease the number of laboratories available to perform hemp tests. AMS also noted some commenters opposed accreditation requirements due to cost implications and additional burden. While we strongly encourage laboratories to be accredited to ISO/IEC 17025 (by an International Laboratory Accreditation Cooperation Mutual Recognition Agreement (ILAC MRA) signatory accreditation body), because it will help ensure lab results are more accurate, ISO 17025 accreditation requires significant time and financial commitment to pursue and maintain. This it is most challenging for smaller and start-up labs. The initial accreditation can cost \$5,000-\$10,000 (and in some case more) and yearly ongoing costs are \$3,000-\$8,000. Smaller labs may not have the resources to pursue accreditation in a timely manner or they may have to spend more time and money for consultants to assist them in setting up a quality management system and to navigate the application and audit processes.

Based on this input, AMS will not require USDA administered lab approval program or require ISO 17025 accreditation because doing so would increase the financial burden on producers and reduce the availability of laboratories that can test for THC level in hemp. AMS is committed to continue looking into this option.

DEA LABORATORY REGISTRATION REQUIREMENT

The IFR required that laboratory testing of hemp for the purpose of determining compliance under the program be conducted by laboratories appropriately registered with DEA. However, on February 27, 2020, USDA announced guidance delaying the requirement to use laboratories registered with DEA for testing. 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 deadline was later extended to December 31, 2022. This change was intended to allow additional time to increase DEA-registered analytical lab capacity.

Comments: A few comments supported the DEA-registration requirement. Some comments favored dual laboratory accreditation (e.g., DEA and ISO 17025 accreditation or DEA and AMS LAP accreditation) saying that such combinations would assure technically competent, unbiased testing and results reporting. One comment agreed with DEA lab registration but said that labs that have applied for DEA registration by Nov 1, 2020, should be allowed to continue testing (as under pilot programs) as the certification process takes so long. It further observed that while the IFR seemed settled on HPCL as the testing method, the rule does not specify the detection method as it should. The comment recommended mass spectrometry as the most accurate.

Another comment agreed with DEA lab registration, saying that otherwise, any lab could be handling controlled substances without observing stringent DEA requirements. The comment argued that allowing any lab to test hemp creates an unfair business advantage for non-DEA labs that do not have to pay high costs of maintaining DEA registrations. Further, those non-DEA labs would be handling controlled substances inconsistent with Federal law.

More commonly, comments opposed the DEA-registration requirement for hemp testing laboratories. Commenter concerns were as follows:

Logistics: Numerous comments stated there are not enough DEA-registered labs to handle the volume of samples required under the IFR's sampling and testing regulations. Comments predicted that such limited capacity would exacerbate existing bottlenecks, greatly increasing the likelihood that THC levels in sampled crops would continue to rise while farmers wait for test results. Several comments noted that the IFR allowed farmers to harvest sampled crops before receiving test results, however many prefer not to expend time and money harvesting a crop that might not be marketable. Comments also anticipated growers' testing fees would increase to cover the addition of testing resources at existing DEA-registered labs.

Some comments noted that not all States or Tribal lands have DEA-registered labs within or near their boundaries. According to comments, where DEA labs do exist, they are generally located in urban areas at some distance from rural farms. They explained that the scarcity of DEA-registered labs in reasonable proximity to farms will increase costs for transporting samples and increase the turnaround time for obtaining test results. Some comments submitted by Indian Tribes also asserted that the DEA had failed to consult with Tribes about its accreditation process and that it failed to timely respond to Tribes' requests for lab results.

Accreditation: Comments said that DEA-registration is costly and time consuming for laboratories and that such expenses would discourage existing labs from seeking DEA registration. One comment said that DEA accreditation is too expensive to be required for "low-level THC testing." Comments suggested alternatives, including:

- Allow testing by labs accredited under ISO 17025
- Allow testing by labs approved under AMS's LAP
- Allow testing by labs accredited by States or Tribes
- Allow testing by labs accredited under other accreditation programs
- Allow testing by labs with dual accreditation (e.g. DEA and ISO, or DEA and LAP)
- Allow continued testing by labs approved to do so under the 2014 Farm Bill
- Allow for a transition period to allow labs time to work toward registration.

One comment suggested that allowing for alternative laboratory accreditation would increase competition between labs, reduce costs for growers, and reduce the potential bottleneck created by allowing for only DEA-registered lab testing.

Another comment argued that although accreditation is costly, relying on it could help enforce strict standards and ensure less variability between testing labs. Some comments suggested USDA fund accreditation of private labs to help offset the cost of expensive accreditations and encourage more labs to seek necessary accreditation.

Other comments suggested DEA expedite its lab approval process and make it easier for existing labs to obtain DEA registration.

Other commenters stated that the DEA lab accreditation process requires State approval and not Tribe approval and that this is unworkable because of occasionally difficult relationships between some Tribes and States and because hemp is prohibited in a couple of States.

Finally, several comments recommended AMS provide a phase-in period of as much as two years to allow existing labs to continue hemp testing while they work toward DEA registration so the industry will have access to adequate testing options during its development.

DEA and Controlled Substances: Comments expressed concern about many aspects of DEA's involvement with the hemp program. Comments argued that hemp is a legal agricultural commodity under the 2018 Farm Bill and requiring testing by DEA labs insinuates hemp is a controlled substance regulated under the Controlled Substance Act. Commenters asserted that treating hemp as a controlled substance exceeds the intent of the 2018 Farm Bill. Comments also suggested USDA's IFR impeded Congressional intent to foster the development of a new agricultural sector.

One commenter representing a processor of hemp, specifically for CBD products, said they were concerned about an IFR published by DEA and that the rule by DEA could inadvertently criminalize hemp at various stages of its production process. They encouraged USDA to eliminate DEA's involvement.

Comments also said DEA involvement in USDA's program discourages participation by laboratories and by growers, neither of whom may care to risk prosecution for inadvertent criminal acts if a test result indicates they raised or possess a controlled substance. Some comments said private labs with ISO or other accreditation don't want to obtain DEA accreditation, fearing the tension it will cause between themselves and their grower customers because of the requirement to report potential criminal activity. Other comments said growers fear repercussions related to possible felony prosecution for growing crops considered illegal,

including loss of chemical application permits that allow them to manage other crops. One comment argued that it isn't necessary to involve DEA in hemp testing, that it distracts that agency from other vital Federal work.

According to some comments, most DEA-registered laboratories are crime labs that do not offer commercial testing services. As reported by a State, the DEA may be reluctant to even visit – let alone approve – certain laboratories because of the handling and testing of marijuana, although considered legal by the State. Other States with legal medical and/or recreational marijuana provisions commented that their labs may not want to seek DEA registration because they choose to focus on marijuana testing. Some comments said labs that handle marijuana may not in fact obtain DEA registration, thus laboratory capacity to process hemp samples at the volume and speed required by the IFR may not materialize.

One comment assumed DEA-registered labs might test only for cannabinoids, while other commercial labs would be able to perform additional testing, for instance for microbes, heavy metals, and pesticide residues, saving growers the additional expense of multiple tests.

Some comments recommended USDA waive the requirement to use DEA-registered labs in States where recreational marijuana is legal, thus increasing the number of labs available for hemp testing. Other comments recommended DEA change its standards to allow labs that handle legal marijuana to also handle hemp.

Cost Management: A few comments suggested that restricting hemp testing to DEA-registered labs creates a monopoly among labs that already have such accreditation or have the financial backing of large, vertically integrated companies to enable them to do so. Comments recommended that existing State, Indian Tribe, university, or other Federal labs with demonstrated ability to perform testing according to USDA standards be allowed to do so, thus providing opportunities for more interested participants and keeping testing costs down for growers. Some comments suggested USDA contract with State, Tribe, or Federal labs to provide

required testing. Other comments recommended capping costs for DEA-registered lab testing at \$25-\$50 per test.

Alternatives: One comment asked USDA to clarify whether all independent labs must be DEA-registered to test hemp or whether only State labs needed to obtain that accreditation.

AMS response: In consultation with the Department of Justice, AMS determined it must retain the provisional requirement that laboratories testing hemp for the purposes of regulatory compliance be registered with DEA. This requirement further extends to any laboratory testing hemp throughout the growing season to informally monitor THC concentration. The basis for this determination is rooted to the statutory requirements of the Controlled Substances Act (CSA), which requires any laboratory that might potentially handle a controlled substance to undergo the DEA registration process. The CSA states that it is unlawful to possess a controlled substance (21 U.S.C 844) and requires any laboratory that might potentially handle a controlled substance to undergo the DEA registration process (21 U.S.C. 822) with a few specific exemptions. Further, 21 CFR 1301.13 includes categories that require registration with DEA, including chemical analysis where laboratories fall.

AMS is aware through stakeholder comment that many stakeholders oppose the DEA registration requirement. AMS is also aware of widely held concern among stakeholders, especially Indian Tribes, that an insufficient number of DEA-registered laboratories exist and have limited accessibility to those in rural or regional locations away from metropolitan areas. AMS understands how this combination of variables leads to delays in sample processing by DEA-registered laboratories and how this affects producers' harvest timetables. AMS also knows that since the IFR was published, numerous laboratories have applied for registration and DEA is working diligently to process these requests. For this reason, DEA is delaying enforcement of this requirement until December 31, 2022. AMS anticipates this delay will provide adequate time for testing facilities to obtain DEA registration.

While we understand the commenters' concern about DEA involvement, the 2018 Farm Bill distinguishes hemp from marijuana, a controlled substance under DEA's regulatory authority, based on the THC concentration level in the cannabis plant. Although a producer may have intended to cultivate hemp, it is possible that the plant is marijuana because of the THC concentration level. If that is the case, the producer would then be subject to DEA regulations and jurisdiction. USDA coordinated with DEA so that producers that inadvertently produce marijuana may be able to take remediation steps consistent with DEA's regulations to avoid potential criminal liability. Additionally, the 2018 Farm Bill makes clear that negligent production of hemp will not subject the producer to criminal enforcement activity. *See* 7 U.S.C. 1639p(e)(2)(C).

AMS also acknowledges that some laboratories believe the DEA-registered laboratories are crime labs that do not offer commercial testing services and DEA may be reluctant to approve laboratories because of the handling and testing of marijuana, although considered legal by the State. However, AMS does not have any information that would support this belief. AMS is aware that DEA continues to add laboratories to their approved list.

Accordingly, any laboratory testing hemp for purposes of regulatory compliance must be registered by DEA to conduct chemical analysis of controlled substances (in accordance with 21 CFR 1301.13). Registration is necessary because laboratories could potentially handle cannabis that tests above the 0.3 percent concentration of THC on a dry weight basis, which is, by definition, marijuana and a Schedule 1 controlled substance. Instructions for laboratories to obtain DEA registration, along with a list of approved laboratories, are available on the USDA Domestic Hemp Production Program website.

Laboratory accreditation options are discussed earlier in this rule. USDA does not have any authority over the DEA's laboratory accreditation process.

DEA's IFR published August 21, 2020, (85 FR 51639) is out of the scope of this final rule.

MEASUREMENT OF UNCERTAINTY (MU) – LABORATORY TESTING

The IFR required that laboratories calculate and include the measurement of uncertainty (MU) when they report THC test results.

Comments: Several comments expressed support for requiring that the MU be accounted for when testing the THC concentration of hemp due to the variability in laboratory testing equipment and complex mathematical principles involved. Comments generally emphasized that the inclusion of a standardized MU was needed for the industry to develop, as hemp farmers should not be exposed to risks of economic loss that are created by mathematical inconsistencies within an individual laboratory's computations. Several comments emphasized the importance of USDA clarifying the method for MU calculation in the rule because it is part of what determines whether hemp must be disposed.

One commenter cited a study²³ that found that test results on samples from each field sent to five different labs deviated significantly, ranging from a low of 22 percent deviation to a high of 41 percent depending on the field.

Some comments expressed the need for a standard, specific MU in the final rule to prevent licensees from “shopping around” for laboratories with the most lenient testing. Comments noted there is no universally accepted way to calculate MU, so differences in MU values used by various laboratories are just as likely to result from differences in calculation method as they are from differences in instrument quality or use. Several comments explained that the lack of a standardized MU in the rule incentivizes inaccuracy by potentially driving customers to laboratories willing to use MUs with greater ranges.

Many comments advocated specifying an MU to create uniformity in testing across the nation. One comment noted that variation in MU values could be problematic for interstate commerce and result in a hemp crop that is compliant in one state being shipped to another state

²³ Evaluation of methods used to sample hemp for regulatory compliance testing;” Gang, David R. and Anna Berim; Washington State University, Pullman, WA; 2020.

where it would be considered noncompliant. Other comments argued that it may be too soon in the scientific process for USDA to include a standard MU because laboratories, particularly in States that didn't previously have cannabis programs, haven't had time to do the research necessary to determine an appropriate MU.

Comments from States that administered pilot programs under the 2014 Farm Bill offered several suggestions on approaches to MU calculations. A comment recommended using laboratories participating in the University of Kentucky – Division of Regulatory Services' Hemp Proficiency Testing Program to establish an MU through a set of guidelines rather than in the rule. The commenter concluded that the Hemp Proficiency Testing Program could be tasked with calculating and announcing an MU that would be used for compliance testing purposes on a nationwide basis. The comment added that including the MU in the guidelines rather in the rule would allow it to be refined over time as instrumentation and calculations develop, rather than having to modify the hemp regulation.

Some comments advocated having multiple testing methodologies to choose from and including requirements for calculating MU for each method. Other comments recommended that instead of requiring a specific MU, USDA should determine a maximum threshold for allowable MU value. Comments argued that a maximum threshold would prevent forum shopping by consumers looking for laboratories with the most lenient MU ranges, but still allow laboratories to use their own calculations. One comment recommended revising the MU provision of the IFR to include a maximum uncertainty level that laboratories cannot exceed and suggested the maximum uncertainty value should be one-third or less of the target uncertainty. Another comment suggested USDA use guidelines from the United States Pharmacopeia for determining THC concentration, which include calculations for significant figures such as MU.

A comment asked USDA to clarify the role of significant figures in using MU to determine total THC concentration because, they argued, in both of the IFR's examples for determining compliance, the lower end of the range can be written as 0.3 percent, if rounding to

match significant figures. It suggested requiring the lower value of the THC calculation distribution range, which accounts for uncertainty, to be less than or equal to 0.30 percent rather than 0.3 percent.

One commenter stated that for the cannabis plants exceeding the acceptable THC levels, USDA should incorporate a MU for laboratory deviation of .0500 percent for the many different variable ways that a sample arriving at a laboratory could result in an inaccurate test. This includes cutting, bagging, sealings, transporting, handling, and other pre-laboratory activities.

One comment cited guidance from the National Institute of Standards and Technology providing that assigned uncertainty should be small relative to the total uncertainty targeted for test samples. The comment asserted that, as a rule of thumb, assigned uncertainties should be about one-third or less of the target uncertainty to ensure that uncertainty in the certified value will have negligible influence on the results of measurements. According to the comment, laboratories with well-developed processes will provide the most accurate and precise results and their uncertainty will be very small. The comment advocated that USDA provide an uncertainty range that cannot be exceeded by participating laboratories, thereby reducing the risk that producers will shop for laboratories with the widest uncertainty. The comment asserted that such a provision would also improve data comparability across the hemp industry.

AMS response: AMS appreciates the different suggestions submitted by commenters on ways to improve the calculation of MU and also acknowledges the variability in laboratory testing equipment that may exist. However, based on the input received and limited data available at the time of its review, AMS will only require that hemp testing laboratories complete a MU calculation as part of the mathematical test result for THC concentration. This final rule does not establish or standardize an upper or lower boundary for general use by laboratories to calculate a measurement of uncertainty. MU is typically not standardized, but rather is controlled using test methods controlled by performance standards (e.g., AOAC Standard

Method Performance Requirements 2019.003 that can be found at

<https://www.aoac.org/resources/smpr-2019003/>).

USDA does not recommend establishing a MU upper limit (maximum) because 1) MU is typically not standardized, but is controlled using standard test methods, and 2) USDA does not have the data to set an upper limit, so setting it would be arbitrary, not scientific. The hemp and scientific industries are just beginning to discuss standard test methods, and the final rule does not establish an explicit test method. Setting an upper limit or maximum MU does not resolve the core issue and would not encourage or drive labs to improve accuracy and precision.

Setting an upper limit would in effect be setting a maximum or absolute MU. This may encourage labs to adopt the maximum MU as their MU, rather than drive for a smaller uncertainty. USDA may allow for establishing limits in the future, if needed, once methods are established and USDA has access to Proficiency Testing results and the reported MUs.

Additionally, this rule retains the flexibility for State and Tribal Departments of Agriculture to include specific requirements regarding MU for laboratories conducting hemp regulatory testing under their specific state or Tribal hemp programs if they meet the minimum standard set in this final rule. AMS encourages State and Tribal regulatory agencies to coordinate in developing proficiency and testing methods, similar to the program administered by the University of Kentucky, but participation in these types of programs is not required by this regulation.

DISPOSAL

The IFR stipulated that cannabis exceeding an acceptable THC level must be disposed of in accordance with the CSA and DEA regulations because such material constitutes marijuana, a Schedule I controlled substance under the CSA, rather than hemp.

Destruction vs. Disposal: Several comments noted that the 2018 Farm Bill specifies only “disposal,” of hemp testing above the acceptable THC level, yet the IFR required “destruction” of such material. Comments argued that the IFR’s destruction requirement is an overreach.

Comments asked USDA to revise the regulations to require only disposal of non-compliant plants or plant parts, and to provide either general parameters or specific provisions regarding acceptable methods of disposal. Several comments asked AMS to provide or expand the requirements for disposal of non-compliant material.

Although a few comments supported destroying non-compliant hemp crops, most comments that addressed the topic argued against total crop destruction if alternative disposal methods are available and practical. Comments explained that crop loss is financially devastating to growers – and doubly punitive if the grower must pay to destroy the crop – as well as a waste of valuable resources that could be repurposed and provide at least some return to growers. Comments explained that crop destruction can be a drain on limited official resources, depending on the availability of law enforcement personnel and equipment for the potential need to collect, transport, and oversee the destruction of non-compliant plant material. Further, a comment from an Indian Tribe noted that requiring crop destruction is culturally offensive to indigenous people that traditionally use every part of every animal and plant that can be utilized.

Disposal Methods: Several comments asserted that the only disposal methods available under DEA regulations are incineration or chemical digestion and argued that the current rules under the CSA are designed for disposal of pharmaceuticals and chemical-based illegal drugs, not for the disposal of agricultural crops. Comments asserted that incineration by DEA is not efficient or environmentally sound, and in some places may not be allowed. They noted that burning crops releases harmful carbon dioxide and other pollutants into the air, contributes to the risk of wildfires, and wastes valuable plant nutrients that could be used elsewhere.

Numerous comments stated that the rule should provide alternative methods of disposal for non-complaint hemp plants to protect growers against total crop loss and preserve valuable resources. Several comments recommended USDA adopt disposal rules established under their various State and Tribal regulations. Comments suggested growers be allowed to mulch or disc the non-compliant crop into the soil at the farm, which would build up soil nutrients, improve

soil water holding capacity, and improve soil tilth. Other comments suggested growers could recuperate some of their investment by marketing non-compliant crops for other non-ingestible or non-consumable products like fiber, building materials, biofuel, biochar, bioplastics, and animal bedding. A few comments suggested growers should be permitted to export or ship non-compliant hemp to countries or States that have legalized recreational or medical marijuana. Numerous comments recommended a surgical approach to disposing of non-compliant plants by allowing for the removal and disposal of only the plant parts testing over the acceptable THC level, while allowing growers to market the remaining parts. One comment suggested the Federal Government could buy non-compliant crops for no less than 50 percent of the market value and use them to manufacture paper, plastics, and fuel for government and military uses. Other comments proposed remediation as an alternative to crop destruction; comments on remediation are discussed in another section of this comment analysis. One comment suggested further research be conducted to identify appropriate alternatives for crop disposal, and one comment suggested that industry stakeholders, governments, regulators, and law enforcement officials work together to develop disposal options under the program.

Disposal Oversight: Several comments recommended that States, Indian Tribes, or local authorities be allowed to determine appropriate crop disposal methods for their jurisdictions. Comments further recommended that State, Tribal, or local regulatory officials be authorized to oversee disposal of non-compliant hemp, as several have done prior to the establishment of the Domestic Hemp Production Program. One comment recommended further that hemp disposals handled by the State should not imply criminal intent on the part of growers. Comments said that allowing for local oversight would reduce strain on DEA and other law enforcement resources and ensure disposals can be handled on a timely basis. One comment from a State agriculture department said that when law enforcement officers have been invited to attend crop disposals in their jurisdiction, officers are typically unavailable. Other comments argued that growers should automatically become DEA-registered reverse distributors if their test results

exceed acceptable hemp THC levels so they can dispose of the non-compliant crops themselves and provide acceptable evidence (e.g., photo or video) that they have done so, or so they can do so in the presence of regulatory officials. Some said USDA should pay for official oversight of crop disposal or there should be no charge for that service.

Comments noted that AMS had not yet posted disposal guidelines on its website at the time those comments were submitted, although the IFR had committed AMS to doing so. Some comments said interested entities were unable to complete applications for program participation because AMS had not yet provided disposal requirements.

Several comments asserted that DEA regulations do not mandate specific disposal methods, so long as the “desired result” is achieved. Comments asked for more specifics on DEA disposal procedures, including what disposal methods or processes were allowed under the IFR, what the timeline is for disposal, and what results are desired.

One comment asked whether all of a grower’s crops would be disposed if one of the lots tested above the acceptable hemp THC level. Others asked whether marketing non-compliant crops for non-ingestible and non-consumable products would be considered a form of disposal. One comment asked whether USDA would consider providing crop insurance for losses due to disposal of “hot” crops. One comment asked whether stored hemp product produced under previous programs that allowed for higher THC levels would be disposed under the new program, or could be “grandfathered” in.

One comment contended that certain language in the IFR was inconsistent, and as a result, the IFR could be interpreted to require disposal of hemp that does not meet the IFR’s definition of hemp, rather than the disposal of hemp that does not meet the acceptable hemp THC level.

AMS response: AMS received significant comments on this requirement from State and Tribal regulatory agencies, producers, and other hemp industry stakeholders and based on this

input, AMS determined it necessary to include specific on-farm hemp disposal activities and to provide oversight flexibilities.

As explained in the IFR, State and Tribal plans are required to include procedures for ensuring effective disposal of plants produced in violation of this Part. As part of its review, AMS noted the cultural implication of the use of the term ‘destruction’ and accordingly amended the regulatory provision to clarify the disposal activities required of growers in cases when a sample tests above the acceptable total THC level.

AMS also determined that producers benefit from greater regulatory flexibility to control on-farm disposal activities according to production schedules that are not dictated by the availability of reverse distributors to physically witness disposal activity. State and Tribal plans must still include procedures to verify disposal. This may come in the form of in-person verification by State or Tribal representatives, or alternative requirements the direct growers to provide pictures, videos, or other proof that disposal occurred successfully. State and Tribal plans must also include requirements to submit to AMS the monthly disposal report documenting any on-farm disposals that occurred during the prior month. Additional information on specific disposal methods is available to producers, State, and Tribal oversight agencies is available on the AMS website.

Disposal through the agricultural practices appearing in this final rule reflected those allowable under the IFR, and previously published to the AMS webpage in February 2020. These included plowing under, mulching/composting, disking, bush mower/chopper, deep burial, and burning. These activities align with normal and routine production actions by farmers. AMS believes specifying these activities help hemp growers determine which activity best supports their operation to transition non-compliant crop into a non-retrievable or non-ingestible form. These methods also allow recycling non-compliant plant materials back into the earth, a viewpoint AMS learned through public comment to be especially relevant for producers practicing cultural conservation practices. AMS recognized that controlled burning is the closest

farm practice to incineration but controlled burns may not be a viable option for producers in some places due to wildfire risk or state prohibition against using controlled burns.

REMEDICATION

The IFR stipulated that cannabis exceeding the acceptable THC level must be disposed of in accordance with the CSA and DEA regulations because such material constitutes marijuana, a Schedule I controlled substance under CSA, rather than hemp. In addition, the IFR stated that noncompliant plants may not be further handled, processed, or enter the stream of commerce, and that the licensee shall ensure the lot is disposed. The IFR did not stipulate any provisions to allow for remediation activities that reduce the THC concentration to levels within the acceptable limit.

Remediation of non-compliant crops into compliant plant biomass: Numerous comments expressed support for remediation of non-compliant plants to help farmers mitigate against financial loss. Comments claimed that not having remediation options would be a barrier to industry growth because farmers would be unable to bear the financial risk of losing crops. One commenter used 2019 production and economic data to project that applying the IFR to 2019 statewide non-compliant test rates (17 percent), farmgate losses due to crop destruction could have totaled \$842.6 million in Colorado.²⁴ According to the comment, adding losses related to lost processing and manufacturing due to the same crop destruction could have brought the economic cost to approximately \$1.2 billion. It suggested that allowing for remediation of non-compliant crops testing between 0.3 and 1.0 percent THC in the same scenario would preserve about \$798 million in direct farmgate value, or \$1.1 billion of total economic value for the State.

Numerous comments explained that non-compliant plants can be remediated by chemical processes that either remove and destroy THC or dilute THC concentrations, thereby

²⁴ Polis, Jared; Phillip J. Weiser; and Kate Greenwood: State of Colorado Comments in Response to USDA Establishment of a Domestic Hemp Production Program; <https://beta.regulations.gov/comment/AMS-SC-19-0042-3358>.

transitioning the remaining material into biomass blends which then test at or below the Federally allowable THC threshold of 0.3 percent. Thus, according to comments, crop remediation through one of these processes is a viable alternative to total crop loss. Some comments suggested processors could be registered with DEA to handle such remediation processes to ensure THC is extracted, handled, and disposed or marketed legally. Other comments suggested that USDA could issue processor permits to allow them to handle hot crops to bridge the perceived legal gap between farmer and consumer. Some comments further suggested growers could bear processing costs then retake possession of the remaining biomass for use or sale elsewhere. Several comments suggested growers themselves could be allowed to merge “hot” lots with lots testing below allowable hemp THC limits to create a compliant, homogenized blend.

Some comments suggested non-compliant crops could be remediated by removing the only flowers and retaining the seeds and stalks for other use. Other comments argued that the IFR testing provisions conflict with CSA provisions that exempt seeds and stalks of plant material from the definition of marijuana, and several comments urged USDA to modify the IFR to require only that the parts of the plant exceeding the THC limit be destroyed.

One comment advocated that States be allowed to remediate non-compliant crops through milling and blending the harvest lot to include the entire plant to a homogenized state, then retesting the lot. The comment included the results of a comparative analysis based on crops that initially tested over the legal threshold of 0.3 percent total THC during Arizona’s 2019-2020 growing season.²⁵ According to the comment, producers opted to attempt remediation as described for a total of 25 lots representing 568.6 acres of hemp. Of the 25, 19 lots representing 507 acres successfully reduced the total THC amount to be compliant, for an 89.71 percent recovery of acres that would otherwise have required disposal. The comment

²⁵ Caravetta, John: Arizona Department of Agriculture Additional Comments on USDA Interim Final Rules on Domestic Hemp Production; <https://beta.regulations.gov/comment/AMS-SC-19-0042-5645>.

reported that the average amount of THC was reduced by 31.61 percent, and suggested that while this remediation process might not be successful for crops that are significantly over the legal threshold, and while the market value of the resulting biomass may be reduced, the process may allow growers to recover some of their losses.

One comment²⁶ reported on a survey of all Minnesota hemp growers who had experienced lot failures since the beginning of their pilot program in 2016. According to the comment, reported losses varied greatly, ranging between \$22,000 and \$70,000 per year. The comment further described the State's analysis of 1,492 hemp lot samples from 2016 through September 2020, which showed that 10.3 percent tested at or above 4.0 percent total delta-9 THC, although there was no indication of non-compliance with program rules or of illegal drug activity on the part of growers. The comment recommended that States and Tribes be allowed to develop remediation plans to salvage non-compliant crops.

Post-harvest sampling and retesting: Several comments suggested retesting post-harvest samples to confirm THC levels. Comments provided examples of some State agriculture departments that implemented post-harvest sampling and testing processes under the 2014 Pilot Programs. For instance, one comment cited results from the 2018 season in which they allowed post-harvest retesting of hemp plots that originally tested between 0.4 and 1.0 percent THC. The comment said under Kentucky rules, farmers were allowed to choose between immediate destruction of the leaf and floral material of the crop, without additional testing, or paying the \$250 fee for a post-harvest retest of harvested and ground up hemp material, in which the THC concentration was diluted. It stated that of 29 growers whose lots tested between 0.4 and 1.0 percent THC, 22 chose retesting and none of those returned a second measurement above 0.3999 percent THC. Thus, those growers were able to realize a return on their investment. The remaining seven cases did not elect to retest - five elected to destroy the entire plant and 2

²⁶ Petersen, Thom: Minnesota Department of Agriculture Comments on USDA Interim Rule: Establishment of a Domestic Hemp Production Program; <https://beta.regulations.gov/comment/AMS-SC-19-0042-5548>.

destroyed only floral and leaf materials, salvaging the stalks. The data showed the acreage destroyed represented approximately one percent of total acreage. The comment concluded that post-harvest grinding and retesting offers a viable economic solution for farmers seeking to recuperate their investment on crops that initially test non-compliant. Other comments urged USDA to provide for retesting provisions, including remediation activities, that more favorably support farmers who seek to salvage crop value. Some of these comments requested that USDA clarify retesting procedures if a harvest has already occurred.

Statutory implications: Comments from Tribes and other stakeholders expressed concern that the 2018 Farm Bill only requires “procedure for effective disposal,” and urged USDA to allow producers greater regulatory leniency as they become familiar with growing a new crop by permitting alternative remediation methods that do not require crop destruction.

AMS Response: This final rule covers testing of the hemp plant to determine acceptable THC levels as required by the 2018 Farm Bill. This final rule does not cover testing for seeds and stalks individually nor does it cover processing or the licensing of processors.

As described in the IFR, hemp exceeding the acceptable THC level may not be further handled, processed, or enter the stream of commerce. The licensee shall ensure the disposal of the noncompliant crop. Before such disposal occurs, AMS believes it important and necessary that hemp growers be provided the opportunity to remediate THC from non-compliant crops in order to stave off financial risk associated with the loss of investment in their hemp crop.

AMS agrees with comments that consider remediation as a viable activity for farmers to minimize crop loss and to salvage the value of remaining compliant plant material. For this reason, the final rule provides regulatory flexibility that allows remediation activities - either disposing of flower materials and salvaging the remainder of the plant or blending the entire plant into biomass plant material. Through both forms of remediation, the farmer may be able to minimize losses and, in some case, produce a return on investment. A guidance document will

be published with this rule to illustrate approved remediation techniques. USDA will also finalize the guidance document on disposal techniques.

Additionally, AMS determined that pre-harvest sampling and testing yield the truest measurement of THC concentration at the point of harvest. AMS further maintains this position in this final rule. AMS notes that if the test results show the original THC concentration exceeded the Federally allowable limit, the licensee may request the laboratory retest the pre-harvest sample. This retest would not entail the use of post-harvest plant material. However, if the farmer elects to perform remediation activities under a USDA, State or Tribal plan, an additional sampling and testing of the remediated crop must occur to determine THC concentration levels. Only those crops testing below the acceptable hemp THC level limit will be considered successfully remediated and thus allowed to enter the stream of commerce. All other remaining non-compliant crops must then be properly disposed.

AMS believes the inclusion in the final rule of remediation and post-harvest sampling after remediation provides the additional flexibility requested by commenters that expressed the need for farmers to have greater opportunity of success entering the hemp production industry.

REVERSE DISTRIBUTORS

The IFR requires the collection and destruction of noncompliant material by a person authorized under the CSA to handle marijuana, such as a DEA-registered reverse distributor, or a duly authorized Federal, State, or local law enforcement officer or their designee.

Comments: Comments largely opposed the use of DEA-registered reverse distributors to dispose of noncompliant material. Comments asserted that many States and producers operating under the 2014 Farm Bill have implemented policies related to disposal of non-compliant material that do not require DEA involvement. Comments argued there are relatively few registered reverse distributors on DEA's 2019 list and pointed out that some of the major hemp production States have very few or no registered reverse distributors. Comments claimed existing DEA-registered reverse distributors haven't the resources or training to oversee

destruction of large plots of agricultural crops in remote areas, and that such limitations would create a compliance bottleneck. Comments asked USDA to clarify who would be responsible for paying DEA reverse distributors for crop disposal services.

One comment asserted that DEA regulations prohibit reverse distributors from accepting controlled substances from other than DEA registrants, making it impossible for hemp farmers to release non-compliant hemp directly to DEA reverse distributors. One comment suggested that hemp growers could automatically become reverse distributors if their hemp samples test above acceptable THC levels so growers could legally manage crop destruction on their own. Another comment asked whether DEA would allow for a waiver from the current limitation on reverse distributors to allow reverse distributors to accept cannabis material for disposal from individuals or entities who cultivate hemp in accordance with their state's approved plan, but who do not hold a Schedule I DEA registration.

Numerous other comments expressed concern that alternative law enforcement agencies (non-DEA) will face the same resource constraints as the DEA. Comments described how State law enforcement officials are typically unwilling or unavailable to participate in the disposal of noncompliant crops and suggested this is due to the lower prioritization of hemp compliance oversight in light of more pressing public safety and crime intervention responsibilities. For example, a comment representing rural counties said this conflict in priorities is particularly acute in rural areas where resources are already stretched too thin. The comment asserted that while preventing serious violations of controlled substances laws is a priority for law enforcement agencies, hemp with slightly elevated THC levels is unlikely to be sold as marijuana. The comment advocated formulating hemp disposal procedures entirely outside the scope of law enforcement. One comment worried about the stress and stigma on growers having law enforcement personnel descend upon their farms in connection with hemp disposals. Other comments supported allowing State regulatory authorities to oversee or authorize disposal of

non-compliant material, asserting that States can safely and efficiently complete the process at a much lower cost to producers and States.

Some comments supported disposal of non-compliant material by law enforcement. Some suggested that States, rather than Federal agencies, work with State and local law enforcement to handle disposals. One comment suggested that the definition of “duly authorized Federal, State, or local law enforcement officer” be modified to include disposal under the authority of State or local law enforcement in order to address the anticipated increase in required disposals. Finally, comments from Indian Tribes urged USDA to expand the definition of law enforcement in the final rule to include Tribal law enforcement.

AMS response: AMS acknowledges the many stakeholders who expressed through comment concerns about the collection of non-compliant plants by DEA-registered reverse distributors, or duly authorized Federal, State, or local law enforcement. AMS notes that law enforcement policies and priorities are not set by USDA and the 2018 Farm Bill does not provide this authority. To address public comment, this final rule will retain disposal requirements stated in the IFR but will further clarify what “disposal” means relative to the role of reverse distributors.

AMS relaxed the disposal requirements enacted under the IFR in February 2020. This decision followed consultation with DEA. This provided growers the added flexibility to conduct on-farm disposal activities themselves, without required onsite law-enforcement supervision. Based on positive feedback received from State and Tribal oversight agencies and producers following the relaxation of disposal requirements, AMS is permanently allowing for on-farm disposal flexibility in the final rule.

Under this final rule producers do not need to use a DEA-registered reverse distributor or law enforcement to dispose of non-compliant plants (7 CFR 990.3(a)(3)(iii)(E) and 990.27) if the producer disposes of the plants using one or more of the means described by USDA at <https://www.ams.usda.gov/rules-regulations/hemp/disposal-activities>. It is the agency’s intent

that these methods allow producers to apply common on-farm practices as a means of disposal while rendering the controlled substance non-retrievable or non-ingestible. Producers must document the disposal of all non-compliant plants in accordance with § 990.27. Reporting can be accomplished by providing USDA with a completed: “USDA Hemp Plan Producer Disposal Form.”

Cannabis with a THC level of over 0.3 percent on a dry weight basis is a controlled substance, that must be disposed of onsite according to the disposal methods approved by USDA. The State, Indian Tribe or the state’s department of agriculture wishing to have primary regulatory responsibility have the responsibility for establishing protocols and procedures to ensure non-compliant plants are appropriately disposed of in compliance with applicable State, Tribal, and Federal law. States and Indian Tribes operating under approved hemp production plans must notify USDA of any occurrence of non-conforming plants or plant material and provide the disposal record of those plants and materials monthly. There is a similar requirement for producers operating under the USDA plan. Additionally, USDA will conduct random audits of licensees to verify hemp is being produced in accordance with the provisions of the rule.

State and Tribal plans must still include procedures to verify disposal but would have the additional flexibility to use in-person verification where deemed necessary or, when practicable, require producers provide pictures, videos, or other proof of disposal. AMS believes this decision will further alleviate the strain to oversight resources and allow State and Tribal authorities to more efficiently and autonomously monitor hemp production in their jurisdictions.

Additionally, the final rule expands the definition of “law enforcement” to include Tribal law enforcement.

NEGLIGENT VIOLATION THRESHOLD

The IFR specified that a producer commits a negligent violation when a reasonable effort to grow hemp is made and the total THC dry weight concentration exceeds 0.5 percent.

Supporting an increase of negligent violation threshold: Most comments that addressed negligent violations opposed the 0.5 percent total THC threshold in the IFR, and many advocated raising the threshold to 1.0 percent or higher, offering suggestions ranging between 0.99 and 5.0 percent total THC. Comments said the 0.5 percent threshold can be too easily breached by prudent farmers for any number of environmental or genetic factors that are beyond grower control. One comment supported the 0.5 percent negligence threshold, and others noted it but signaled neither support for nor opposition to the threshold particularly.

Some comments suggested that a 1.0 percent threshold would provide a safe environment in which both new and veteran farmers can operate comfortably. Comments in favor of a 1.0 percent negligence threshold noted that several States and other countries have established a 1.0 percent threshold for their jurisdictions that seems reasonable and achievable in most situations. A few comments pointed out that a 1.0 percent threshold is relatively low compared to the THC levels in marijuana, which commenters said typically range from 10 to 15 percent. Other comments advocated higher thresholds that they claim would give farmers the peace of mind to continue building an industry that is just taking off. Finally, one comment asked whether an MU was figured into the IFR's negligent violation threshold and advocated setting the threshold at 1.5 percent THC and specifying that that threshold includes the MU.

A state department of agriculture estimates that 42 licenses would need to be revoked at 0.5 percent stated in the IFR. They further estimate that this number would shrink to only about 12 licenses were the threshold increased to 1.0 percent under the final rule.

A state hemp steering committee commented that a 0.5 percent threshold will deter the experimentation of different varieties and that this research is essential to discovering which varieties work best in different climate zones and soil types as well as for the development of better genetics.

Another state department of agriculture explained that 13 percent of the hemp samples taken in 2019 tested over the THC limit. The average THC level in those failures was 1.07

percent Delta-9 THC post-decarboxylation. A hemp association within the state agreed with the commenter's recommendation that the level defined for negligence should be increased to 1 percent THC.

One comment reported that more than 5.5 percent of the pre-harvest samples collected under the State's plan in 2019 were found to have a THC concentration of greater than 0.5 percent. Another comment reported that 13 percent of hemp samples taken in 2019 tested over the THC limit. According to the comment, data for all years through September 2020 show that most hemp lot failures occur between 0.4 percent and 1.0 percent THC.

Data submitted with a comment from a State University researcher showed that 8.5 percent of 3,508 samples tested during 2018-2020 exceeded the IFR's negligent violation threshold of 0.5 percent THC. The comment said that 65 percent of those would not be considered negligent violations if the threshold were raised to 1.0 percent. Framing study results another way, the comment explained that at a negligence threshold of 0.5 percent, the State would have revoked 42 producer licenses, whereas at a 1.0 percent threshold, the State would have revoked only 12 licenses, given three negligent violations in a five-year period, a reduction of 72 percent in revocations by changing the threshold to 1.0 percent.

One comment reported that based on test results they'd seen this year, 1.0 or 1.5 percent would be a more appropriate threshold for negligence, due to the heterogeneity of the plant and the awareness of the industry.

Implementation timeframe: Some comments suggested that it is too early in the industry's development to determine a realistic numeric threshold, and they recommended USDA delay fixing a uniform standard until the industry has more experience and better understanding of the relationship between all the hemp production factors. Still other comments asserted that negligence should not be determined numerically at all, but by a determination about the farmer's intent. Several comments said that "negligence is a state of mind, not a number."

General comments on 0.5 percent threshold: Several comments argued USDA arbitrarily determined the 0.5 percent negligence threshold. One comment asked USDA to provide the research reports used to inform the selection of the 0.5 percent negligence threshold. Another questioned whether USDA used test results based on the total THC standard established in the IFR to set the negligence threshold, since it was the commenter's experience that producers routinely report difficulty meeting that standard. One comment reported anecdotally that its farm sends three samples from the same composite lot sample to three testing laboratories and gets three different results, which the comment ascribes to the variation in lab procedures. Another comment said that there are no established uniform standards for cannabinoid testing, such that even from reputable labs it will not be entirely clear what the results mean.

The impact of the 0.5 percent threshold on production: Several comments said the 0.5 percent negligence threshold in the IFR provided very little buffer (at 0.2 percent) between the 0.3 percent THC allowed under the program and the 0.5 percent threshold for determining a negligible violation. What several comments called a "safe harbor" for growers was nevertheless considered too narrow by many, saying that it left virtually no room for error. Comments argued that requiring growers to both exercise reasonable care *and* produce crops with only 0.5 percent THC or less is too stringent a standard and does not really offer the "safe harbor" intended. One comment argued that USDA cannot provide a "safe harbor" for violations of the 0.3 percent THC cap because that cap is enforced by other Federal and State agencies. A few comments said that the THC levels in 2014 DEA confiscations averaged 11.84 percent THC and argued that the negligence level under USDA hemp program rules should be closer to the average DEA culpability level.

A comment from a state department of agriculture used 2019 production and testing data to demonstrate that raising the IFR's threshold from 0.5 percent to 1.0 percent could theoretically reduce the number of its farmers exceeding the negligent violation threshold by more than 75

percent. Several comments advocated a 2.0 percent threshold, while others suggested the elimination of the negligence threshold altogether.

Comments highlighted uncertainty in the genetic variation of hemp varieties and other factors like weather conditions, soil type, plant disease, and pest pressures that may further exacerbate the risk of exceeding the 0.5 percent threshold. As well, comments explained that hemp plants mature rapidly just before harvest. One commenter described seeing plants go from 0.18 to 0.62 percent total THC in one week. Comments suggested that enforcing the 0.5 percent negligence threshold on growers who truly do not intend to grow marijuana is excessive penalization when THC levels can change that rapidly. Comments argued that it is not appropriate to add further penalties to hot crop destruction. Other comments suggested that administrative and logistical factors beyond the grower's control, such as bottlenecks in sampling and testing, can likewise create compliance risks for growers under the 0.5 percent threshold.

AMS response: Based on these comments, AMS is increasing the negligent violation to a 1.0 percent threshold. AMS acknowledges that a lower total THC threshold will result in a higher number of negligent violations. AMS also understands that factors beyond the control of farmers may cause an increase in total THC-levels, such as seed genetic, weather and climate, and may contribute to crops exceeding the negligent violation threshold. AMS believes that the data provided in the comments clearly showed that increasing the negligent violation threshold to 1.0 percent would diminish the risk that producers would incur negligent violations without adding a greater risk of non-compliant material reaching channels of commerce.

AMS also reviewed the test results of certified hemp varieties planted in Kentucky in 2017 and 2018 under its 2014 Farm Bill program. Kentucky has a certified seed program that it believes will yield hemp. The plants from the certified varieties tested below 0.8 percent THC concentration level. Additionally, AMS reviewed the test results of varieties that were eligible to be cultivated under the Nevada 2014 Farm Bill program in 2018. The plants from those varieties

tested below 0.9 percent THC concentration level. Given those test results based on varieties that those two states believed would yield hemp, AMS determined that a 1 percent THC concentration level for negligence would account for the fact that a reasonable reliance on certified or eligible varieties may still yield a plant that tests above the acceptable hemp THC level.

The impact of the 0.5 percent threshold on crop research: Comments described the IFR's 0.5 percent negligent violation threshold as a rate limiting factor to industry innovation and hemp research. One comment said that hemp farmers, growing under pilot authorization of the 2014 Farm Bill, routinely planted multiple varieties of hemp to see which performed best. According to the comment, the low negligence threshold in the IFR discourages such hemp trialing and innovation because farmers face greater risk of receiving three negligent violations in one or two seasons and losing eligibility to grow hemp for another five years. Comments from research universities found the IFR's negligent violation provisions unworkable for institutions testing numerous varieties and production variables each season for the same reason. Comments suggested a higher threshold for negligent violation would give industry the regulatory flexibility to conduct research with reduced risk of violating regulatory requirements.

AMS response: AMS recognizes the violation threshold may incentivize (or disincentivize) innovation by research institutions and producers. AMS acknowledges more innovation and research across industry will bring more stability to stakeholders. The 1.0 percent negligent violation threshold provides new and existing producers across States and Indian Tribes additional flexibility to innovate and research with reduced risk for noncompliance. AMS believes the 1.0 percent threshold incentivizes innovation across industry more so than a 0.5 percent violation threshold.

Statutory implications: Some comments argued that establishment of the 0.5 percent negligence threshold in the IFR was arbitrary and capricious under the APA and asked USDA to provide more information about how the threshold for negligence was determined. Some

comments asserted that *negligence* is a well-established legal doctrine, and they argued that USDA cannot artificially and arbitrarily declare a threshold for negligence. A couple of comments suggested that putting farmers on probation, suspending them from program participation, and requiring them to destroy their crops based on an arbitrary number rather than on court findings is a violation of due process under the U.S. Constitution's Fifth Amendment.

AMS response: Congress established the definition of hemp and defined the threshold of THC concentration at 0.3 percent dry weight. The statute did not define negligent violation. USDA derived the definition of negligence from the definition of negligence in Black's Law Dictionary (10th ed. 2014). USDA set the level of total THC concentration at 0.5 percent for a negligent violation to establish a clear buffer so that any crop testing out of compliance would not automatically trigger a violation. The 0.5 percent was based on data from three states participating in the 2014 Farm Bill pilot program. AMS believes raising the negligent violation threshold from 0.5 percent to 1.0 percent in the final rule provides a greater buffer and reduces farmers' exposure to risk of violation accrual and license suspension.

Oversight Authority: Several comments suggested the government should have the ability to determine negligence and culpability based on facts and circumstances surrounding violations and not solely on a numeric threshold. Other comments asserted that the 2018 Farm Bill's language leaves room for an Indian Tribe to apply its own negligence standard. Similarly, other comments from the industry said that States should be allowed to evaluate potentially negligent violations of State plans.

AMS response: With regard to violations and culpability determination, AMS seeks to establish a regulatory framework that ensures consistency in oversight activities of hemp production. Variations of criteria or the use of subjectivity in oversight could result in bias against or leniency to some hemp farmers simply based on location. Leaving the decision of what constitutes a negligent violation to abstract factors rather than objective metrics may result in differences between States and Indian Tribes. Because farmers may grow hemp in different

locations, and in some cases are subject to multiple oversight authorities, it is important the thresholds for violations are consistent across oversight authority jurisdictions to which the grower is responsible. Having a threshold that is well established and transparent provides a minimum framework to producers.

In developing the compliance requirements for State and Tribal plans, USDA recognizes that there may be significant differences across States and Indian Tribes in how they will administer their respective hemp programs. Accordingly, if, at a minimum, the requirements of the 2018 Farm Bill and applicable parts of this regulation are met, States and Indian Tribes are free to determine whether or not a licensee under their applicable plan has taken reasonable steps to comply with plan requirements. As previously stated, this final rule provides that a producer shall not be subject to more than one negligent violation per calendar year. State and Tribal plans may tailor the timing around this requirement to align with their growing season or other applicable dates.

Financial and business risk: Several comments linked the 0.5 percent THC threshold with a greater likelihood of producers committing negligent violations, receiving corrective action plans, and even committing culpable negligent violations. Comments stressed that a low negligence threshold puts farmers at higher risk of accumulating negligent violations, even when growers take reasonably prudent steps to mitigate against the production of noncompliant plants. According to comments, this, in addition to the loss of the crop, jeopardizes farmers' access to crop insurance and business loans.

Comments addressed the negative impact of the accrual of negligent violations on the financial stability of the individual business. They described how a hemp grower's access to credit and insurance is jeopardized when negligent violations accumulate and lead to a determination of culpable negligence. Comments explained that lending institutions and insurance providers look for risk factors. They also raised questions about how the accrual of negligent violations may be interpreted by lender or providers. Comments said that many

insurers will not cover crop losses if losses are due to the growers' negligence. Commenters implored USDA to explain how violations can lead to determinations of culpable negligence and to provide guidance about how a reasonable farmer can avoid growing noncompliant hemp.

AMS response: AMS acknowledges institutional lenders view violations as risk factors in decision making. AMS also notes that not all culpable violations are derived from the accrual of negligent violations. Culpable violations may be the result of producers violating other parts of the 2018 Farm Bill. However, the 2018 Farm Bill explicitly considers certain actions as constituting negligent violations. AMS's intention is to provide a threshold between 0.3 percent THC level and what would be considered a negligent violation so not all hemp that tests over the 0.3 percent be considered a negligent violation. Because a producer will not have committed a negligent violation every time he or she grows hemp with a concentration of hemp above the 0.3 percent level, this will assist producers when requesting loans or other financial assistance. AMS will provide risk mitigation activities such as remediation and disposal provisions as well as increasing the negligent violation threshold to 1.0 percent to diminish the number of violations that are considered negligent.

Some producers have more than one field or farm in a state or across state boundaries. Assigning more than one negligent violation might be detrimental to these producers. For example, if a producer uses the same seed in multiple locations, and that seed results in a THC level over 0.3 percent, all of that production must be disposed or remediated. All of these locations could be determined a separate violation. However, AMS wants to clarify that a producer may not be found to have committed more than one negligent violation per year.

Barriers to entry: Several comments suggested that a 0.5 percent negligence threshold threatens the survival of farmers in an emerging industry. Comments suggested that the low threshold is a barrier to entry for new farmers or farmers with no experience growing hemp, who risk high initial capital investments to establish operations. Comments argued that the low threshold favors larger farms using industrialized hemp varieties and production practices, and

that the low negligence threshold in the IFR would unnecessarily criminalize farmers working with a legal agricultural commodity.

AMS response: All persons interested in growing hemp must meet the eligibility criteria established in the 2018 Farm Bill and this final rule. Negligent violations document instances when the statute or rule are violated such as when a grower fails to report a legal description of land on which hemp is grown or fails to dispose of a noncompliant crop. All farmers, regardless of the size of their operations, face the same set of requirements. Even though the 2018 Farm Bill sets the THC concentration level at 0.3 percent, it does not define what THC level in cannabis will give rise to a negligent violation. Left undefined, this lack of definition is troublesome as it could make enforcement uneven among States and Indian Tribes. The IFR provided that hemp producers do not commit a negligent violation if they make reasonable efforts to grow hemp and the marijuana does not have a THC concentration of more than 0.5 percent. Increasing this threshold to 1.0 percent benefits producers, including small and new farmers, that intended to grow hemp but whose crops tested “hot” even though they made reasonable efforts to grow hemp.

Resources and enforcement: One State commented that it currently enforces a 1.0 percent negligence threshold. According to the comment, lowering the threshold to 0.5 percent would significantly increase the rate of negligent violations in that State, require more State and Federal resources to enforce the regulation, and be financially burdensome to novice farmers. It stated that the 0.5 percent negligence threshold is lower than the threshold DEA designates as the upper THC limit for “inconclusive marijuana/hemp.” The comment found the IFR’s 0.5 percent threshold inconsistent with some laboratories’ testing capabilities and suggests raising the rule’s threshold to 1.0 percent.

AMS response: AMS anticipates that the closer the negligent violation threshold is to 0.3 percent total THC, the greater the likelihood that oversight authorities issue more negligent violations. Moreover, whenever a producer commits a negligent violation, the oversight

authorities must also establish a corrective action plan as required by regulation. AMS believes that increasing the negligent violation threshold to 1.0 percent would therefore reduce some burden to oversight authorities by reducing the number of negligent violations and corrective action plans that oversight authorities must issue and administer. AMS notes that regardless of the negligent violation threshold, any crop exceeding the Federal allowable total THC concentration must be disposed of according to regulatory requirements. AMS disagrees that the DEA's enforcement program for marijuana should affect how AMS manages its compliance program for hemp.

STATE AND TRIBAL RESOURCES

The IFR required States and Tribal governments to certify they have the resources and personnel to carry out the practices and procedures of their respective plans. Further, the IFR provided for audits of State and Tribal plans to include review of the resources and personnel employed to administer and oversee its approved plan. Finally, the IFR specified audit reporting requirements and remediation steps for States and Tribal governments found to be non-compliant with USDA requirements.

Comments: Comments from many States expressed enthusiasm for partnering with USDA in the regulation of domestic hemp production. The comments were supportive of establishing a national regulatory framework that would bring clarity and consistency to the regulation of hemp production across the U.S. They emphasized that many States have enacted legislation to facilitate the regulation of hemp production. No comments received from the States demonstrated a reluctance to work with USDA in establishing regulations.

The requirement for States and Indian Tribes to certify to USDA that they have the capacity to administer a domestic hemp program was not addressed explicitly in any of States' comments. However, many of the comments from the States and Indian Tribes registered concerns with some aspects of the IFR. Most of the comments from States and Indian Tribes

delineated areas where the burden of regulatory oversight might be reduced, or efficiencies realized, by revisions to the regulations.

Several comments expressed concern that State and Tribal governments would not be able to perform their responsibilities under the program as currently established. One comment said the lack of appropriate personnel, training, and protocol would lead to an untenable backlog in the collection and testing of samples. Many comments focused on the sheer number of samples that must be collected, processed, and tested under the program. The shortage of DEA-registered labs in the States and the new sample collection protocols were also areas of concern, although that was addressed shortly after the IFR went into effect with the announcement of enforcement discretion.²⁷ Points of potential weakness in the States' and Tribal governments' implementation of the IFR were raised by many commenters, both explicitly and in implied remarks. Many of the comments referenced State and Tribal government infrastructures being strained under the new regulatory requirements, especially during peak harvest intervals, and that those factors could contribute to the failure of the States and Indian Tribes to fulfill their oversight obligations. A number of comments alluded to the burden of any breakdown in the regulatory scheme being borne by hemp producers directly, as with samples that are not timely collected by State inspectors and the samples then testing "hot" without any remediation options, or labs that are not able to process samples due to capacity issues.

Numerous comments made recommendations to address the increased regulatory burden on States and Tribal governments. Many recommended changing the 15-day post-sample harvest period to 30 days to allow more time for States and Tribal governments to collect and process samples, balance workloads, and alleviate potential backlogs. In addition, several comments contended that the increased sampling requirements in the proposal (i.e. requiring sampling of every lot) would burden the process and contribute to delays in growers receiving results. Those comments recommended revising the sampling protocol (reducing number of

²⁷ <https://www.ams.usda.gov/rules-regulations/hemp/enforcement>

samples required per producer) to help relieve the strain on government resources. Lastly, comments suggested that allowing labs that are ISO 17025 accredited to process samples, as opposed to only allowing labs with DEA registration, would enhance the State's ability to provide validated, accurate, and timely testing.

One commenter said they had talked with a number of States that expressed strong concerns over the additional burdens as a result of the IFR. The commenter further stated that some states they are considering whether to "opt-out" of administering a hemp production plan themselves in favor of USDA administering a plan.

Lastly, one comment stated that if there was a bureaucratic slow down or insufficient resources on the part of USDA, a farm should be allowed to have some recourse to be able to harvest. That comment, and others that were similar in spirit, effectively questioned what mitigation efforts would be undertaken for producers in the short run if a State or Indian Tribe ultimately lacks the necessary resources and personnel to administer its plan and fails to perform the obligations it certified it could undertake.

AMS Response: The issues raised in these comments are mostly addressed under other sections in this rule (e.g., 15-day harvest window, laboratory accreditation). AMS agrees that there are regulatory burdens of this program, which are discussed in this rule. States and Indian Tribes have multiple options that would allow producers in their States or territories to grow hemp. States and Indian Tribes can develop their own plan, send their producers to grow under the USDA plan, or States can continue under the 2014 Farm Bill pilot program. Many States and Indian Tribes assess fees on producers to cover their expenses for sampling, oversight and other costs of this program. These options provide producers different alternatives to grow hemp under different regulatory schemes. Additionally, USDA has decreased the risk of the regulatory burden on States and Indian Tribes being borne by hemp producers by addressing various issues commenters identified that could cause States and Indian Tribes to be unable to timely fulfill their responsibilities such as by modifying the sampling protocol and changing the 15-day post-

sample harvest period to 30 days. Other burdens associated with this final rule that the producer must cover should be considered by producers, as in any agricultural business, before a decision to grow hemp is made.

APPEALS – DENIAL OF APPLICATION AND APPEAL OF TEST RESULTS

The IFR addressed the denial of applications to grow hemp in Part V. APPEALS. The IFR also provided an option to appeal test results in which producers can request that a second test be performed if they disagree with the first test results.

Comments: A comment recommended that USDA establish a clear deadline for applicants who wish to appeal the denial of their grower applications. The comment noted that the IFR already required a State or Indian Tribe appealing the suspension or revocation of a hemp production plan to file an appeal “within the time-period provided in the letter of notification or within 30 business days from receipt of the notification, whichever occurs later.” The commenter noted that no such similar deadline is identified for applicants who have been denied USDA hemp grower licenses.

One comment asserted that denials of “licensure” may occur for “whatever reason.” Two other commenters submitted examples of State regulatory language from California and Ohio, each of which include provisions for the denial of applications for license.

Several comments suggested USDA establish an appeals process through which someone with a felony conviction may demonstrate completion of appropriate steps to become eligible hemp producers.

AMS response: This rule retains the IFR provision that an applicant for a USDA hemp production program license may appeal a license denial to the AMS Administrator. USDA licensees may appeal denials of a license, renewals, license suspensions, or license revocations to the AMS Administrator must be submitted in writing and received within 30 days of the receipt of notification of the denial or within the time-period provided in the letter of notification, whichever occurs later. State and Tribal plans reviewed and approved by USDA are required to

include an appeal process for producers to appeal licensure decisions. In response to the comment that USDA should establish an appeals process through which someone with a relevant felony conviction may demonstrate completion of appropriate steps to become eligible hemp producers, it is important to note that limitations as a result of relevant felonies are set in the 2018 Farm Bill.

APPEALS – TECHNICAL

The IFR stated that producers can request a second test be performed if they disagree or have doubts about the original test results.

Comments: One comment indicated that if there is a discrepancy between compliance testing for THC concentration, there needs to be a process for farmers to appeal. Another comment noted that no administrative appeal process exists for producers who wish to challenge a decision they believe adversely affects them, such as test result. Another commenter cited personal experience with one State agriculture department and described as “unfair” a regulatory system that does not allow for an appeal process through which a farmer may contest test results.

AMS response: USDA is maintaining its position that producers *under a USDA plan* are able to request a second test be conducted when they do not agree or have questions about a test result. This rule provides flexibility to allow States and Indian Tribes to provide for retesting if the State or Indian Tribe chooses to do so.

TRANSPORTATION AND SHIPPING DOCUMENTS

Under the 2018 Farm Bill and the IFR, neither States nor Indian Tribes may interfere with the transportation of lawfully produced hemp through States or Tribal territories, even if hemp production is prohibited within a particular State or Tribal territory. Public comments related to transporting hemp focused primarily on facilitating the interstate transportation of hemp.

Interstate commerce: Many comments applauded the IFR’s reiteration of the statutory provision that allows for interstate shipments of lawfully produced hemp and hemp products

without interference by State or Tribal law enforcement. Some asked USDA to clarify that prohibited interference includes that from State, Tribal, or Federal law enforcement, including DEA. Other comments wanted confirmation that interstate commerce includes entry into and egress from Tribal territories and that Tribal hemp production licenses be honored for purposes of interstate commerce transport and commerce.

Commenters stated they had already encountered situations where States passed temporary regulations conflicting with the 2018 Farm Bill and impeding interstate commerce. For example, comments noted an Idaho Executive Order – Transportation of Hemp – issued in 2019, that they claimed would “excessively frustrate interstate hemp transportation and growth of the hemp industry.” One airline carrier comment explained that under this Order, “transporters may have to stop, get inspected, and be subject to detention each time they cross jurisdictional boundaries” and that airlines would avoid carrying hemp if this issue is not remedied.

Comments from Indian Tribes expressed concern that despite the 2018 Farm Bill, Tribes transporting hemp through States have a bias against Tribal hemp production. There were suggestions of the use of a USDA form or stamp authorizing transportation to address these obstacles. One commenter also requested that USDA provide for recourse for Indian Tribes that are prohibited from moving hemp through neighboring States.

AMS Response: At this time, USDA recommends that transporters carry a copy of the producer’s license or authorization, as well as any other information the governing State or Indian Tribe recommends or requires that will validate that the transporter is transporting legally-grown hemp. As allowed under the 2018 Farm Bill, States and Indian Tribes can be more restrictive, which includes possible transportation paperwork requirements by States or Indian Tribes. USDA is not adding transportation paperwork requirements to this rule because it does not have jurisdiction over common carriers or other types of transporters.

Comment: A comment asserted that intrastate commerce of hemp that does not meet all the requirements of the IFR should remain under the State’s authority, and farmers producing hemp compliant with the 2018 Farm Bill but not the IFR should be allowed to do so, as long as that hemp is not transported across State lines. The comment advocated for no Federal preemption, citing to section 297B(a) of the 2018 Farm Bill, which provides that “nothing in this subsection preempts or limits any law of a State or Indian Tribe that (i) regulates the production of hemp; and (ii) is more stringent than this subtitle.”

AMS Response: The 2018 Farm Bill does not preempt State law provided that the State adopts a plan that is approved by USDA and the plan may provide for more stringent requirements. A State has the responsibility for enforcing the requirements of its plan. Thus, hemp that is produced under a State’s plan should meet the requirements of the final rule.

Shipping Documentation: Several comments encouraged USDA to facilitate the unimpeded flow of hemp in interstate commerce by implementing identity preservation or tracking systems or requiring the use of standardized shipping labels, packaging, or other documentation to certify to stakeholders and law enforcement authorities that the cargo in transport is Federally legal hemp. Comments suggested the use of USDA-issued stamps or forms that are recognizable, understood, and accepted by all law enforcement authorities. Several Indian Tribes made this suggestion because they are concerned about law enforcement transportation issues, particularly in Idaho, South Dakota, Maine, New York and Wisconsin. According to comments, such forms could verify that cargo hemp is compliant with USDA-approved production plans. Other comments suggested the use of a standardized bill of lading across the industry that sets out essential information about the shipment for easy reference by transporters, regulators, processors, and law enforcement officials to ensure all loads have been lawfully produced in accordance with Federal, State, or Tribal law. A comment from an association of county agriculture commissioners and sealers suggested USDA require the

officially certified lab report to accompany shipments of hemp product during interstate shipment.

Comments suggested various commercial systems for recognizing legally produced hemp in transport. Other comments asked USDA to devise a standard documentation system for hemp carriers that would more easily absolve them of legal liability related to transporting hemp. Comments recommended that USDA coordinate with the hemp industry; Federal agencies such as DEA, the Department of Transportation, and the Department of Justice; and State agencies, including law enforcement and transportation departments, to develop such documentation.

Some comments additionally recommended adopting specific hemp packaging and labeling requirements on the basis that they would support compliance and enforcement tasks. Some comments advised USDA to provide specific regulations for testing hemp in transit so that such testing, if necessary, be conducted in a standard manner, consistent with the requirement that all pre-harvest Total THC testing be conducted by DEA-registered laboratories. Other comments recommended that hemp loads be sealed to ensure their integrity and mitigate the interference of illicit products.

Comments advocated that USDA host a central hemp database for reporting data applicable to all phases of hemp production that would be “read only” to law enforcement, saying such a system would be particularly beneficial in resolving questions related to interstate commerce. One comment advocated for the use of a centralized hemp clearinghouse to capture hemp flower transfer to processors or manufacturers for CBD extraction, including information on the licensed producers and receivers of raw materials, the total weight of materials being transferred, testing certificates indicating THC levels of the materials being transferred, and other State-mandated criteria, as well as information on the vehicles being used to transport the materials. It further recommended USDA evaluate methods to physically identify and segregate products containing hemp-derived CBD to differentiate legitimate from potentially illicit products.

AMS response: AMS understands the importance of ensuring safe passage of hemp across states and Tribal jurisdictions. Section 10114 of the 2018 Farm Bill specifically states that “Nothing in this title or an amendment made by this title prohibits the interstate commerce of hemp.” USDA issued a memorandum addressing this issue²⁸. Several States already identified documents to facilitate transportation of hemp across states. AMS strongly encourages producers of hemp and carriers providing transportation services to provide the following documentation accompanying the hemp cargo: copies of the laboratory testing report(s), hemp grower license, invoice / bill of lading, and contact information of buyer and seller. The 2018 Farm Bill does not provide specific authority to USDA to This final rule does not adopt any requirement for interstate transportation of hemp. As required by the 2018 Farm Bill, USDA is developing a database that will share information about hemp production with law enforcement. The database will identify the contact information for the producer, a legal description of the land on which hemp is produced, and status of the producer’s license or other required authorization from the State or Indian Tribe.

“IN-PROCESS” MATERIAL

Comments: Several comments mentioned “in-process material,” described as material made from otherwise qualifying hemp plant material, such as crude CBD oil and distillate, or as any hemp material that is compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any way for use in the manufacture of hemp products. Commenters asked USDA to clarify that once hemp has been tested and allowed to enter commerce, it should be considered legal material thereafter. One comment suggested the establishment of specifications or guidance for any part in the “in-process material” manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the hemp products and, as necessary, for limits on

²⁸ Memorandum from Stephen Vaden, Office of General Counsel to Sonny Perdue, Secretary of Agriculture, LEGAL OPINION ON CERTAIN PROVISIONS OF THE AGRICULTURE IMPROVEMENT ACT OF 2018 RELATING TO HEMP (May 29, 2019).

those types of contamination that may adulterate or may lead to adulteration of the finished batch of the hemp product.

One comment explained the perception that in-process materials are not allowed to transfer freely between processors, causing bottlenecks in product processing. According to the comment, some hemp processors may be limited to performing only one step of a multi-step process to derive hemp products, such as distilling CBD oil and isolating the CBD molecule. It said processor-to-processor transfers of in-process hemp materials should be authorized between U.S. States with valid hemp programs, which would open a processing bottleneck and allow both hemp materials and cash to flow more freely. The comment asserted such authorization would improve prices for CBD end-products, which would trickle down to hemp growers.

Some commenters stated that it is commonly known that THC levels in initially compliant hemp may rise above the 0.3 percent delta-9 THC limit during subsequent processing. Commenters expressed concern that some jurisdictions believe the “in-process material” should be diluted to always maintain the level below 0.3 percent delta-9 THC, even during transportation to another processor. However, several comments argued that “in-process material” is neither consumer ready nor a “finished” product and that dry-weight measurements related to hemp THC levels are calculated on the initial plant material and not the finished product to ensure compliance with the threshold.

AMS response: The 2018 Farm Bill directed USDA to establish a national regulatory framework for hemp production in the U.S., and the final rule outlines provisions for this mandate. The IFR and this final rule do not cover hemp or its products beyond production. Further, DEA has issued regulations covering some of these products or “in-process materials”.²⁹ Accordingly, this final rule does not address “in-process materials,” processors, end-products,

²⁹ <https://www.govinfo.gov/content/pkg/FR-2020-08-21/pdf/2020-17356.pdf>

processing of CBD or other cannabinoids or anything that may contain hemp or hemp byproducts.

EQUAL TREATMENT FOR TRIBES

Comments: Some commenters said that final rule should provide Indian Tribes at least as many opportunities regarding hemp production and regulation as those granted to States and that the final rule should allow Indian Tribes to catch up quickly with States that have been allowed to develop production methods and markets under the 2014 Farm Bill provisions.

AMS Response: This final rule does not distinguish between States and Indian Tribes. USDA recognizes that both State and Tribal governments have the ability to authorize and to regulate the production of hemp within their States or territories consistent with the 2018 Farm Bill and the final rule.

PSYCHOACTIVE EFFECTS OF CANNABINOIDS

Delta 9 THC or THC is the primary psychoactive component of cannabis. As mandated by the 2018 Farm Bill, hemp must be verified as having THC concentration levels of 0.3 percent or below on a dry weight basis.

Comments: Several comments referenced different studies to support conflicting positions regarding the psychoactive effects of THC and used study findings to argue that the IFR's THC limit should be revised. Many comments cited the "Defining Hemp: A Fact Sheet" from the Congressional Research Service, updated March 22, 2019, that said a level of about 1 percent THC is considered the threshold for cannabis to have a psychotropic effect or an intoxicating potential. Other commenters argued THC levels of 5 percent or more are necessary for marijuana to have a psychoactive impact or commercial value. Comments noted that hemp is generally characterized as plants that are low in delta-9 THC and high in levels of CBD, the primary non-psychotropic compound. Many comments stated that research shows that CBD affects the ability of THC to bind to CB1 receptor in cells, thus blocking the psychoactive effects of THC.

Other comments representing health organizations stated that research is challenging the widely accepted premise that CBD is not intoxicating. They further stated that the THC found in CBD products can be intoxicating and has caused significant and serious consequences in terms of job loss, health, and exposure to pediatric populations. Some comments provided personal testimony that while using CBD for health benefits they had not experienced psychoactive or intoxicating effects.

Other comments reported that the United Nations standard STR/NAR/40 uses a ratio of $([THC] + [CBN]) / [CBD]$ to determine whether a plant is likely to have a psychoactive effect.

AMS response: AMS appreciates understanding different views on the psychoactive effects of THC. However, this topic is outside the scope of the final rule, and AMS made no revisions to the program based on these comments. The 2018 Farm Bill defined hemp as having a THC concentration of 0.3 percent or less. Medicinal use of hemp or CBD is covered under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ch. 9, sec. 301, et seq. and under the FDA's jurisdiction.

MISCELLANEOUS COMMENTS

Comments: One comment pointed out that the IFR's hemp definition did not include the application of an MU, but that the definition of acceptable hemp THC level does. The comment said references to the definition of hemp should be changed to refer to acceptable hemp THC level so there is uniformity across the final rule.

AMS Response: USDA has made references to acceptable hemp levels when appropriate. The acceptable hemp levels include the MU to account for differences in laboratory conditions or environments. There is no intention to change the definition of hemp that is stated by the 2018 Farm Bill.

Comments: Another comment recommended improving the clarity of the final rule by deleting the words "or THC" from the definition of delta-9 THC, as well as deleting the sentence "For the purposes of this part, delta-9 THC and THC are interchangeable." The comment further

recommended that the definition of Total delta-9 THC be expanded to clarify that it includes delta-9 THC combined with delta-9 THCA to account for the conversion of delta-9 THCA into delta-9 THC when the plant material is dried. Finally, the comment recommended that in all cases where “THC” is referenced throughout the final rule document with no further clarification, “THC” should be changed to “delta-9 THC.” The comment said these clarifications will be helpful in administration of the rule.

AMS Response: AMS is adding a definition of “Total THC” to clarify the use of the term in this rule. Total THC accounts for the conversion of THCA into THC. We believe using THC and delta-9 THC interchangeably is appropriate.

Comment: One comment claimed that making the IFR effective immediately gave farmers preparing for imminent harvest no time to comply with the new testing and threshold requirements, increasing their risk of producing plants that were legal under the 2014 and 2018 Farm Bill statutes but potentially illegal under the IFR.

AMS response: USDA’s decision to make the IFR effective immediately was to provide a framework for the 2020 growing season. However, States had the option to continue operating under the 2014 Farm Bill. States and Indian Tribes were provided time to develop plans on time for their planting and harvest season.

Comment: USDA should work with other agencies, including DEA and DOJ, to develop cohesive information and guidance regarding enforcement related to hemp.

AMS response: AMS has worked with DEA and other agencies in developing these regulations to assure that the intent of the 2018 Farm Bill provisions for hemp are met. USDA is responsible for the regulatory oversight of hemp production and DEA and other law enforcement agencies are responsible for enforcing the law regarding marijuana.

MISCELLANEOUS COMMENTS – OUT OF SCOPE

In addition to addressing specific provisions of the IFR, comments also addressed other topics related to the hemp industry.

Comments: One comment advocated the creation of a USDA commodity checkoff program for one or more categories of hemp (e.g. grain, fiber, CBD) and recommended that USDA work with hemp industry trade organizations and stakeholders to administer checkoff funds to support hemp agronomic and market development. Another comment included a newsletter item quoting USDA as saying that such a program could be developed.

One comment asked USDA to support the hemp industry by adding hemp seed foods to those offered through school lunch and other government feeding programs.

One comment said that hemp extracts and concentrates and byproducts from hemp should be afforded the same legal status and protections as the hemp from which they originated.

One comment suggested that the IFR did not consider compliant hemp topical products that make up a large portion of the market or other applications that cannot be inhaled or ingested.

One comment advocated that hemp and CBD should be covered and protected under the Perishable Agricultural Commodities Act (7 U.S.C. 499 *et seq.*).

Some comments said farmers should only be allowed to sell hemp to licensed brokers, handlers, and processors, and not directly to the public. They further advocated requiring license information to be part of the documentation that accompanies hemp shipments.

A couple of comments urged USDA to establish good manufacturing practices for CBD manufacture.

One comment claimed that chemical and seed providers have developed aggressive tactics which may be used to hamper hemp producers.

One comment requested updating banking regulations to allow banks to do business with entities whose income is derived from hemp and/or legal cannabis. Another comment requested an examination on how bonding could protect hemp farmers against companies and contracts that have not been honored, causing financial harm to the grower.

One commenter suggested to discontinue the program totally or at least discontinue the CBD portion because there is too much potential for abuse and waste of taxpayer dollars. The commenter stated that it could be okay to continue the coverage for the seed and fiber. They also stated that USDA should not be in the marijuana business.

AMS received comments on the impact of the current statutory and regulatory structure on banking and insurance related to hemp production. Commenters expressed concern that the 0.3 percent THC ceiling and the required disposal of cannabis testing above 0.3 percent THC would hinder the ability of hemp producers to obtain insurance, loans, or other financial services. One commenter also urged AMS to clarify if the preemption language in section 10114(a) of the 2018 Farm Bill encompasses interstate banking, financial services, and insurance transactions and if USDA intends to supersede, coordinate, or adopt guidance issued by other Federal agencies related to hemp production.

A comment suggested banks could offer insurance for crop losses if the hemp had a THC concentration that was greater than 0.3 percent but less than or equal to 0.5 percent, similar to offering coverage for losses due to factors beyond the grower's control, depending on various USDA culpability findings. Another comment advocated that crop insurance be available for hot hemp.

A comment stated that Non-Irrigated (NI) acreage should be uninsurable because good producers who are serious about growing the crop would not bother with NI acreage. Another comment discussed establishment of "Earliest Plant Dates" (EPD), Late Plant Period (LPP), and Final Plant Date (FPD), and references sections of what may be a State or Tribe plan and the difficulty of finding farmers growing hemp in comparable environments for determining such dates and insurance coverage. It also recommended developing a Replant Endorsement (with premium associated) to insure 50 to 75 percent of seed costs for replant. Finally, a commenter stated that germination tests should be required before the crop is planted and set a minimum standard of 85 percent germination—and those under that standard would be uninsurable.

Several commenters argued that USDA should (1) ban hemp and hemp related products imported into the United States; (2) establish import limits on the number of clone material; (3) eliminate all imported hemp and concentrates into the U.S. for the next 2 years, except for trades to the Canadian marketplace, but exportation must still be open for our country and product markets outside the United States; and (4) establish clear rules on how imported hemp and hemp products will be regulated.

One commenter expressed concern about the current regulation of CBD as a prescription drug arguing that the prescription-only status for CBD is unwarranted and will facilitate the illegal market that continues to exist for these products. One commenter noted that the regulatory ambiguity resulting from the FDA's lack of guidance on CBD negatively impacts hemp producers and requires greater clarity.

One commenter raised concerns about the ability of farm workers seeing U.S. naturalization to be able to participate in hemp production based on a fear that U.S. Immigration and Customs Enforcement will view work in hemp production as an "exclusionary activity" that would be a barrier to naturalization.

Several commenters expressed concern regarding hemp production in close proximity to other agricultural crops. Commenters also expressed concern regarding drying and processing of hemp near other crops and residential areas. One commenter suggested that AMS support research on pollination and drift related to hemp production.

One comment asked USDA to clarify whether section 10114(a) of the 2018 Farm Bill extends to interstate banking, insurance, or financial services involving hemp and hemp products. According to the comment, it is not clear whether interstate commerce in hemp and hemp products necessarily includes the payment for any hemp and hemp products through various methods, such as wires, checks, automated clearinghouse transactions, credit card or other financial transactions, including loan proceeds.

One comment advocated the use of their company's blockchain technology to address industry and law enforcement concerns about chain-of-custody in sampling, transporting, and testing hemp.

One comment requested that a clear statement be included in the final rule that USDA concurs that the exportation of hemp and hemp products is legal. It noted that the 2018 Farm Bill does not prohibit exports, and stated, without providing any empirical evidence, that there is sufficient interest in exporting hemp and hemp products from the U.S. It also suggested that a dedicated tariff code for hemp and hemp-derived products be established to facilitate export trade.

AMS Response: These comments all address issues that are beyond the scope of the rule. This rule only covers the production of hemp. Issues such as promotion of hemp under a research and promotion program; adding this product to other programs including feeding programs or PACA; importing or exporting of hemp; who can produce hemp in the U.S.; processing the commodity; insurance and banking; research or setting production boundaries; requirements on further products such as CBD; or other subjects mentioned above, are not the subject of this rulemaking or within other USDA or federal, State, Tribal, or private industry responsibilities and authorities.

COMMENTS ON THE IFR'S REGULATORY ANALYSES

CIVIL RIGHTS REVIEW

The IFR included a Civil Rights review that found the rule would not have adverse effects on protected persons or groups, deny them program benefits, or subject them to discrimination.

Comments: One comment indicated that small farmers face challenges related to costs of seed. Another commenter associated the destruction of non-compliant hemp as posing a great risk of economic hardship on hemp farmers, especially the small minority farmers.

Several comments from Indian Tribes explained that certain provisions of the IFR, for example laboratory DEA-registration requirements, the definition of key participants, and Tribal law enforcement availability, did not sufficiently account for the specific circumstances and challenges facing Indian Tribes across the nation such as the remote location of many Indian Tribes, the limited economic resources of Indian Tribes, and Tribal decision-making structures. Comments pointed out that this final rule must ensure Tribal civil regulatory authority to help Tribal nations build and implement successful plans. Other Tribal comments identified the requirements for the complete destruction of the plant as, “disproportionately economically disastrous for our small Native American farmers,” explaining that Native American farmers tend to be significantly smaller and operate on very small margins.

One commenter suggested that AMS reconsider the potential civil rights implications of this rule on the convicted felons because the IFR, if unchanged, will have a disproportionate negative impact on both Black and Latino Americans, who according to DOJ data, represent 38.8 percent and 37.2 percent (respectively) of the total population of Federally sentenced drug offenders. The commenter compares this data to the data from U.S. Department of Health and Human Services’ rates of illicit drug use among White Americans (9.5%), Black Americans (10.5%), and Latino American (8.8%).

Another commenter claimed that using “flawed/inaccurate science with lower standards is a direct example of failing to preserve the protection of the public at large,” and “USDA cannot legally implement their proposed rules without violating the mission statement of the agency.”

AMS response: AMS considered the potential civil rights implications of this rule on minorities, women, and persons with disabilities to ensure that no person or group shall be discriminated against on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. Additionally, this rule would not deny any persons or groups the benefits of the

program or subject any persons or groups to discrimination. This rule is neutral and of general applicability.

We also note that some of the burdens or hardship described in the comments are required by the 2018 Farm Bill. First, the 10-year ineligibility restriction applicable to persons convicted of a State or Federal felony is a requirement of the 2018 Farm Bill. Also, as stated previously the basis for the DEA lab registration is rooted to the statutory requirements of the Controlled Substances Act, that requires any laboratory that might potentially handle a controlled substance to undergo the DEA registration process and thus cannot be eliminated. Additionally, the 2018 Farm requires effective disposal of non-compliant plants.

Moreover, AMS conducted a Civil Rights Impact Analysis in accordance with USDA's Departmental Regulation 4300-004: Civil Rights Impact Analysis.³⁰ AMS's analysis did not find any evidence that the final rule would adversely or disproportionality impact hemp producers in protected groups, regions or Tribes as compared to the general population of hemp producers or State Departments of Agriculture.

REGULATORY IMPACT ANALYSIS

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives when an action is deemed to have significant impacts. If regulation is necessary, then agencies must select the action that maximizes net benefits, including potential economic, environmental, public health and safety effects, and equity. Executive Order 13771 mandates that agencies provide the best approximation of total costs associated with a new or repealed regulation. AMS prepared a Regulatory Impact Analysis (RIA) with the purpose of accomplishing these objectives.

Comments: Very few comments addressed the RIA specifically, but we received many comments with information related to assumptions that fed into the RIA such as percent of hot

³⁰ <https://www.ocio.usda.gov/sites/default/files/docs/2012/CRIA%20DR%204300-004-final.pdf>

hemp, testing burdens, lab registration burdens. AMS addressed these comments in the general comment section and took into consideration information provided for the RIA.

One comment acknowledged that USDA's economic analysis was based on sound and reasonable methodology but said that its expectations were not confirmed by actual market events in 2019. The commenter compiled production data provided in other comments in an effort to present a more current analysis of the hemp market. The comment pointed out that the RIA underestimated the number of hemp production licenses that would be issued and hemp acres that would be planted in the 2019 growing season. According to the comment, while the RIA called only for a doubling of licenses beyond the 2018 benchmark, the actual rate of licenses increased by 476 percent in 2019. Similarly, the comment reported actual planted hemp acreage in 2019 to be close to 230,000 acres, well over the 155,000 acres assumed by the RIA. The comment went on to say that the rate of growth for new licenses outpaced the rate of growth for consumer sales by 3:1, while the RIA had assumed a 1:1 rate over the next four years. The comment explained that supply growth has outstripped demand and created significant market imbalance and, as a result, market prices have dropped and driven down revenues to hemp producers.

The comment cited the gross revenue for floral material estimated in Table 1 of the RIA, which ranges from \$2,333 to \$24,000 per acre under the assumption that two-thirds of an acre is planted for floral material. Based on market data published in November 2019, after the IFR's publication, the comment suggested that the actual range of gross revenue for floral material per two-thirds of an acre was \$2,728 to \$17,261. The comment then applied the variable cost of planting one full acre of floral material estimated in the RIA, \$28,638 per acre, to this range of gross revenue. This calculation resulted in a loss of \$11,377 to \$25,910 per acre, which the comment said is incorrect given that the variable cost per acre of floral material was deducted from the gross revenue per two-thirds of an acre. For an accurate estimate of net revenue, it

stated that gross revenue and costs must be represented in terms of the same unit of measurement.

The comment suggested that the downstream effects of an unbalanced economic supply equation would further disrupt the profitability of sectors that are intended to support the transportation, processing, and retail sales of the product. It cited sales data reporting a 50 percent decline in the price of CBD extracts and concentrates from April 2019, stating that the oversupply of hemp has affected the entire commercial supply chain.

The commenter disagreed with the methodology used to project the net social benefit of hemp per acre in the IFR, saying that methodology assumed social benefit is a static figure. The commenter asserted instead that social benefit is “a fluid figure that is heavily influenced by time and supply and demand economics” and that it will likely fall over time.³¹

Further, it argued that the estimated 2019 societal willingness to pay of \$2,650 per acre, which was calculated in the RIA using Kentucky grower sales and planted acreage, is not representative of the rest of the United States. Based on the hemp product sales in Chart 1 of the RIA, the estimated return to producers of processor sales of 31 percent, which was calculated in the RIA by comparing Kentucky grower and processor sales, and total U.S. planted acres estimated in Table 3 of the RIA, the comment calculates a 2019 national societal willingness to pay of \$2,325 per acre. This result indicates that the societal willingness to pay based on Kentucky data is 14 percent higher than the estimate for the United States as a whole. The comment also calculates a national societal willingness to pay for 2018 of \$4,047, which illustrates that a decline in societal willingness to pay of 42.5 percent occurred in 2019.

The comment cautioned that the net social benefit calculated in the IFR was over inflated because it represents a point in time during the industry’s infancy. The comment argued that the industry faces a market depression and recommended a quota system for licensing classified by intended use. In this recommendation, the comment offered a detailed approach to estimating

³¹ <https://beta.regulations.gov/comment/AMS-SC-19-0042-1490>

acreage required to meet demand for hemp grown for use in the CBD market. The analysis resulted in an estimated 44,509 acres required to meet demand in 2020, 83,336 acres for 2021, 188,558 acres for 2022, 255,899 acres for 2023, and 309,773 acres for 2024. The comment expanded upon its recommendation of a quota licensing system, suggesting that a number of licenses be granted by range of acreage, thereby ensuring that a share of licenses is reserved for small farmers.

Another comment asserted that unless the IFR definition of hemp is revised to include cannabis with a total THC level of not more than 1.0 percent on a dry weight basis, it will not be economically viable to grow hemp for flower in the U.S. According to the comment, if the THC limits of the IFR are maintained in the final rule, the RIA should be revised to reflect the impact of the rule on total yield and CBD concentration of harvestable flowers, reduced value of CBD hemp seed, and the unknowable market value of CBD. The comment predicted that although the value of hemp seed for flower might be reduced marginally, other input costs would remain very high.

One comment recommended differentiation between hemp biomass and hemp flowers in the IFR's analysis of market prices for floral material. The comment said that hemp biomass refers to full plant material, including stems, leaves, and flowers, while hemp flower refers to the part of the plant that contains trichomes which houses richly and densely populated cannabinoid content. The comment said the prices in the RIA are consistent with prices for hemp biomass, and suggested prices for hemp flowers ranging from \$25 to \$800 per pound, depending on the percentage of CBD present.

Two comments asserted that USDA grossly underestimated the sampling time and cost in the IFR. Comments were concerned that readers might assume hemp sampling and testing costs fees are preset. The comments suggested that hemp sampling is a more complex logistical problem than contemplated in the IFR because of the geography and scope of sampling on farms. The comments encouraged USDA to calculate anticipated sampling costs to include a minimum

number of hours for each step in the sampling process, and to consider factors such as travel time and coordination of supplies and personnel for the sampling effort.

One comment disagreed with the IFR statement that the new hemp production program would expand production and sales of domestic hemp, benefitting U.S. growers and consumers. The commenter said that production costs for his CBD hemp farm were approximately \$16,000 per acre, but because of the IFR’s restrictiveness and his resulting inability to bring the crop to full maturity, the crop would likely only return \$9,000 per acre. The commenter said they were unwilling to make that kind of risky investment and was unwilling to decide whether to plan for future crops until USDA finalizes its rule.

AMS response: AMS is aware that the number of licenses and amount of acreage that were estimated in the RIA of the IFR were underestimated. Entrance of producers into the market spiked at an unexpected rate in 2019, driving up acreage along with licenses. AMS utilized the most current data available to it in its analysis of the hemp market in the IFR and the final rule.

Regarding the estimate in one comment of net loss ranging from \$11,377 to \$25,910 per acre, it is important for gross revenue and costs to be represented in the same unit of measure for an accurate net revenue calculation, which, in this case, they are not. The variable cost per one acre of floral material was deducted from the gross revenue per two-thirds of one acre of floral material, resulting in a larger loss than if calculated using the same unit of measurement. AMS has adjusted the calculation of net revenue in the table below using the market price data cited by the comment. AMS appreciates the comment’s citation of its sources and utilized similar sources in the RIA of this final rule.

Low estimate					
Planted acres	Yield	Price	Gross revenue	Variable cost	Net revenue
2/3	1,000	\$ 4.09	\$ 2,727	\$ 19,092	\$ (16,365)
1	1,000	\$ 4.09	\$ 4,090	\$ 28,638	\$ (24,548)
High estimate					
2/3	1,200	\$21.58	\$ 17,264	\$ 19,092	\$ (1,828)
1	1,200	\$21.58	\$ 25,896	\$ 28,638	\$ (2,742)

Furthermore, AMS understands and appreciates the commenter's argument that net social benefit and societal willingness to pay are over inflated in the IFR. Due to the relative scarcity of industry data, AMS made many assumptions in its analysis in the IFR, some of which were not realized. In order to caution industry stakeholders of the volatility of the hemp market, however, AMS used variable cost estimates to calculate net returns to producers, which ranged from a loss of nearly \$17,000 to a gain of \$6,240. In the single year since publication of the IFR, a greater amount of data has become available to AMS, which allows the analysis in the final rule to rely less on assumptions that may not be actualized.

AMS only has the authority regarding hemp regulation granted to it by the 2018 Farm Bill. The recommendations to establish a quota system for issuing licenses based on intended use and to revise the definition of hemp such that it includes cannabis with up to 1.0 percent total THC on a dry weight basis are outside of the authority of USDA. The 2018 Farm Bill provided USDA no authority to regulate production volume. Additionally, USDA cannot adjust the statutory definition of hemp.

AMS has also reviewed the sampling procedures and costs characterized in approved state and Tribal plans to better estimate the time and resultant fees that will be charged to producers for sampling in the hemp program.

SMALL BUSINESS IMPACTS

AMS performed a Regulatory Flexibility Analysis (RFA) in conjunction with the IFR that considered the effects of the rule on small businesses particularly.

Comments: One organization that represents the views of small entities stated that small hemp producers have significant startup costs that affect their ability to be competitive in the hemp industry. The comment notes that hemp production is labor-intensive and has licensing and regulatory costs that are not typically incurred by producers of other agricultural 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 this rule. Further,

comments conveyed that this rule will raise real barriers to entry for small and disadvantaged producers and could prevent these critically important producer groups from even entering the hemp industry.

Other comments stated that the negative effects of the regulatory incongruence in the IFR disproportionately affect farmers, in particular new and small farmers—and small or already disadvantaged hemp farmers will face additional risks if the IFR is not changed.

One comment claimed the 2014 and 2018 Farm Bills presented an innate prejudice for institutional research, including State departments of agriculture and institutions of higher education and this prejudice continued in the IFR. The commenter says this is similar to the bias of California's draft State plan, where individuals permitted to be grower or breeders, but the program's compliance burdens are effectively beyond the reach of most individuals.

Commenters stated that this rule will disrupt small producers who were successfully producing hemp under prior pilot programs. One organization reported that hemp producers have stopped growing hemp altogether until they can be certain about what the requirements for producing hemp. Comments also reported that some hemp buyers have not renewed their contracts. Comments stated that several of the provisions of this rule impose unnecessary burdens on small entities. Comments suggested that many of the sampling and testing requirements should be revisited and alternatives should be considered and analyzed to minimize the burden to small producers. In addition, comments said that small business are very concerned about the risk of losing their economic investment due to mandatory disposal, the lack of control over growing conditions, genetics of neighboring crops, and timing and precision of the testing.

Comments from State departments of agriculture expressed strong concern as to the additional burdens they would incur as a result of the rule. These 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.

One comment claimed that, based on six years of administering their hemp program, many of the most rigid requirements of the IFR are not only unnecessary, but also likely to have a disproportionately adverse impact on new farmers and farmers with smaller operations. According to the comment, these farmers already face great risk in the current marketplace, and need regulatory help, rather than impediments, in order to grow and thrive. The comment urged AMS to provide a more sensible, flexible, and practical regulatory scheme to encourage industry growth.

AMS response: AMS understands that there is a great deal of uncertainty in the hemp industry currently and has made efforts to minimize any burden which may befall producers as a result of this rule. To that end, USDA is not charging producers any fees for licensing or collecting any fees from producers to support AMS' administration of the hemp program. The fee structure developed by States and Indian Tribes to administer their hemp programs lies outside of the purview of USDA. On average, AMS anticipates total fees paid by producers under a State or Tribal Plan to amount to \$800 per grower. This amount includes licensing and other fees intended to generally fund the operations of States or Tribal Programs. Fees for sampling and testing, on average, amount to about \$300 per lot. The cost for an annual background check for three key participants is \$54. AMS estimates an annual reporting and recordkeeping burden of \$129 per grower. Altogether, these costs total \$1,283 per grower, assuming one lot requires sampling and testing. This total cost is 0.1 percent of \$1 million, which is the largest amount in annual receipts that a grower may receive to be considered to be a "small business" under the Small Business Size Standards of the U.S. Small Business Administration (SBA).

In response to comments, AMS has revised its sampling and testing methodology to allow for performance-based sampling, which should reduce the burden on all producers, large

and small. Section 990.3 details this revised methodology. In addition, AMS has modified its disposal requirements, and allows for remediation of noncompliant crops. These remediation options are described in § 990.27.

AMS understands the concerns raised by state departments of agriculture regarding the requirements of administering a commercial hemp program. For this reason, AMS has made every effort to provide States and Indian Tribes flexibility to administer their hemp programs, including whether they charge for fees or other costs or cover those expenses from other State or Tribal resources. If the burden for a State or Indian Tribe to administer its own hemp program remains too great, however, the State or Indian Tribe may elect to participate in the Federal plan and allow AMS to administer the program. By providing this flexibility, USDA believes it is less likely that the burdens on State and Tribal resources will be passed on to small businesses.

TRIBAL MATTERS

The IFR provided that States and Indian Tribes may submit hemp production plans to USDA for approval. Individual producers from States or Tribal territories that do not have USDA-approved plans may file separate applications for hemp production licenses under the general USDA hemp production plan. Below are several comments and AMS's responses regarding matters of particular concern to Indian Tribes and Tribal members.

Comments: Comments said the regulations fail to treat Indian Tribes on an equal basis with States by repeatedly failing to include the term "Tribe" when referring to the State and local jurisdictions. According to comments, by doing so, the regulations fail to respect Tribal sovereignty and self-government.

AMS response: USDA agrees that Indian Tribes must be treated the same as States under the regulations. There were a few occasions where USDA mistakenly left out "Tribe" from the language in the regulation. USDA is correcting these mistakes in the IFR by revising the language of the final rule to insert "Tribe" after "State" in the definition of *Law Enforcement Agency* in § 990.1; insert "Tribe" after "State" in § 990.24(a); and revise § 990.40(d), which

incorrectly referred to “States and territories of Indian Tribes,” to refer to “States and Indian Tribes”.

Comments: Several comments asserted that USDA should not define “territory of an Indian Tribe” and claimed that by doing so, USDA violates Tribal treaty rights to farm on Tribal territories. Comments argued that such a definition should be left up to each Indian Tribe. Further, comments contended that the definition of “territory of an Indian Tribe” at § 990.1 inappropriately refers to a criminal statute, 18 U.S.C. 1151, to define an Indian Tribe’s territory and regulatory jurisdiction. Other comments supported the use of the Indian country definition, but asked for the removal of the requirement that the lands must be within the Indian Tribe’s jurisdiction, primarily because it causes uncertainty as to whether Indian Tribes may regulate hemp production on non-Indian owned fee lands within a Tribe’s territorial boundaries. Comments also asked that AMS clarify that States cannot interfere with hemp production within the territory of an Indian Tribe.

AMS Response: If an Indian Tribe does not assume primary jurisdiction over the Tribe’s Indian territory, USDA has jurisdiction over the hemp production on an Indian Tribe’s territory pursuant to the 2018 Farm Bill. USDA, therefore, must know the limits of its jurisdiction over such Indian territory, just as it must know its jurisdiction over lands ordinarily within State jurisdiction.

The IFR defined “territory of the Indian Tribe” at 7 CFR 990.1 as having the same meaning as “Indian Country” in 18 U.S.C. 1151. Upon consideration of comments submitted by Indian Tribes, USDA concurs that reference to the criminal law definition of Indian country could be confusing.

Therefore, in the final rule USDA revised the definition of “territory of the Indian Tribe” to incorporate language from other Federal statutes, but without explicitly cross-referencing such statutes. Specifically, the final rule defines “territory of the Indian Tribe” to mean (a) all land within the limits of any Indian reservation under the jurisdiction of the United States

Government, notwithstanding the issuance of any patent, including rights-of-way running through the reservation; (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state; (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same; and (d) any lands title to which is either held in trust by the United States for the benefit of any Indian Tribe or individual or held by any Indian Tribe or individual subject to restriction by the United States against alienation and over which an Indian Tribe exercises jurisdiction.

In the 2018 Farm Bill, Congress provided authority for any Indian Tribe to seek USDA approval to become the primary regulator of hemp production within the “territory of the Indian Tribe.” The 2018 Farm Bill did not provide a definition of the term territory of the Indian Tribe, and there is no universally accepted definition of that term, or similar terms, within the field of Federal Indian law. In describing jurisdictional boundaries associated with Indian Tribes, various Federal statutes use several terms, including Indian country, Indian lands, Federal Indian reservations, and areas within the Indian Tribe’s jurisdiction, among others.

Thus, by its very nature and history, the statutory term “territory of the Indian Tribe” is ambiguous. According to the Indian canon of construction, “statutes are to be construed liberally in favor of the Indians, with ambiguous provisions interpreted to their benefit. . . .” *Montana v. Blackfeet Tribe of Indians*, 471 U.S. 759, 766 (1985) (citations omitted). In addition, USDA may address ambiguities in a statute that it administers, with any reasonable interpretation of the ambiguous term entitled to judicial deference. *Chevron U.S.A. Inc. v. Nat. Res. Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984). In this case, Congress provided no indication that the term “territory of the Indian Tribe” should apply more narrowly than similar terms that have been defined and interpreted in other Federal statutes and programs. Moreover, a narrow interpretation that excluded nontribal fee lands within reservations would perpetuate the problem of checkerboard jurisdiction over lands within Indian reservations, adding unnecessary confusion

and uncertainty to the challenges of implementing the hemp program in Indian country.

Therefore, the USDA includes a regulatory definition of the term “territory of the Indian Tribe” that is based on the definition of Indian country in 18 U.S.C. 1151 and the definition of Indian lands in the Indian Gaming Regulatory Act, 25 U.S.C. 2703(4).

The definition includes all lands within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, which encompasses on-reservation parcels held in fee simple by non-members of the Indian Tribe.

Similar provisions are found in the criminal jurisdiction definition of Indian country, 18 U.S.C. 1151; in the Clean Water Act, 33 U.S.C. 1377(h); the Clean Air Act, 42 U.S.C. 7601(d)(2)(B).

The U.S. Environmental Protection Agency (“EPA”) interpreted the statutes that it administers as providing authority to Indian Tribes over non-Tribal fee lands within Indian reservations. EPA Final Rule: Indian Tribes—Air Quality Planning and Management, 63 FR 7254 (Feb. 12, 1998); EPA Interpretive Rule: Revised Interpretation of Clean Water Act Tribal Provision, 81 FR 30,183 (May 16, 2016). EPA found that the Clean Water Act and Clean Air Act provided a delegation of authority to Indian Tribes over non-Tribal fee land within reservations. *See Arizona Public Serv. Co. v. EPA*, 211 F.3d 1280 (D.C. Cir. 2000). The agency found legislative intent and a common-sense reasoning to treat Indian reservations holistically for purposes of environmental regulation.

Similarly, USDA interprets the 2018 Farm Bill as authorizing Indian Tribes to become—with USDA’s approval of a hemp plan—the primary regulators of hemp production within their territories, including on nontribal fee lands within reservations. This authority applies without regard to the Indian Tribe’s ability to demonstrate inherent regulatory authority over non-Indians under the factors set forth in *Montana v. United States*, 450 U.S. 544 (1981). Additionally, this definition will make clear the area over which USDA will have regulatory authority including licensing if the Indian Tribe does not have an approved plan or a plan submitted to USDA for approval.

Comment: Some comments said Indian Tribes did not have the benefit of operating under the 2014 Farm Bill and, consequently, have not developed the farming techniques and regulatory systems that States have. Therefore, according to comments, Indian Tribes should be given a grace period while they develop best practices.

AMS response: Not all States operated under the 2014 Farm Bill, and some Indian Tribes did enter into Tribal – State agreements under the 2014 Farm Bill. Therefore, establishing a regulatory grace period for Indian Tribes only is not workable. Indian Tribes may take advantage of training and technical assistance offered by the USDA and other entities to ensure that they implement the best systems possible.

Comments: Some comments claimed that negligent violations by Indian Tribes under §990.6 may cause Indian Tribes to be ineligible for other programs.

AMS response: The 2018 Farm Bill describes three types of negligent violations under State and Tribal plans. The negligent violations detailed in §990.6 are required to be included in State and Tribal plans pursuant to the 2018 Farm Bill.

Comment: A comment contended that the requirement for a geospatial site identification at §990.3(a)(1)(ii) is too expensive for Indian Tribes, unnecessary, and not readily available. Comments said the Department of the Interior has land records that could be used to obtain necessary information.

AMS response: A legal description of the land where hemp is grown is required by the 2018 Farm Bill. Geospatial location is one form of meeting such requirement. Producers are required to provide information to FSA on the geographical location of hemp production. FSA offices will provide assistance in identifying such location at no cost to producers.

Comments: Some comments said USDA should conduct more Tribal consultations and provide USDA and DEA training for hemp producers. One Indian Tribe requested more time to allow Indian Tribes to organize a Tribal Advisory Council of Tribal Leaders to continue with the development and implementation of federal hemp policy.

AMS Response: In addition to previous Tribal consultations and extending and reopening the IFR's comment period, USDA added a September 2020 Tribal consultation to receive additional information, particularly from 2020 growing season producers. See the section on *E.O. 13175 Consultation and Coordination with Indian Tribal Governments* in this document for further discussion about the consultations. If Indian Tribes organize a Tribal Advisory Council of Tribal Leaders, USDA would appreciate any future feedback. Additionally, USDA is available to provide technical assistance when requested, including training. USDA is adding training for sampling to its website.

Comments: Comments said that Indian Tribes and individuals within the territory of the Indian Tribe should not have to be regulated by States, but should be able to go directly to USDA for licensing if the Indian Tribe opts out of developing its own Tribal plan and the Indian Tribe does not otherwise prohibit hemp production.

AMS Response: Subpart C, the USDA Hemp Production Plan, governs hemp producers in the absence of a Tribal plan. Therefore, any Indian Tribes or individuals wishing to produce hemp must comply with those regulations if not covered under a State or Tribal plan. If an Indian Tribe decides not to develop its own hemp plan, a producer may directly apply for a USDA license. States were not delegated authority under the 2018 Farm Bill to regulate hemp production within the territory of an Indian Tribe.

Comment: Indian Tribes should be allowed to implement their Tribal preference laws.

AMS Response: Nothing in the IFR or the final rule prevents Indian Tribes from implementing their Tribal preference laws.

Comment: A comment said that Tribal ordinances and interstate commerce regulations need to address price gouging in seeds and input.

AMS Response: This comment is outside the scope of this rule.

Comment: A comment said the Bureau of Indian Affairs and USDA should review 25 CFR part 162 governing agriculture and business leases to ensure that the hemp regulations here do not conflict with that part or cause additional regulatory hurdles.

AMS response: 25 CFR part 162 establishes certain requirements for leasing trust or restricted Indian lands. USDA conferred with the Department of the Interior, the agency regulating Indian land, and did not identify any conflicts between the two sets of regulations.

Comment: A comment suggested USDA hire an Indian law expert to assist with development of the final rule.

AMS response: USDA agreed and hired a consultant with 40 years-experience as an Indian law attorney to assist with the development of the final regulations and the review of Tribal plans.

Comment: Comments said the criminal history checks required by the IFR should be expanded to include the Department of Justice Tribal Access Program (TAP). According to comments, those using TAP would then be able to directly access criminal history checks. Comments also said the regulations need to clarify whether the criminal history check can be a name check or a finger-print check.

AMS Response: USDA conferred with the DOJ Office of Tribal Justice and was informed that Indian Tribes can use the TAP program to access the FBI Identity History Summaries. The FBI Identity History Summaries may be based on name check or a finger-print check.

Comment: Comments noted that the term “key participant” is defined at § 990.1 in a manner that is not necessarily consistent with an Indian Tribe’s unique organization and methods of doing business. Comments explained, for example, that an Indian Tribe may be the owner of a hemp farm. Comments asserted that although the Indian Tribe’s governing council may be the ultimate decision-maker as the owner, it would not be appropriate to include them in the felony and background investigations. Therefore, comments said Indian Tribes should be permitted to

identify their own “key participants” if they are operating under a USDA plan and the requirements of § 990.22.

AMS Response: USDA understands the concerns raised by Indian Tribes regarding the application of the criminal history report requirement and the felony conviction restriction on Tribal leaders. However, USDA must ensure that entities operating under a USDA plan comply with the felony conviction restriction in the AMA. For reasons explained in the IFR, USDA believes that the appropriate approach in determining who participates in the program, and therefore subject to the felony conviction restriction, is to focus on those who exercise executive managerial control over hemp production. USDA also believes that this focus should be consistent across the USDA plan regardless of the person who is applying for a license. For the foregoing reasons, USDA has clarified the definition of key participants in the final rule to provide that the definition “does not include a member of the leadership of a Tribal government who is acting in their capacity as a Tribal leader except when that member exercises executive managerial control over hemp production.” AMS notes that an Indian Tribe may adopt its own hemp plans subject to USDA approval. When adopting a hemp plan, the Indian Tribe can determine who participates in its plan and will be subject to a criminal history check.

Comment: USDA received a comment that it should affirm Tribal sovereignty by not allowing other federal agencies, such as the DEA, to interfere with Tribal hemp remediation.

AMS Response: USDA does not have the authority to control the actions of other federal agencies acting properly within their authority.

Comment: USDA received comments that USDA owes a trust responsibility to Indian Tribes. According to commenters, that trust responsibility requires acknowledging the unique challenges that Indian Tribes face including that 1) most tillable land was taken from Indian Tribes during homesteading; 2) Tribes’ participation in the farm program results in only a 60 percent yield of their non-Indian counterparts; 3) the finance system is usurious as financiers discount the value of Tribal assets or refuse to consider them at all; and 4) American Indian

producers will be disproportionately disadvantaged because their farms are significantly smaller and are generally run with only one crop by families with small margins.

AMS Response: USDA acknowledges that it has a special government-to-government relationship with Indian Tribes, and believes that, in preparing and issuing this final rule it has acted in accordance with that relationship. In response to concerns regarding the unique challenges Indian Tribes face, as explained in the Civil Rights Review of this final rule, AMS conducted a “Civil Rights Impact Analysis” and did not find any evidence that the final rule would adversely or disproportionately impact Indian Tribes or Tribal members producing hemp as compared to the general population of hemp producers or State Departments of Agriculture. Indian Tribes may take advantage of training and technical assistance offered by the USDA to ensure that they implement the best systems possible. Additionally, USDA is available to provide technical assistance when requested.

STATE AND TRIBAL VS. FEDERAL REGULATION

The preamble of the IFR stated that “[n]othing preempts or limits any law of a State or Indian Tribe that regulates the production of hemp and is more stringent than the provisions in the 2018 Farm Bill.” Further, Section 297B of the AMA expressly states that it does not preempt a State or Indian Tribe’s ability to adopt more stringent requirements or to prohibit the production of hemp. This was codified in the IFR in §990.3(b)(1), which provides that nothing in the part preempts or limits any law of a State or Indian Tribe that regulates the production of hemp and is more stringent than this part or Subtitle G of the Act.

Comments: Many of the comments received stated that the provisions of the IFR were more stringent than the regulations of pilot programs established by States under the authority of the 2014 Farm Bill. In fact, the majority of all comments received either took exception to the perceived increase in regulatory requirements for hemp production under the IFR, or presented recommendations for alternative requirements under the final rule that would not be as restrictive or burdensome as the provisions in the IFR.

No comments were received that either affirmed or opposed the rights of States and Indian Tribes to promulgate more stringent regulations for their jurisdictions. However, one comment said rather than using the flexibility allowed in the law to let states develop sensitive state plans, the IFR had rigid controls not required by law or correlated to the relatively low-level risk of non-compliant hemp. The comment further said USDA should establish baseline requirements but provide States flexibility to consider the dynamics of agricultural production that depend on farm and field conditions, weather, and the timing appropriate for planting, harvesting, the varieties being cultivated and the marketing of crops. Other comments agreed with recommendations to allow States and Indian Tribes to determine certain provisions that are not central to the minimum regulatory requirements of the IFR, such as application windows and reporting.

AMS response: The 2018 Farm Bill expressly preserved the ability for State and Tribal hemp production plans to establish additional provisions stricter than the baseline regulations required by the 2018 Farm Bill. These baseline regulations require all State and Tribal plans to include certain minimum requirements for licensing, sampling, testing, disposal, and information collection. These requirements could certainly be considered “more burdensome” than certain State hemp production plans operated under 2014 Farm Bill pilot program provisions, but they are intended to provide consistency and transparency among the U.S. hemp industry as it matures. Prior to the passage of the 2018 Farm Bill, States operating hemp pilot programs could administer these programs with minimal Federal oversight, and without baseline requirements around sampling, testing, and other program requirements because the 2014 Farm Bill programs are for research. The 2018 Farm Bill established baseline requirements for hemp production for hemp production across the U.S. regardless of the purpose of the production.

Preemption

Comment: AMS received comments asserting that the IFR did not abide by the mandate of the 2018 Farm Bill that there be no preemption of state or Tribal laws that regulate the production of hemp and are more stringent than the hemp provisions in the federal statute.

AMS response: Section 297B(a)(3) of the AMA provides that for States and Indian Tribes with primary regulatory jurisdiction over the production of hemp, there is no preemption if that State or Indian Tribe both regulates the production of hemp and that regulation is more stringent than the 2018 Farm Bill or the implementing regulations. Thus, the no preemption provision of the 2018 Farm Bill is to make clear that more stringent requirements are not preempted. AMS finds that the 2018 Farm Bill requires the implementation of federally mandated minimum standards, which all jurisdictions must follow, allowing for certain further restrictions by States and Indian Tribes.

Recordkeeping Requirement

Comment: One commenter argued that the recordkeeping requirements of the IFR violated the 4th Amendment's prohibition against unreasonable search and seizure and was "arbitrary and capricious" and a violation of the APA.

AMS Response: The 2018 Farm Bill established a hemp production program in the U.S. subject to oversight from the Secretary of Agriculture. Part of that congressional mandate is for the Department of Agriculture to establish a plan by which it collects information from producers to ensure compliance. While hemp is no longer a Schedule 1 drug, USDA can only make the determination of whether the crop is legal hemp (which it regulates) or illegal marijuana (which it does not regulate) through the mechanisms Congress has authorized. Recordkeeping requirements are paramount to that determination, which is required by Congress. AMS is retaining the recordkeeping requirements of the IFR.

APA Notice and Comment Concerns

Comment: Some commenters claimed that in issuing an IFR, AMS acted arbitrarily and capriciously in violation of the APA. Commenters argued that the good cause statement included

in the IFR was not adequate to support its issuance rather than going through notice and comment rulemaking.

AMS Response: AMS does not agree with these comments and believes that there was good cause to issue the IFR. AMS has encouraged public input on the IFR since its issuance and has provided many opportunities for public comment.

Criminal Background Checks and Definition of Key Participants

Comment: Several commenters argued that the restrictions on participation in hemp production for people with criminal convictions related to a violation of a state or Federal controlled substance law are not necessary and that hemp should be treated the same as all other commodities, which do not have similar restrictions. Commenters argued that there should be an exception for people with disqualifying criminal convictions who could demonstrate rehabilitation and that this restriction conflicts with state statutory requirements in some states. One commenter argued that USDA should conduct all criminal background checks rather than States or Indian Tribes.

AMS Response: AMS acknowledges various stakeholders' advocacy for reduced restrictions to entry in hemp production. However, the restriction on participation-based on a criminal conviction for violation of a state or Federal law related to controlled substances is a requirement established by statute and AMS does not have the authority to change to waive this restriction.

Definition of Key Participants

Comment: Some commenters requested that AMS change the definition of key participants to more clearly state which individuals within a business entity would be required to submit a criminal history report. One commenter requested that AMS align the definition of key participant with the definitions of "legal entities" and "beneficial owners" in Department of Treasury regulations. Another commenter suggested that AMS define who must submit a

criminal history report in States and Indian Tribes that have an approved plan for primary regulatory authority over hemp in their jurisdiction.

AMS Response: AMS acknowledges various stakeholders' advocacy for a single definition of "key participants" for all hemp producers. However, AMS will not require that States or Indian Tribes with an approved plan for primary regulatory authority over the production of hemp in their jurisdiction adopt the USDA definition of "key participants." States and Indian Tribes are free to incorporate the AMS definition of key participants into their plan but they are not required to do so. They must, however, define who participates in their plan and, for each license or authorization they issue, must identify at least one individual who will be subject to a criminal history check. The Department of Treasury definitions of "legal entities" and "beneficial owners," while similar to the definition of "key participants" adopted herein apply broadly to the corporate structure of a business entity. USDA finds the "key participant" definition to best describe those individuals responsible for compliance with this program or "leadership structure of a business entity."

X. Regulatory Analyses

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Domestic Hemp Production Program's information collection requirements have been previously approved by Office of Management and Budget (OMB) and assigned OMB No. 0581-0318. The 60-day public comment period was imbedded in the interim final rule (IFR) which was published on October 31, 2019, and ended on December 30, 2019. Because of the very tight timeline for publishing the IFR, OMB granted conditional emergency approval of these seven forms on December 3, 2019. The USDA Office of Chief Information Officer (OCIO) published the 30-day Notice for the three-year renewal at 85 FR 36828 on Thursday, June 18, 2020.

While writing the IFR there was very limited data available to make the initial burden

calculations under the Paperwork Reduction Act (PRA). Since the IFR was published, USDA has been able to gather much more accurate data on the number of producers, disposal rates, and time burdens for completing the forms. Because of this new information, AMS is updating the burden calculations currently approved by OMB. AMS will submit an updated Information Collection to align the new calculations in the FR with the 0581-0318 package.

AMS received over 4,600 comments in the first public comment period and 1,100 during the second comment period on the overall regulation. A specific analysis of each topic area in the comment analysis section of the final rule. AMS did not receive public comments specifically on the PRA nor on the time burden hour calculations to complete any of the forms. One comment from the Alabama Department of Agriculture wrote that 10 minutes for a State or Tribal producer license application was too low, so that has been increased to 20 minutes.

AMS used an initial estimate of 9,000 total producers for the IFR. This was based on the limited data from State Departments of Agriculture and the hemp advocacy group, Vote Hemp. Based on a review of hemp production data from State Departments of Agriculture, and the data reporting services from Hemp Benchmarks and Vote Hemp, AMS now estimates 20,000 producers as a yearly average to use for the purposes of reporting calculations. These numbers will be updated every three years. While the current percent of hemp growers licensed under USDA is drastically smaller than this, AMS assumes approximately 20 percent or 4,000 producers will be licensed under the USDA plan, and the other 80 percent or 16,000 producers licensed under State and Tribal USDA-approved programs.

The description and function of the seven reporting forms remains the same from the IFR and initial OMB approval. These forms require specific information be submitted by States and Tribes operating their own domestic hemp plans, from producers participating in the USDA Plan, and from laboratories testing for THC content. Reporting and recordkeeping burdens reflecting revised reporting hours and the projected additional producers are described in the following sections. All time and cost figures have been approximated to the nearest whole

number. The table below explains these changes numerically.

Costs of Reporting and Recordkeeping

The initial estimate of 100 State and Tribal plans remains accurate since the majority of States and Indian Tribes will have their own programs. As of the Fall of 2020, USDA has already approved 65 individual State and Tribal programs, with more to come. The amount of State approved programs will also increase once the 2014 Farm Bill pilot authority expires and those additional States submit plans. States and Indian Tribes with approved plans are required to report certain information to USDA through three forms: the “State and Tribal Hemp Producer Report”, the “State and Tribal Hemp Disposal Report”, and the “State and Tribal Hemp Annual Report”. USDA collects information from all hemp producers under a State, Tribal or USDA program through the FSA report form “Report of Acreage”. USDA collects information from USDA producers through the “USDA Producer Application”, the “USDA Annual Report” and the “USDA Disposal Report”. Laboratories provide information on the “Laboratory Test Report”.

AMS has updated PRA calculations using the Occupational Employment Statistics Survey of the Bureau of Labor and Statistics³² using the 2019 data. The mean hourly wage of a compliance officer, as reported in May 2019, was \$35 per hour. This is the same numerical value as the May 2018 report. Assuming 39 percent of total compensation accounts for benefits, the total compensation of a compliance officer is \$57 per hour. This \$57 per hour will be used throughout the PRA section.

Respondents: States or Tribes with approved plans

AMS initially estimated that the time required for States and Indian Tribes to fill in the information for each of these forms will be 20 minutes or 0.33 hours with a 5 minute or 0.08 hours record keeping burden. This estimate has been updated from 20 minutes to 60 minutes or one hour. The “State and Tribal Hemp Producer Report” and the “State and Tribal Hemp

³² <https://www.bls.gov/oes/home.htm>

Disposal Report” are due to USDA every month. The “State and Tribal Hemp Annual Report” form must be submitted to USDA once per year. Similar to the other two State and Tribal forms, the annual time burden was initially 20 minutes but has been updated to 60 minutes. The time burden for each State and Indian Tribe to complete and maintain these three forms is now 12 hours for each monthly form and 1 hour for the annual report, for a total of 25 hours per State and Tribe with an approved plan. Given the estimated number of approved State and Tribal plans is 100, the total cost is 250 hours and \$14,250.

Respondents: Producers under State or Tribal plans (information only, not completing the forms)

The time required of producers to supply the information for the “State and Tribal Hemp Disposal Report” and the “State and Tribal Hemp Annual Report” will stay the same at 10 minutes for reporting and 5 minutes for recordkeeping burden for each producer for these two forms. The “State and Tribal Hemp Producer Report” time estimate is now increased to 20 minutes with a 5 minute record keeping burden for each producer, per the suggestion from the Alabama Department of Agriculture.

In the IFR, AMS originally estimated that the majority of States and Indian Tribes would have three-year producer licenses, and producers would only submit this information once every three years. Since approving 60 State and Tribal plans, the majority of State and Tribal licenses are issued on a yearly basis instead. AMS estimates that the 16,000 State and Tribal producers will submit license information each year for State and Tribal programs. In addition to obtaining a license, all hemp producers are required to prove that they do not have prior drug related convictions that would disqualify them from participation in the program. States have some flexibility in what they require of applicants to make this demonstration. However, for purposes of this analysis, AMS will use the cost of the FBI Identify Summary, \$18, as a proxy cost for all background reports, and 3 key participants for each license each year, although if we were to take into account comments, it is likely there will be more than 3 key participants each year. In

the chart below is a cost breakdown of the application and background check for producers under a State or Tribal program.

FBI Identity Summary	# of Respondents	# of Responses per Respondent	Total Annual Responses	* 3 Key Participants	Cost of background check (\$18)	Plus burden cost of application	Total cost
cost for State and Tribal producers (3 key participants every year)	16,000	1.0000	16,000.00	48,000.00	\$864,000.00	\$379,666.00	\$1,243,666.00

In the IFR, AMS estimated that 20 percent of lots will need to be disposed even though the current rate of disposal is closer to 12%. This assumption is based on the increased number of new entrants to the market who may not be successful in their first year or two. AMS is introducing a new performance-based method to sampling, which will decrease the amount of testing and noncompliant tests. Therefore, AMS estimates that 1,600 lots will be disposed under State and Tribal programs. The producers under a State or Tribal program will provide their disposal information to their individual regulatory body. The States and Indian Tribes will then use that information to complete the monthly “State and Tribal Hemp Disposal Report”.

These are just the costs and burden of collecting and maintain the information associated with the disposal, not the actual disposal. The actual cost of disposing of the non-compliant “hot” hemp is discussed in the RIA.

In total, producers under a State or Tribal program provide information and hold records for three forms. The total time burden for these producers providing and maintaining this information is estimated at 11,061 total hours and \$630,466.

Respondents: Producers participating in the USDA plan

To produce hemp under the USDA Plan, a producer, which may be an individual producer or a business, completes the “USDA Hemp Plan Producer Licensing Application” and an FBI Identity Summary. If all parts of the application and summary are valid, AMS issues a license. The total burden per respondent of this form will maintain the same as in the IFR; 10 minutes for the time and 5 minutes for record keeping for a total of 15 minutes, or .25 hours.

Licenses under the USDA Plan must be renewed every three years, so each producer only submits this information once every three years. In the IFR, AMS initially estimated that there will be 1,000 participants in the USDA Plan. AMS has now updated this estimate to be 20 percent of the total hemp producers, or 4,000 producers each year. Because the USDA license is valid for three years, approximately 1,332 producers will complete this form each year. The total annual burden for this form is 544 hours and \$31,603.

In addition to the “USDA Hemp Plan Producer Licensing Application” submitted once every three years, producers must submit criminal history reports for each of their key participants. AMS estimates each producer to have three key participants submit criminal history reports to USDA. The cost of a criminal history report is \$18 apiece, so three key participants would cost \$54 per participant. As stated previously, AMS estimates that it will receive 1,332 license renewals in each year. Each of these 1,332 renewals will include a background summary for three key participants. Adding the cost of 1,332 renewals at \$71,928 with the cost of the background check is \$31,603 for the renewals and means there is an annual cost of \$103,531.

FBI Identity Summary	# of Respondents	# of Responses per Respondent	Total Annual Responses	* 3 Key Participants	Cost of background check (\$18)	Plus burden cost of application	Total cost
cost for USDA producers (3 key participants every three years)	4,000	0.3330	1,332.00	3,996.00	\$71,928.00	\$31,603.00	\$103,531.00

Similar to the required annual report submitted by States and Indian Tribes to USDA, producers operating under the USDA Plan must submit the “USDA Hemp Plan Producer Annual Report” to USDA each year. AMS estimates the time burden of submitting this form will maintain the same, at 25 minutes, or 0.42 hours, per respondent. AMS has updated the initial estimate of 1,000 participants in the USDA Plan, to 4,000 producers. Therefore, the total burden of this form has increased from 416 hours to 1,665 hours, costing \$94,916 annually.

When a hemp sample tests above the acceptable hemp THC level, the material from the specific lot must be disposed. The producer and disposal agent must complete the “USDA Hemp

Plan Producer Disposal Form”. The burden for this form will stay at 25 minutes, or 0.42 hours, per respondent.

Using the same assumptions regarding the prevalence of non-compliant crops and the costs of disposal that were used in generating the estimates of hemp disposal reporting (and disposal) for State and Tribal programs, the 4,000 producers that will participate in the USDA Plan will generate 400 samples that test high for THC content. The total reporting burden of this form will amount to 167 hours and cost \$9,492 annually.

Altogether, the annual burden for the USDA producers completing and maintain the three USDA forms “USDA Hemp Plan Producer Licensing Application”, the “USDA Hemp Plan Producer Disposal Form”, and the “USDA Hemp Plan Producer Annual Report” amounts to an annual total of 2,386 hours and a cost of \$136,011.

Respondents: Laboratories

The 2018 Farm Bill requires that all domestically produced hemp be tested for total THC content on a dry-weight basis, whether produced under a State or Tribal Plan or the USDA Plan. Using data from FSA the initial estimate of two lots of hemp per producer remains accurate. However, the new performance-based sampling process will decrease the number of total samples that are collected and tested.

AMS requires all laboratories testing hemp for THC to submit all test results, whether passing or failing, via the “Laboratory Test Results Report”. AMS maintains the estimated reporting and recordkeeping burden for this form at 35 minutes, or .58 hours. AMS originally estimated that 7,700 total hemp producers would submit 15,400 samples to test. AMS has updated this estimate to 8,000 total tests annually. Therefore, the total annual burden of these tests and the accompanying “Laboratory Test Results Report” form decreased from 8,399 hours to 4,664 hours, and costs \$265,848.

Respondents: All producers

The FSA collects information on crop acreage through the “Report of Acreage” form.

Hemp producers under all plans are required to fill in the information for this form once they receive their license or authorization from USDA, a State, or Indian Tribe and have planted the crop. AMS will keep the initial reporting burden and record keeping burden at 35 minutes, or 0.58 hours. AMS has added 60 minutes or one hour for the travel time to and from the FSA office, for a total of 90 minutes. With the increased number of producers and the addition of travel time, AMS estimates the burden for the 20,000 producers will be 31,660 hours and cost \$1,804,620.

Total reporting and recordkeeping costs for all respondents

Altogether, the annual burden for reporting and recordkeeping for all respondents is 52,296 hours, costing a total of \$2,980,864 per year. This is the sum of the annual burden of reporting and recordkeeping to States and Indian Tribes operating their own plans, to producers participating in the State and Tribal Plans, to producers participating in the USDA Plan, including the cost of a criminal history report for three key participants, and to laboratories testing samples for THC content.

Table: Each column is a section of the burden estimate, with the cost of \$57 per hour calculated in the last column. Each row represents the old or the new reporting calculations.

Name	Form	# of Respondents	# of Responses per Respondent	Total Annual Responses	Hours per Response	Total Reporting Hours	# of Record Keepers	Annual Hours per Record Keeper	Total Record Keeping Hours	Total Hours	x \$57
State and Tribal Forms											
State and Tribal Hemp Producer Report (Old)	AMS-23	100	12.0000	1,200.00	0.3333	399.96	100	0.083	8.30	408.26	\$23,270.82
State and Tribal Hemp Producer Report (Update)	AMS-23	100	12.0000	1,200.00	1.0000	1,200.00	100	0.083	8.30	1,208.30	\$68,873.10
State and Tribal Producer Responses (Old)	information only	8,000	0.3330	2,664.00	0.1670	444.89	2,664.00	0.083	221.11	666.00	\$37,962.00
State and Tribal Producer Responses (Update)	information only	16,000	1.0000	16,000.00	0.3333	5,332.80	16,000	0.083	1,328.00	6,660.80	\$379,665.60
State and Tribal Hemp Disposal Report (Old)	AMS-24	100	12.0000	1,200.00	0.3333	399.96	100	0.083	8.30	408.26	\$23,270.82

State and Tribal Hemp Disposal Report (Update)	AMS-24	100	12.0000	1,200.00	1.0000	1,200.00	100	0.083	8.30	1,208.30	\$68,873.10
State and Tribal Producer Disposal Responses (20% then x 2 for 2 lots/producer) (Old)	information only	2,680	1.0000	2,680.00	0.1670	447.56	2,680	0.083	222.44	670.00	\$38,190.00
State and Tribal Producer Disposal Responses (25% of lot from 80% of producers) (Update)	information only	1,600	1.0000	1,600.00	0.1670	267.20	1,600	0.083	132.80	400.00	\$22,800.00
State and Tribal Hemp Annual Report (Old)	AMS-25	100	1.0000	100.00	0.3333	33.33	100	0.083	8.30	41.63	\$2,372.91
State and Tribal Hemp Annual Report (Update)	AMS-25	100	1.0000	100.00	1.0000	100.00	100	0.083	8.30	108.30	\$6,173.10

State and Tribal Hemp Annual Report Response (Old)	information only	6,700	1.0000	6,700.00	0.1670	1,118.90	6,700	0.083	556.10	1,675.00	\$95,475.00
State and Tribal Hemp Annual Report Response (Update)	information only	16,000	1.0000	16,000.00	0.1670	2,672.00	16,000	0.083	1,328.00	4,000.00	\$228,000.00
USDA Producer Forms											
USDA Hemp Plan Producer Licensing Application (Old)	AMS-26	1,000	0.3330	333.00	0.1670	55.61	333	0.083	27.64	83.25	\$4,745.25
USDA Hemp Plan Producer Licensing Application (Update)	AMS-26	4,000	0.3330	1,332.00	0.1670	222.44	4,000.00	0.083	332.00	554.44	\$31,603.31
USDA Hemp Plan Producer Disposal Form (20% x 2 lots for 2 lots/producer) (Old)	AMS-27	400	1.0000	400.00	0.3333	133.32	400	0.083	33.20	166.52	\$9,491.64

USDA Hemp Plan Producer Disposal Form (25% x lots from 20% of all producers) (Update)	AMS-27	400	1.0000	400.00	0.3333	133.32	400	0.083	33.20	166.52	\$9,491.64
USDA Hemp Plan Producer Annual Report (Old)	AMS-28	1,000	1.0000	1,000.00	0.3333	333.30	1,000	0.083	83.00	416.30	\$23,729.10
USDA Hemp Plan Producer Annual Report (Update)	AMS-28	4,000	1.0000	4,000.00	0.3333	1,333.20	4,000	0.083	332.00	1,665.20	\$94,916.40
All Producer Forms											
Report of Acreage (Old)	FSA-578	7,700	1.0000	7,700.00	0.5000	3,850.00	7,700	0.083	639.10	4,489.10	\$255,878.70
Report of Acreage (Update + 60 min travel time)	FSA-578	20,000	1.0000	20,000.00	1.5000	30,000.00	20,000	0.083	1,660.00	31,660.00	\$1,804,620.00
Laboratory Test Results Report (2 lots/ all producers) (Old)	AMS-22	7,700	2.0000	15,400.00	0.5000	7,700.00	7,700	0.083	639.10	8,339.10	\$475,328.70

Laboratory Test Results Report (100% of CBD; 50% of fiber; 50% of grain) (Update)	AMS-22	8,000	1.0000	8,000.00	0.5000	4,000.00	8,000	0.083	664.00	4,664.00	\$265,848.00
								Total for Updates		52,295.86	\$2,980,864.25

E-Government Act

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes. We recognize using an electronic system will promote efficiencies in developing and implementing the new USDA Domestic Hemp Production Program. Since this is a new program, AMS is working to make this process as effective and user-friendly as possible.

Civil Rights Review

AMS has considered the potential civil rights implications of this rule on minorities, women, and persons with disabilities to ensure that no person or group shall be discriminated against on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic information. This review included persons that are employees of the entities who are subject to these regulations. This final rule does not require affected entities to relocate or alter their operations in ways that could adversely affect such persons or groups. Further, this rule does not deny any persons or groups the benefits of the program or subject any persons or groups to discrimination.

This final rule reflects AMS's response to public comment and input provided by stakeholders. The final rule provides States and Indian Tribes the regulatory authority over hemp production in their jurisdictions. It also establishes a Federal plan for hemp producers located in States or territories of Indian Tribes that do not have their own USDA-approved hemp oversight plan. There is no evidence that the final rule will potentially adversely or disproportionality impact hemp producers in protected groups, regions or Indian Tribes differently than the general population of hemp producers or State Departments of Agriculture.

Executive Order 13132 – Federalism

AMS has examined the effects of provisions in this final rule on the relationship between the Federal Government and the States, as required by Executive Order 13132 on "Federalism." Our conclusion is that this rule does have federalism implications because the rule has substantial and direct effects on States, on the relationship between the National Government and States, and on the distribution of power and responsibilities among the various levels of government. The federalism implications of the rule, however, flow from and are consistent with the underlying statute. Section 297B of the AMA, 7 U.S.C. 1639p, directs USDA to review and approve State plans that meet statutory requirements and to audit a State's compliance with its State plans. Overall, the final rule attempts to balance both the autonomy of the States with the necessity to create a Federal framework for the regulation of hemp production.

Section 3(b) of E.O. 13132 recognizes that national action limiting the policymaking discretion of States will be imposed ". . . only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance." Section 297B of the AMA is the statutory authority underlying the rules for USDA to review, approve, disapprove, or revoke State plans for hemp production. Until the passage of the 2018 Farm Bill, hemp was a Schedule I controlled substance as it fell within the CSA definition of marijuana. When hemp was exempted from the definition of marijuana as part of the 2018 Farm Bill, in connection with removing it from that list, Congress established a national regulatory framework for the production of hemp. Because cannabis plants with a THC level higher than 0.3 are marijuana and on the Federal controlled substances list, ensuring that hemp produced under this program is not marijuana is of national significance.

In addition to establishing a national regulatory framework for hemp production, Congress expressly preempted State law with regard to the interstate transportation of hemp. Section 10114 of the 2018 Farm Bill States that "[n]o State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products produced in accordance with subtitle G of

the Agricultural Marketing Act of 1946 (as added by section 10113) through the State or the territory of the Indian Tribe, as applicable.” Thus, States and Indian Tribes may not prevent the movement of hemp through their States or territories even if they prohibit its production. Congress also expressly preempted a State’s ability to prosecute negligent violations of its plan as a criminal act in section 297B(e)(2)(c). That preemption is incorporated into this rule.

Section 3(d)(2) of the E.O. 13132 requires the Federal Government to defer to the States to establish standards where possible. Section 4(a), however, expressly contemplates preemption when there is a conflict between exercising State and Federal authority under Federal statute. Section 297B of the AMA requires State plans to include six practice and procedures and a certification. It also expressly states that it does not preempt a State’s ability to adopt more stringent requirements or to prohibit the production of hemp. Section 297D of the AMA requires USDA to promulgate regulations to implement subtitle G of the AMA, which includes section 297B. Subpart B of the final rule repeats those requirements, providing more detail where necessary. States have wide latitude to develop the required practice and procedures. Subpart B includes more details on the testing and sampling of hemp plants to establish a national standard to determine whether the plants meet the statutory definition of hemp. Likewise, the final rule requires States to follow DEA requirements for disposal of marijuana for cannabis plants exceeding the acceptable hemp THC level. Finally, the final rule also reaffirms that States may adopt more stringent standards and prohibit hemp production within their jurisdiction.

Section 6 of E.O. 13132 requires consultation with State officials in development of the regulations. AMS conducted significant outreach with State officials including individual meetings, participation in conferences with State officials, and listening sessions where State officials from all States were invited. During our consultation with the States, representatives from various State agencies and offices expressed the following concerns about sampling and testing procedures. Most requested that USDA adopt uniform, national requirements to facilitate the marketing of hemp. Some States advocated that USDA defer to each State to determine the

appropriate procedures for its plan. USDA recognizes the value of a national standard to promote consistency while allowing States the flexibility to adopt procedures that fit their circumstances. As explained above, USDA is adopting performance standards for sampling and testing. As long as the procedures in the State plans meet those standards, AMS will find those procedures acceptable.

As AMS implements this new program, we will continue to consult with State officials to obtain their feedback on implementation.

Finally, we have considered the cost burden that this rule would impose on States as discussed in the Regulatory Impact Analysis of this document.

AMS has assessed this final rule in light of the principles, criteria, and requirements in Executive Order 13132. We conclude that this final rule: is not inconsistent with that E.O.; will not impose significant additional costs and burdens on the States; and will not affect the ability of the States to discharge traditional State governmental functions.

Executive Order 13175 Consultation and Coordination with Indian Tribal Governments

AMS examined the effects of provisions in the final rule on the relationship between the Federal Government and Tribal governments, as required by E.O. 13175 on “Consultation and Coordination with Indian Tribal Governments.” We concluded that the final rule does have substantial direct effects on Tribal governments, on the relationship between the National Government and Tribal governments, and on the distribution of power and responsibilities among the various levels of government. The effects of the rule, however, flow from and are consistent with the underlying statute. Section 297B of the AMA, 7 U.S.C. 1639p, directs USDA to review and approve Tribal plans that meet statutory requirements and to audit a Tribal government's compliance with its Tribal plans. Overall, the final rule attempts to balance both the autonomy of the Tribal governments with the necessity to create a Federal framework for the regulation of hemp production.

As with States, Tribal governments will have wide latitude in adopting procedures including adopting requirements that are more stringent than the statutory ones. For reasons stated in the federalism analysis, AMS is adopting national standards for sampling, testing, and disposal of non-compliant plants that Tribal plans must also incorporate.

AMS conducted extensive outreach to Tribal governments through individual discussions with Tribal representatives, by extending the regulatory comment periods and through the following more formal consultations.

Tribal Consultation May 2019: On May 1 and 2, 2019, USDA held a formal Tribal consultation on the 2018 Farm Bill including a session on hemp production. This consultation occurred at the National Museum of the American Indian located in Washington DC. In addition to listening sessions for the general public, USDA hosted a listening session for Tribal governments following the formal Tribal consultation on May 2, 2019. USDA officials attended meetings with representatives of Tribal governments. On December 11, 2019, roughly 41 days after the publication of the domestic hemp production program interim final rule, USDA held a second formal Tribal consultation. This consultation provided information on the interim final rule. This consultation occurred in Las Vegas, Nevada, and attendees included USDA officials, Tribal leaders, Tribal proxies, non-consulting Tribal members, non-profit representatives, businesses, law firms, private individuals, and other government employees. On September 24, 2020, USDA held a third formal Tribal consultation and provided information on the interim final rule. This consultation occurred virtually and attendees included USDA officials, Tribal leaders, Tribal proxies, non-consulting Tribal members, non-profits representatives, Businesses, law firms, private individuals, and other government employees.

During the May 2019 consultation, Tribal representatives from several Tribal Governments expressed their opinions that the 2018 Farm Bill permitted the USDA Secretary to allow AMS to approve Tribal plans ahead of issuing regulations of the USDA plan. Indian Tribes stated that approving hemp plans immediately would allow those Indian Tribes (and States) with

a plan to begin planting for the commercial production of hemp in 2019. The USDA Secretary released a Notice to Trade (NTT) on February 27, 2019, to explain that Tribal and State plans would not be reviewed or approved until AMS finalized regulations ahead of the 2020 planting season. Additionally, the NTT stated that until regulations were in place, States, Indian Tribes, and institutions of higher education could continue operating under authorities of the 2014 Farm Bill. The 2018 Farm Bill extension of the 2014 authority expired 12 months after USDA had established the plan and regulations required under the 2018 Farm Bill. Congress extended this expiration until January 1, 2022. After the May Tribal consultation, USDA issued a second NTT on May 27, 2019, to clarify that Tribal governments through the authorities in the 2014 Farm Bill are permitted to grow industrial hemp for research purposes during the 2019 growing season. USDA appreciates the urgency in which the Indian Tribes wish to engage in this new economic opportunity. We worked expeditiously to develop and promulgate the IFR so that States and Indian Tribes could submit their plans in time for the 2020 season.

Tribal Consultation December 2019: During this consultation Indian Tribes expressed how some provisions of the interim final rule are too rigid and that USDA did not consider practical problems and potential economic harm faced by Indian Tribes under the program.

Indian Tribes requested more extensive Tribal consultation and the inclusion of other agencies involved in hemp production and enforcement. In response, USDA extended the public comment date by thirty additional days to January 29, 2020 and agreed to conduct an additional consultation after the first growing season. AMS also reopened the public comment period for thirty days in the Fall of 2020.

Tribal Consultation September 2020: Consultation also occurred on September 24, 2020.

Based on the comments and consultations received, we made changes to the final regulations. Although Indian Tribes will still incur costs in complying with final rule, those costs should be outweighed by the benefits that the Indian Tribes realize in commercial hemp production occurring within their territories.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The USDA's Office of Tribal Relations (OTR) has assessed the impact of this rule on Indian tribes and determined, in agreement with AMS, that this rule has substantial direct tribal implications that require continued outreach efforts to determine if tribal consultation under EO 13175 is required. Based on AMS outreach efforts to date, OTR does not believe that tribal consultation is necessary at this time. If a tribe requests consultation AMS will work with the OTR to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives when an action is deemed to have significant impacts. If regulation is necessary, then agencies must select the action that maximizes net benefits, including potential economic, environmental, public health and safety effects, and equity. This rule meets the definition of an economically significant regulatory action under Executive Order 12866, as it is likely to result in an annual effect on the economy of \$100 million or more. USDA considers this to be a deregulatory action as it allows the development of a niche market that cannot exist under the state pilot programs authorized under the Agricultural Act of 2014

(2014 Farm Bill). This action finalizes the interim final rule published on October 31, 2019, that expanded production options and enabled interested farmers to grow hemp.

Executive Order 13771 mandates that agencies provide the best approximation of total costs associated with a new or repealed regulation. AMS has prepared this Regulatory Impact Analysis with the purpose of accomplishing these objectives. USDA considers this to be a deregulatory action under Executive Order 13771 as it allows for the development of a niche market that cannot exist under current regulation. This rule removes barriers to entry and enables domestic farmers to grow hemp.

Regulatory Impact Analysis

Regulations must be designed in the most cost-effective manner possible to obtain the regulatory objective while imposing the least burden on society. This rule finalizes and updates the interim final rule that established a national regulatory oversight program for the production of hemp. This program is necessary to effectuate the mandate in the Agriculture Improvement Act of 2018, known as the 2018 Farm Bill, to coordinate State and Tribal government hemp production regulations with the newly established federal regulations for hemp production in States and Indian Tribes not regulated by State or Tribal plans. This program is intended to provide consistency in production, sampling and testing of hemp product to ensure compliance with the acceptable hemp THC level.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform, and is not intended to have retroactive effect. The discussions on Executive Orders 13132 (Federalism) and 13179 (Consultation and Coordination with Tribal Governments), above, address the extent to which the rule preempts State law, and the impacts of the rule to Tribal governments. The discussion above regarding appeals under new part 990, subpart D, describes the administrative procedures that must be exhausted prior to a judicial challenge.

Introduction

On October 31, 2019, USDA promulgated an interim final rule establishing a national program for the production of industrial hemp. A regulatory analysis was performed in support of that regulation and published as part of the preamble to that rule. This analysis is intended to update the previous analysis to reflect additional information gained through the first year of operation of that program and to assess whether any of the modifications to the program made in response to public comment have significant impacts on the estimated costs or benefits of the final program.

In the IFR, AMS estimated lower and upper bounds to calculate the total net benefits of the rule to society at large. These net benefits were calculated for 2020 through 2022 only due to lack of data for future years. In the IFR, 2020 estimated net benefits ranged from a loss of nearly \$4 million to a gain of \$17.6 million; for 2021, a net benefit of \$23 million to \$46 million; and, for 2022, a net benefit of nearly \$49 million to \$74 million. In this final rule, the estimated net benefits, as shown in Table 12, are \$46 million in 2020; \$87 million in 2021; \$135 million in 2022; \$190 million in 2023; \$226 million in 2024; and, \$351 million in 2025.

The estimates of net benefits resulting from this final rule differ from those in the IFR due to a variety of factors. First of these is the large increase in planted acreage and market entrants in 2019, the scale of which was unexpected. (There may be other unexpected changes due to the pandemic, but we cannot estimate those at this time.) Changes in other variables, as well, contributed to the increase in net benefits in the final rule over the IFR. A comparison of the variables that are assumed constant (across years 2020 through 2025) in the IFR and the final rule is shown in Table 1 below. In the year between publication of the IFR and this final rule, additional information regarding the hemp industry has emerged to the benefit of this analysis. AMS believes that the modifications to the analysis from the IFR to the final rule represent the state of the hemp industry to the greatest extent practicable. The modifications in this final rule are intended to further support the hemp marketplace and provide the greatest flexibility possible while still ensuring the program complies with the 2018 Farm Bill.

AMS suspects that this rule, compared to the IFR, will incentivize participation in the market and allow for more farmers to be successful. In particular, AMS attributes this to two policies. First, AMS anticipates that the flexibilities in disposal and remediation of non-compliant hemp will help minimize the risk to farmers, therefore increasing participation in the industry. Second, AMS anticipates that the increased threshold for negligent hemp (from 0.5 percent to 1.0 percent) will also reduce risk to farmers and allow for more innovation.

AMS received numerous comments providing data on the different aspects of the hemp industry, that while informative, could not be incorporated in the RIA due to such factors as they were too regionally focused, small in sample size, or lacked the depth of data points to be representative of the national hemp market. An example of this is the portion of retests performed on hemp samples that initially tested higher than 0.3 percent THC.

Variables	Intended Use	IFR		Final Rule	Final Rule Data Sources
		Low	High		
Price per lb	Cannabinoids	\$ 3.50	\$ 30.00	\$ 3.90	The Jacobsen. Estimates based on 2019 and 2020 prices.
	Fiber	\$ 0.07	\$ 0.67	\$ 0.09	
	Grain	\$ 0.65	\$ 1.70	\$ 0.53	
Yield per acre	Cannabinoids	1,000	1,200	1,500	Hemp enterprise budgets from seven universities.
	Fiber	2,000	11,000	8,000	
	Grain	800	1,600	1,200	
Portions of planted acreage by intended use	Cannabinoids	67%		80%	The Jacobsen. Hemp Daily Bulletin, September 8, 2020.
	Fiber	17%		3%	
	Grain	17%		17%	
Variables	Plans	IFR		Final Rule	Final Rule Data Sources
		Low	High		
Portions of lots sampled & tested	USDA	100%		Based on 95% CI and 1% margin of error	Standard statistical performance objective.
	State/Tribal	100%			
Sampling & testing cost	USDA (per lot)	\$ 599	\$ 830	\$ 565	State departments of agriculture.
	State/Tribal (per license)	Included in program administration cost			
Variables	IFR		Final Rule	Final Rule Data Sources	
Portion of sales attributable to the rule	50% of growth		20% of total	State depts. of ag.	
Opportunity cost per acre	\$ 591		\$ 630	NASS.	
Program administration cost	\$ 1,000		\$ 800	State depts. of ag.	
Portion of lots testing > 0.3% THC	40%		25%	National Industrial Hemp Regulators.	
Disposal cost per acre	\$ 200		\$ 14.25	State depts. of ag.	

The 2014 Farm Bill defined hemp as the plant *Cannabis sativa* L. and any part of that plant with concentrations of THC no greater than 0.3 percent on a dry weight basis. While belonging to the same species as the plant that produces marijuana, hemp is distinctive from marijuana in its chemical makeup. The marijuana plant contains high levels of the cannabinoid delta-9 tetrahydrocannabinol (THC), which is the chemical that produces psychoactive effects. Hemp may contain no greater than 0.3 percent THC on a dry weight basis.

Prior to the 2014 Farm Bill, hemp had never been designated in a Federal law as different from cannabis generally. The first regulation of hemp occurred in 1937 with the Marihuana Tax Act, which required all producers of the species *Cannabis sativa* to register with and apply for a license from the Federal government. The “Hemp for Victory” Campaign during World War II promoted production of hemp for rope to be used by U.S. military forces. At the end of the war, however, the requirements in the Marihuana Tax Act resumed. In 1970, Congress passed the Controlled Substances Act, granting the Attorney General the authority to regulate production of cannabis, including hemp.

The 2014 Farm Bill authorized pilot programs, as permitted by State law, for hemp cultivation for research purposes to be administered by academic institutions and State departments of agriculture. By 2019 approximately half of the states had developed such a pilot program. The research under these pilot programs included market research, which allowed cultivated hemp to enter the stream of commerce as inputs into various consumer products. For example, in Kentucky, one of the first states to enact a pilot program, producer sales to processors totaled \$1.6 million in 2016, \$7.5 million in 2017, \$17.7 million in 2018, and \$51.3 million in 2019.³³ Hemp biomass contains concentrations of the cannabinoid cannabidiol, known as CBD. High prices for hemp harvested for cannabinoids, relative to those of other agricultural commodities, have fueled producer interest in hemp production since 2014.

2018 Farm Bill

³³ Kentucky Department of Agriculture.

The 2018 Farm Bill allowed the production and sale of industrial hemp either under a State or Tribal program approved by the USDA or under a Federal license for producers in areas with no approved plan and no explicit State or Tribal statute prohibiting the production of hemp. The 2018 Farm Bill explicitly preserved the authority of the U.S. Food and Drug Administration (FDA) to regulate hemp products under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act (PHS Act). Accordingly, products containing cannabis and cannabis-derived compounds are subject to the same authorities and requirements as FDA-regulated products containing any other substance. The 2018 Farm Bill removed hemp from the list of controlled substances, decontrolling hemp production in all U.S. States, territories, and lands belonging to Indian Tribes, unless prohibited by State or Tribal Law. This action eliminates the uncertain legal status at the Federal level of hemp production and allows the U.S. Department of Agriculture (USDA) to provide hemp producers with crop insurance programs, potentially reducing risk to producers and providing easier access to capital. The statute also prohibits interference in the interstate transport of hemp by States, including those States that prohibit hemp production and sales. As a result, hemp producers will have access to nationwide markets.

Need for Regulation

The rule is necessary to facilitate the domestic cultivation of hemp for sale into the market for hemp products by creating a set of minimum standards to ensure that hemp being produced under this program meets all statutory requirements. The rule establishes minimum requirements for States and Indian Tribes to obtain program approval and, for producers operating under the Federal program to obtain a license and meet operating requirements under that license. Without these provisions, it would not be possible to grow hemp legally.

Both the declassification of hemp, and the prohibition on interference with interstate transportation apply to hemp that is grown under an approved State or Tribal plan, or under a

Federal license. As a result, this regulation facilitates provisions of the 2018 Farm Bill that would otherwise be self-implementing.

Overview of the Action

The 2018 Farm Bill granted regulatory authority of domestic hemp production to the State departments of agriculture, Tribal governments, and USDA. States and Indian Tribes wishing to operate their own programs must submit to USDA plans that include provisions for maintaining information regarding the land on which hemp is produced, for testing the levels of THC, for disposal of plants that do not meet necessary requirements, and for procedures to ensure compliance with the requirements of the new part, including background checks of all key participants. State and Tribal Plans must be approved by USDA. This rule outlines requirements by which the USDA would approve plans submitted by States and Tribal governments for oversight of hemp production. The 2018 Farm Bill also directs USDA to develop a plan for use by hemp producers in States or Indian Tribes where no State or Tribal Plan has been approved and that do not prohibit the cultivation of hemp. These actions will promote consistency in regulations governing the legal production of hemp across the country.

Baseline Definition

The 2014 Farm Bill authorized hemp research pilot programs to be administered by states and universities. The 2018 Farm Bill repealed these pilot programs beginning one year from the publication of a USDA rule; however, the 2021 Continuing Appropriations Act extended the authorization of the 2014 pilot programs until January 1, 2022. From 2014 to 2018, planted acreage tripled in every year, reaching nearly 63,500 acres in 2018. In the year following the signing of the 2018 Farm Bill, planted acreage increased by more than 400 percent to 327,600 acres in 2019.³⁴ The surge of entrants into the hemp market in 2019 left many producers with

³⁴ Sources include the following: State Departments of Agriculture; Vote Hemp. 2016-2019 Crop Reports; and,

unsold inventory. In Kentucky alone, more than \$100 million of hemp material went unsold due to lack of buyers in 2019. The large number of entrants into the market in 2019 caused a surplus of hemp production, which in turn caused prices to fall and revenue losses to producers.

Despite the producer excitement that ensued in 2019 following the signing of the 2018 Farm Bill, only 17 states opted to participate in the new hemp programs in time for the 2020 growing season. These 17 states accounted for about 20 percent of the total estimated planted acreage in 2020. Given the apparent affinity by states for the 2014 pilot programs, AMS assumes that in the absence of the 2018 Farm Bill, the 2014 Farm Bill pilot programs would have continued indefinitely. Indeed, the 2014 Farm Bill offered no sunset date for these programs. In order to capture the impacts of this rule on affected entities, AMS attributes 20 percent of the estimated planted acreage from 2020 through 2025 to the 2018 Farm Bill and this rule which enables its prescriptions. This 20 percent reflects the amount of planted acreage in the 17 states that opted to participate in the 2018 Farm Bill hemp programs for the 2020 growing season. The 2020 growing season was the final opportunity for producers to cultivate hemp under the 2014 pilot programs until the 2021 Continuing Appropriations Act extended the authorization of the 2014 pilot programs to January 1, 2022. By enrolling in the new hemp programs, these 17 states expressed a preference for the hemp programs authorized by the 2018 Farm Bill over the 2014 Farm Bill pilot programs. The remaining 80 percent of planted acreage estimated from 2020 through 2025 will be treated as attributable to the 2014 pilot programs under the assumption that they would have continued in the absence of the 2018 Farm Bill which terminated them.

In the interim final rule (IFR), AMS attributed 50 percent of the growth in producer sales from 2020 through 2022 to the 2018 Farm Bill and this enabling rule. In deriving this assumption, AMS considered the rate at which hemp acreage had increased in recent years, the

Mark, Tyler, Jonathan Shepherd, David Olson, William Snell, Susan Proper, and Suzanne Thornsby. February 2020. Economic Viability of Industrial Hemp in the United States: A Review of State Pilot Programs, EIB-217, U.S. Department of Agriculture, Economic Research Service.

number of States whose hemp pilot programs produced a crop in recent years, and the number of States that passed legislation following the signing of the 2018 Farm Bill in anticipation of this rule’s enactment in time for the 2020 growing season. In the time between publication of the IFR on October 31, 2019, and the beginning of the 2020 growing season, 17 states representing 20 percent of planted acreage opted to participate in the hemp programs mandated by the 2018 Farm Bill. This portion of enrollment is less than AMS anticipated in the IFR.

Affected Entities

As of July 2020, States, Indian Tribes, and USDA had issued 19,121 producer licenses. This figure represents licenses issued in 44 States and one Tribe. About 70 percent of states reported at the time that they were still accepting applications, which indicates that the number of 2020 producer licenses issued is likely to grow. For this reason, AMS estimates that up to 20,000 producer licenses will be issued in 2020. Based on the slowed pace in growth of producer licenses from 2019 to 2020, AMS assumes an annual growth rate in producer licenses of 10 percent from 2020 through 2025, for the purposes of this analysis. The result is shown in Table 2. AMS is unaware of any estimates that exist regarding the number of producer licenses that will be issued in the coming years; however, the novelty of hemp as a commercial agricultural commodity, the resolutions of uncertainty surrounding regulations, the expected growth in demand for existing and new hemp products, and the effective establishments of State, Tribal, and Federal hemp programs may continue to draw producers into the market.

Table 2. Estimated projection of number of producer licenses issued						
Year	2020	2021	2022	2023	2024	2025
Growers	20,000	22,000	24,200	26,620	29,282	32,210
Sources and notes: 2020 figure based on July 2020 National Industrial Hemp Regulators conference call. 2021-2025 figures based on assumed annual growth rate of 10% in producer licenses.						

As of the writing of this analysis, three states had opted to participate in the USDA Federal Plan authorizing producers to cultivate hemp. These states are Hawaii, Mississippi, and New Hampshire. Together, they represent more than 300 producers in 2020. The number of

licensed producers participating in the Federal Plan is likely to grow over time due to both greater entrance of producers into the market in these three states and additional states, Indian Tribes, and territories opting to participate in the USDA Plan. At the end of 2020, less than 2 percent of the total number of producers were licensed by USDA. The extension of the 2014 pilot programs to 2022, which was included in the 2021 Continuing Appropriations Act published October 1, 2020, resulted in fewer producers participating in the USDA Plan. Prior to the extension of the 2014 pilot programs, the portion of participants under the USDA Plan was about 10 percent of the total number of 2020 producers, with the expectation for further enrollment. For the purposes of this analysis, therefore, AMS assumes that 20 percent of the total number of licensed producers will be participants of the USDA Plan, and the remaining 80 percent will be participants of a State or Tribal Plan.

In addition to hemp producers, this rule will impact state departments of agriculture, Tribal governments, and USDA as these entities will bear the responsibility to ensure that hemp producers abide by the State and Tribal Plans and the USDA Plan for regulating hemp. At the time this document was written, more than 40 Indian Tribes, at least 40 states, and two U.S. territories had plans approved by USDA or were in the process of submitting plans for USDA approval. At least three states have opted to participate in the USDA plan, and one state and one territory await legislation authorizing hemp production. AMS anticipates receiving further interest in both the Federal Plan and the plans administered by states, Indian Tribes, and territories in the coming months when the provisions of the 2014 Farm Bill expire and States and Tribes start implementing their programs. For the purposes of this analysis, AMS assumes that 100 states, Indian Tribes, and territories will administer their own plans in every year from 2020 through 2025. AMS acknowledges that this number is likely to change from year to year, depending on market conditions, which affect the ability of a state, tribe, or territory to manage its own hemp program. Because AMS has no way to predict future market or state political

conditions, for simplicity, it assumes a constant of 100 states, Indian Tribes, and territories administering their own plans from 2020 through 2025.

Finally, this rule will impact laboratories that will provide testing services to producers and program administrators. As of the writing of this analysis, there were 67 laboratories that test hemp that are registered with the DEA. USDA is requiring that all samples tested for THC concentration levels be conducted in DEA-registered laboratories; however, enforcement of this requirement has been delayed until December 31, 2022.

Expected Costs and Benefits of the Rule

The 2018 Farm Bill grants authorization for production of hemp to all states and Indian Tribes, unless prohibited by State or Tribal Law. This rule enables states, Indian Tribes, and USDA to regulate this authorization. This rule is expected to generate benefits and costs to hemp producers, state departments of agriculture, Tribal governments, USDA, and laboratories. The benefits of this rule are expected to outweigh the costs, however, and the burden on the impacted entities is anticipated to be minimal.

Producers

Using figures from Hemp Industry Daily and the Brightfield Group, AMS estimates retailer sales of hemp products to range from \$2.5 billion in 2020 to nearly \$17 billion in 2025. Based on price spreads from farm to consumer, published by the Economic Research Service (ERS), AMS assumes a pass-through rate of 20 percent from retailer to producer.³⁵ AMS also assumes that import values account for 15 percent of the producer share of retail sales. This estimate was derived using 2019 and 2020 import data from the Foreign Agricultural Service (FAS) of USDA. At the time of this analysis, import data for 2020 was only available for the months of January through August. In order to gauge what total 2020 imports might be, AMS applied to the figure of total imports for January through August 2020 (\$55 million) the average

³⁵ ERS. Price Spreads from Farm to Consumer. September 2020.

percentage change that occurred in the four months from August through December of recent years (40 percent). Applying the assumptions of 20 percent price pass-through from retailer to producer and import values of 15 percent of the producer share of retail sales to the estimates of retailer sales results in estimated total producer sales of \$432 million in 2020 to \$2.9 billion in 2025, shown in Table 3.

Table 3. Estimated retailer and producer hemp product sales (millions)						
Year	2020	2021	2022	2023	2024	2025
Total retailer sales ¹	\$ 2,540	\$ 4,485	\$ 6,740	\$ 9,310	\$ 10,995	\$ 16,800
Producer share of retail sales ²	\$ 508	\$ 897	\$ 1,348	\$ 1,862	\$ 2,199	\$ 3,360
Imports ³	\$ 76	\$ 135	\$ 202	\$ 279	\$ 330	\$ 504
Total producer sales ⁴	\$ 432	\$ 762	\$ 1,146	\$ 1,583	\$ 1,869	\$ 2,856
¹ Retailer sales estimates based on the following sources: 2020-2024 estimates from Hemp & CBD Industry Factbook 2019, Hemp Industry Daily. "Annual U.S. Hemp-Derived CBD Retail Sales Estimates". Published October 16, 2019. 2025 estimate from Brightfield Group. "US CBD Market Forecast Reduced Due to Healthy Consolidation". Published July 31, 2020; ² Product of total retailer sales and 20% share of retail sales passed to producers; estimate of 20% share of retailer prices based on Economic Research Service publications of "Price Spreads from Farm to Consumer". ³ Assumes imports account for 15% sales at the producer level; source for assumption is FAS 2015-2019 import data, HTS codes 1207990320 and 5302100000. ⁴ Difference of producer share of retail sales and imports.						

The estimates in Table 3 reflect total producer sales in aggregate. AMS is unaware of any data that currently exists that would indicate sales by individual producer. Given the varied nature of the hemp industry, producer sizes are anything but uniform; therefore, AMS has not attempted to project sales by individual producer as it would likely result in false conclusions and misleading information. Similarly, data comparing sales by producers under the 2018 Farm Bill and what sales under the 2014 Farm Bill may have been in the absence of the 2018 Farm Bill does not currently exist. Further, AMS believes that this estimate would not differ greatly given the greater access to nationwide markets and flexibilities provided to producers under the 2018 Farm Bill.

In addition, AMS acknowledges that raw harvested hemp product may take years to enter the retail market after it passes through the supply chain. For instance, product sold at the retail

level in 2021 may include hemp that was harvested in 2019. In acknowledging this, AMS understands that the estimated producer sales for a given year in Table 3 may not represent actual producer sales for that year, but rather, sales from prior years. AMS is unaware of any data that exists that would identify when a harvested hemp crop is sold into the retail market. For the purposes of this analysis, therefore, and for simplicity, AMS assumes that the producer sales estimated in Table 2 represent sales at the producer level for the same year as the retail sales from which they are derived.

As discussed in the “Baseline Definition” section of this analysis, AMS estimates that 20 percent of the producer planted acreage from 2020 through 2025 will be attributable to the 2018 Farm Bill and this rule which enables its prescriptions. This 20 percent reflects the amount of planted acreage in the 17 states that opted to participate in the 2018 Farm Bill hemp programs in time for the 2020 growing season. The 2020 growing season was the final opportunity for producers to cultivate hemp under the 2014 pilot programs. By enrolling in the new hemp programs, these 17 states expressed a preference for the hemp programs authorized by the 2018 Farm Bill over the 2014 Farm Bill pilot programs. The remaining 80 percent of producer planted acreage estimated from 2020 through 2025 will be treated as attributable to the 2014 pilot programs under the assumption that they would have continued in the absence of the 2018 Farm Bill which terminated them. In Table 4, AMS has calculated total planted acreage inclusive of all domestic producers, using the estimates of total producer sales in Table 3 and assumptions that are stated and cited in the table. From the estimates of total planted acreage in Table 4, AMS calculated the planted acreage due to the rule in Table 5, along with the estimate of sales attributable to the rule. These estimates of sales due to the rule will be referenced as the benefits of the rule to producers in the calculation of net benefits in Table 10.

Table 4. Calculation of planted acreage required to meet estimated total producer sales								
Assumed constant in each year								
Intended use	Portion of total sales ¹	Yield (lbs/acre) ²	Price per lb ³	Price per acre ⁴	Portion of harvested volume sold ⁵	Portion of planted acreage harvested ⁶		
Cannabinoids	99%	1,500	\$ 3.90	\$ 5,850	65%	75%		
Fiber	0.5%	8,000	\$ 0.09	\$ 720	90%			
Grain	0.5%	1,200	\$ 0.53	\$ 636	95%			
Year	Total producer sales (millions) ⁷	Intended use	Sales by use (millions) ⁸	Acres-worth sold ⁹	Volume sold (lbs) ¹⁰	Volume harvested (lbs) ¹¹	Harvested acreage ¹²	Planted acreage ¹³
2020	\$ 432	Cannabinoids	\$ 427	73,074	109,610,769	168,631,953	112,421	159,102
		Fiber	\$ 2	2,999	23,988,889	26,654,321	3,332	
		Grain	\$ 2	3,395	4,073,585	4,287,984	3,573	
2021	\$ 762	Cannabinoids	\$ 755	129,030	193,545,000	297,761,538	198,508	280,934
		Fiber	\$ 4	5,295	42,358,333	47,064,815	5,883	
		Grain	\$ 4	5,994	7,192,925	7,571,500	6,310	
2022	\$ 1,146	Cannabinoids	\$ 1,134	193,905	290,856,923	447,472,189	298,315	422,184
		Fiber	\$ 6	7,957	63,655,556	70,728,395	8,841	
		Grain	\$ 6	9,008	10,809,434	11,378,352	9,482	
2023	\$ 1,583	Cannabinoids	\$ 1,567	267,842	401,762,308	618,095,858	412,064	583,165
		Fiber	\$ 8	10,991	87,927,778	97,697,531	12,212	
		Grain	\$ 8	12,443	14,931,132	15,716,981	13,097	
2024	\$ 1,869	Cannabinoids	\$ 1,850	316,318	474,476,538	729,963,905	486,643	688,711
		Fiber	\$ 9	12,980	103,841,667	115,379,630	14,422	
		Grain	\$ 9	14,695	17,633,491	18,561,569	15,468	
2025	\$ 2,856	Cannabinoids	\$ 2,827	483,323	724,984,615	1,115,360,947	743,574	1,052,327
		Fiber	\$ 14	19,833	158,666,667	176,296,296	22,037	
		Grain	\$ 14	22,453	26,943,396	28,361,470	23,635	

Sources and notes:

¹ Kentucky Department of Agriculture 2019 producer data.

² Hemp Enterprise Budgets from University of Kentucky, University of Tennessee, University of Georgia, North Dakota State University, Alabama A&M and Auburn Universities, Cornell University, and Penn State University.

³ The Jacobsen. Estimates based on 2019 and 2020 prices; for biomass, CBD% assumed to be 6%.

⁴ Product of yield and price per lb.

⁵ Kentucky Department of Agriculture 2019 producer data.

⁶ State departments of agriculture.

⁷ See Table 3.

⁸ Product of total producer sales and portions of total sales.

⁹ Quotient of sales by use and price per acre.

¹⁰ Product of yield and acres-worth sold.

¹¹ Quotient of volume sold and portion of harvested volume sold.

¹² Quotient of harvested volume and yield.

¹³ Quotient of the sum of harvested acreage and portion of planted acreage harvested.

To calculate total planted acreage nationwide in Table 4, from which planted acreage due to this rule will be estimated in Table 5, AMS assumed the following to remain constant in each year from 2020 through 2025: portion of total sales by intended use; yields by intended use; prices per pound by intended use; portions of harvested volume sold by intended use; and the portion of planted acreage that is typically harvested. Using 2019 producer data from the Kentucky Department of Agriculture, AMS estimates that of total sales of hemp products,

cannabinoids accounts for 99 percent, and fiber and grain each account for 0.5 percent. Also based on data from the Kentucky Department of Agriculture, AMS estimates that 65 percent of the harvested volume of hemp for cannabinoids is sold, 90 percent of hemp harvested for fiber is sold, and 95 percent of hemp harvested for grain is sold.³⁶ This assumption is also referenced in Table 5. AMS compared the hemp enterprise budgets published by seven different academic institutions for yield estimates which represent the growing conditions across the country. Aside from these seven, AMS is unaware of any other hemp enterprise budgets published by an academic institution.

Based on 2019 and 2020 prices published by the Jacobsen, AMS assumes constant per-pound prices for cannabinoids, fiber, and grain of \$3.90, \$0.09, and \$0.53, respectively.³⁷ AMS acknowledges that prices are unlikely to remain constant from year to year, particularly for cannabinoids; however, AMS has considered 68 weeks of cannabinoids prices in determining its estimate of \$3.90 per pound. This price assumes 6 percent CBD at \$0.65 per CBD percentage per pound. Using these prices and yield estimates, AMS calculated a price per acre for each intended use of hemp. Finally, the assumption that 75 percent of planted acreage is harvested was estimated using data from multiple state departments of agriculture. The assumed constants of the portion of planted acreage that is harvested, yield by intended use, portion of harvested volume that is sold, and prices by intended use are also utilized in Table 5.

³⁶ The Kentucky Department of Agriculture is widely recognized as a reliable source for hemp market data as it has collected data from its producers since the inception of its hemp program in 2014. Much of this data is publicly available and was cited by many commenters.

³⁷ The Jacobsen Publishing Company. Weekly hemp prices from July 2019 through August 2020.

Table 5. Calculation of producer sales attributable to the rule									
Assumed constant in each year									
Intended use	Portion of planted acreage due to the rule ¹	Portion of planted acreage ²	Portion of planted acreage harvested ³	Yield (lbs/acre) ⁴	Portion of harvested volume sold ⁵	Price per lb ⁶			
Cannabinoids	20%	80%	75%	1,500	65%	\$ 3.90			
Fiber		3%		8,000	90%	\$ 0.09			
Grain		17%		1,200	95%	\$ 0.53			
Year	Total planted acreage ⁷	Planted acreage due to rule ⁸	Intended use	Planted acreage due to rule by use ⁹	Harvested acreage due to rule ¹⁰	Volume harvested due to rule ¹¹	Volume sold due to rule ¹²	Sales by use due to rule (millions) ¹³	Total sales due to rule (millions) ¹⁴
2020	159,102	31,820	Cannabinoids	25,456	19,092	28,638,339	18,614,920	\$ 72.6	\$ 76
			Fiber	955	716	5,727,668	5,154,901	\$ 0.5	
			Grain	5,409	4,057	4,868,518	4,625,092	\$ 2.5	
2021	280,934	56,187	Cannabinoids	44,949	33,712	50,568,090	32,869,259	\$ 128.2	\$ 133
			Fiber	1,686	1,264	10,113,618	9,102,256	\$ 0.8	
			Grain	9,552	7,164	8,596,575	8,166,747	\$ 4.3	
2022	422,184	84,437	Cannabinoids	67,549	50,662	75,993,072	49,395,497	\$ 192.6	\$ 200
			Fiber	2,533	1,900	15,198,614	13,678,753	\$ 1.2	
			Grain	14,354	10,766	12,918,822	12,272,881	\$ 6.5	
2023	583,165	116,633	Cannabinoids	93,306	69,980	104,969,659	68,230,279	\$ 266.1	\$ 277
			Fiber	3,499	2,624	20,993,932	18,894,539	\$ 1.7	
			Grain	19,828	14,871	17,844,842	16,952,600	\$ 9.0	
2024	688,711	137,742	Cannabinoids	110,194	82,645	123,967,928	80,579,153	\$ 314.3	\$ 327
			Fiber	4,132	3,099	24,793,586	22,314,227	\$ 2.0	
			Grain	23,416	17,562	21,074,548	20,020,820	\$ 10.6	
2025	1,052,327	210,465	Cannabinoids	168,372	126,279	189,418,934	123,122,307	\$ 480.2	\$ 499
			Fiber	6,314	4,735	37,883,787	34,095,408	\$ 3.1	
			Grain	35,779	26,834	32,201,219	30,591,158	\$ 16.2	

Sources and notes:

¹ Portion of planted acreage in states which had plans approved by USDA for a hemp production program to begin in time for the 2020 growing season; planted acreage data from state departments of agriculture.

² The Jacobsen. Hemp Daily Bulletin, September 8, 2020. Estimated US Hemp Acreage 2020.

³ State departments of agriculture.

⁴ Hemp Enterprise Budgets from University of Kentucky, University of Tennessee, University of Georgia, North Dakota State University, Alabama A&M and Auburn Universities, Cornell University, and Penn State University.

⁵ Kentucky Department of Agriculture 2019 producer data.

⁶ The Jacobsen. Estimates based on 2019 and 2020 prices; for biomass, CBD% assumed to be 6%.

⁷ See Table 4.

⁸ Product of total planted acreage and portion of planted acreage due to rule.

⁹ Product of planted acreage due to rule and portion of planted acreage by use.

¹⁰ Product of planted acreage due to rule by use and portion of planted acreage harvested.

¹¹ Product of harvested acreage due to rule and yield.

¹² Product of volume harvested due to rule and portion of harvested volume sold.

¹³ Product of volume sold due to rule and price per lb.

¹⁴ Sum of sales by use due to rule.

In addition to the assumptions already identified in reference to Table 4, AMS assumes constant the portion of planted acreage due to the rule and portions of planted acreage by intended use. As described in the “Baseline Definition” section, AMS assumes that 20 percent of total planted acreage can be considered as attributable to the rule. This proportion represents the amount of planted acreage of the states that had plans approved by USDA for a hemp production program, as authorized by the 2018 Farm Bill, in time for the 2020 growing season. The 2020 growing season was the final opportunity for producers to cultivate hemp under the

2014 pilot programs. By enrolling in the new hemp programs, these states expressed a preference for the hemp programs authorized by the 2018 Farm Bill over the 2014 Farm Bill pilot programs.

The Jacobsen estimated that of total planted acreage in 2020, 80 percent was for cannabinoids, 3 percent was for fiber, and 17 percent was for grain. AMS acknowledges that planted acreage by intended use is likely to change from year to year as a result of market conditions. The portion of acreage intended for cannabinoids has, indeed, decreased from its levels in 2019, with grain and fiber gaining greater consumer attention. AMS is unaware of any data that forecasts planted acreage by intended use in years beyond 2020. For the purposes of this analysis, and for simplicity, therefore, AMS assumes constant the portions of planted acreage by intended use as reported for 2020.

To reiterate, AMS is aware that raw hemp product at the producer level may take years to enter the retail market. The analysis in Tables 4 and 5 is meant to show potential consumer demand for hemp products at the producer level in years 2020 through 2025, and not necessarily the producer sales of hemp cultivated in these specific years. These estimates are sensitive to changes in price. Because planted acreage is derived from total sales, a change in price causes an inverse change in the estimate of planted acreage; however, the relationship between price and sales is, of course, positive.

Many states reported to AMS that the land on which hemp is currently grown was previously utilized for cultivation of corn. Using data from the National Agricultural Statistics Service (NASS) on the production value of corn for grain and acres harvested, AMS determines a value per harvested acre of corn of \$630. This value is a national average of the three-year period of 2017 through 2019, which are the most recent years for which data is available.³⁸ For the purposes of this analysis, this value of \$630 per acre will serve as the opportunity cost to

³⁸ NASS. Quick Stats. Variable “Corn, grain – production, measured in \$” divided by variable “Corn, grain – acres harvested”.

hemp producers. The opportunity cost is the potential returns that are foregone in pursuit of an alternative. The potential foregone returns, in this case, are \$630 per acre for corn cultivation; and, the alternative is hemp cultivation. Applying this value to the estimates of acreage required to meet estimated producer sales as calculated in Table 5 results in the total opportunity cost to producers in years 2020 through 2025 as shown in Table 6.

Table 6. Calculation of opportunity cost to producers of hemp cultivation under rule						
2017-2019 average returns per acre of corn for grain ¹						\$ 630
Year	2020	2021	2022	2023	2024	2025
Planted acres due to rule ²	31,820	56,187	84,437	116,633	137,742	210,465
Opportunity cost (millions) ³	\$ 20	\$ 35	\$ 53	\$ 73	\$ 87	\$ 133
Sources and notes:						
¹ National Agricultural Statistics Service (NASS).						
² See Table 5 for estimate calculation.						
³ Product of 2017-2019 average returns per acre of corn for grain and acres worth of hemp sold.						

In the IFR, AMS calculated an opportunity cost of \$591 per acre, using an average of returns per acre for all cropland, weighted by area planted or bearing. This estimate utilized NASS crop totals for fruits, vegetables, and traditional field crops. At the time of the writing of the IFR, AMS had little information as to the prior uses of land currently being cultivated for hemp. To address this in the final rule, AMS sought input from state departments of agriculture, most of which reported that the land on which hemp is currently grown was previously utilized for cultivation of corn.

AMS has modified its sampling and testing requirements, which are described in the section in this rule titled “Sampling for total THC”, to allow for “performance-based sampling”. A performance-based protocol must have the potential to ensure at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level. Performance-based sampling achieves defined objectives and focuses on results. It differs significantly from a prescriptive action in which licensees are provided detailed direction on how those results are to be obtained. A performance-based approach would simply set a performance objective (e.g., reliability of 95 percent) and allow the States and Indian Tribes

considerable freedom in how to achieve that reliability objective with their sampling methodology.

To estimate the number of lots to be sampled in each year, AMS employs the Cochran Formula:

$n_0 = \frac{Z^2 p(1-p)}{e^2}$, where n_0 is the sample size, Z is the z-value associated with a confidence interval, p is the estimated proportion of the population that has the attribute in question, and e is the margin of error or the desired level of precision.

Inserting the z-value that corresponds to a 95 percent confidence interval, assuming maximum variability for p at 50 percent, and applying the margin of error of one percent results in the following sample size:

$$n_0 = \frac{1.96^2(0.5(1-0.5))}{0.01^2} = 9,604 \text{ samples.}$$

The Cochran Formula assumes an unlimited population size; however, the formula can be modified to return a smaller sample size for a finite population:

$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$, where n is the modified sample size, n_0 is the Cochran Formula sample size, and N is the population size.

Table 7 shows the number of sampled lots, n , required for a 95 percent confidence interval and one percent margin of error for each year's total number of lots, N . The total annual cost of sampling and testing borne by producers is calculated using a cost per lot of \$565, which was estimated using hourly rates for inspectors and for laboratory services of \$75 and \$98, respectively; two hours, apiece, spent sampling, driving, and testing; 120 miles driven; and, \$0.58 per mile compensation. In its calculation of total number of lots from total planted acreage, AMS utilized the portions of planted acreage by intended use, introduced in Table 5, and data from the Farm Service Agency (FSA) from which average lot sizes for hemp by intended use were derived.

Table 7. Calculation of sampling and testing costs to producers							
Assumed constant in each year							
Intended use	Portions of planted acreage by use ¹	Average number of acres per lot ²	Cochran Formula ³	Modification for small sample size ⁴	Sampling & testing cost per lot ⁵		
Cannabinoids	80%	10	$n_0 = \frac{Z^2 p(1-p)}{e^2}$	$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$	\$ 565		
Fiber	3%	15					
Grain	17%	37					
Year	Total planted acreage ⁶	Intended use	Total planted acreage by use ⁷	Total number of lots ⁸	n_0	n	Sampling & testing costs (millions) ⁹
2020	159,102	Cannabinoids	127,282	12,728	9,604	5,659	\$ 3.20
		Fiber	4,773	318			
		Grain	27,047	731			
2021	280,934	Cannabinoids	224,747	22,475	9,604	6,886	\$ 3.89
		Fiber	8,428	562			
		Grain	47,759	1,291			
2022	422,184	Cannabinoids	337,747	33,775	9,604	7,606	\$ 4.30
		Fiber	12,666	844			
		Grain	71,771	1,940			
2023	583,165	Cannabinoids	466,532	46,653	9,604	8,069	\$ 4.56
		Fiber	17,495	1,166			
		Grain	99,138	2,679			
2024	688,711	Cannabinoids	550,969	55,097	9,604	8,272	\$ 4.67
		Fiber	20,661	1,377			
		Grain	117,081	3,164			
2025	1,052,327	Cannabinoids	841,862	84,186	9,604	8,688	\$ 4.91
		Fiber	31,570	2,105			
		Grain	178,896	4,835			

Sources and notes:

¹ The Jacobsen. Hemp Daily Bulletin, September 8, 2020. Estimated US Hemp Acreage 2020.

² Farm Service Agency producer data.

³ Where n_0 is the sample size, Z is the z-value associated with a confidence interval, p is the estimated proportion of the population that has the attribute in question, and e is the margin of error or the desired level of precision.

⁴ Where n is the modified sample size, n_0 is the Cochran Formula sample size, and N is the population size.

⁵ Assumes hourly rates for inspector of \$75 and for laboratory services of \$98; also assumes time spent sampling, time spent driving, and time spent testing of 2 hours each; assumes 120 miles driven and mileage compensation rate of \$0.58 per mile.

⁶ See Table 4.

⁷ Product of total planted acreage and portions of planted acreage by use.

⁸ Quotient of total planted acreage and average number of acres per lot.

⁹ Product of sample size n and sampling & testing cost per lot.

Some portion of tested lots are likely to return results with THC concentrations greater than 0.3 percent. To estimate this percentage, AMS utilized data, specific to this very question, collected by the National Industrial Hemp Regulators during a November 2019 meeting. The average portion of tests that would return results of THC concentrations greater than 0.3 percent, weighted by the number of tests administered in each state, was 25 percent. In Table 8, AMS

applies this percentage to estimate total noncompliant lots in each year and the cost to dispose of noncompliant acreage. AMS is aware of other estimates of THC concentration failure rates. As of November 2020, States and Tribes operating under the 2018 Farm Bill reported 4,192 licensed producers representing 6,166 acres planted. Of these acres planted, approximately 12 percent were destroyed due to THC levels exceeding 0.3 percent. This data, however, is limited because many approved plans have not all been fully implemented. USDA expects more data will be available as the 2021 season begins and States and Tribes implement their programs.

Table 8. Calculation of disposal costs to producers						
Assumed constant in each year						
Intended use	Portion of tests with results of noncompliant THC levels ¹	Portions of planted acreage by use ²	Average number of acres per lot ³	Disposal time per acre of hemp (hours) ⁴	Compliance officer hourly salary ⁵	Cost per acre of noncompliant hemp disposal ⁶
Cannabinoids	25%	80%	10	0.25	\$ 57	\$ 14.25
Fiber		3%	15			
Grain		17%	37			
Year	Intended use	Sampled & tested lots ⁷	Noncompliant lots ⁸	Noncompliant acres ⁹	Total noncompliant acreage disposal costs (millions) ¹⁰	
2020	Cannabinoids	5,659	1,415	11,319	\$	0.30
	Fiber			637		
	Grain			8,899		
2021	Cannabinoids	6,886	1,721	13,772	\$	0.36
	Fiber			775		
	Grain			10,828		
2022	Cannabinoids	7,606	1,902	15,212	\$	0.40
	Fiber			856		
	Grain			11,961		
2023	Cannabinoids	8,069	2,017	16,139	\$	0.42
	Fiber			908		
	Grain			12,689		
2024	Cannabinoids	8,272	2,068	16,544	\$	0.43
	Fiber			931		
	Grain			13,008		
2025	Cannabinoids	8,688	2,172	17,377	\$	0.46
	Fiber			977		
	Grain			13,663		

Sources and notes:

¹ National Industrial Hemp Regulators' conference call. November 2019.
² The Jacobsen. Hemp Daily Bulletin, September 8, 2020. Estimated US Hemp Acreage 2020.
³ Farm Service Agency producer data.
⁴ AMS estimate based on state and producer feedback.
⁵ Bureau of Labor and Statistics. Occupational Employment Statistics Survey. May 2019; see PRA section.
⁶ Product of disposal time per acre of hemp and compliance officer hourly salary.
⁷ See Table 7 sample size *n*.
⁸ Product of sampled & tested lots and portion of tests with results of noncompliant THC levels.
⁹ Product of noncompliant lots, portions of planted acreage by use, and average number of acres per lot.
¹⁰ Product of the sum of noncompliant acres and cost per acre of noncompliant hemp disposal.

AMS has issued guidance on approved methods for disposal of noncompliant hemp material, including plowing under, mulching or composting, disking, bush mowing or chopping, deep burial, and burning. AMS requires disposal of noncompliant hemp using one of these methods. Discussion with state departments of agriculture and producers led AMS to estimate an average of 15 minutes per acre required to dispose of noncompliant material. This 15-minute estimate is an average across all disposal methods. According to the May 2019 Occupational

Employment Statistics Survey of the Bureau of Labor and Statistics, the mean hourly wage of a compliance officer is \$35. Assuming 39 percent of total compensation accounts for benefits, then total compensation of a compliance officer is \$57 per hour. This is described in the Paperwork Reduction Act (PRA) section of this rule. Applying the total hourly salary of a compliance officer to the disposal time per acre of hemp results in a per acre cost of \$14.25 for disposal of noncompliant hemp acreage.

The PRA section details the burdens of reporting and recordkeeping and their associated costs. Table 9 shows the calculations of the reporting and recordkeeping costs to producers that will be imposed by this rule. All assumptions in this table have been previously introduced. The PRA section describes how each estimate of time was calculated per required form.

Table 9. Calculation of total reporting and recordkeeping costs to producers								
Assumed constant in each year								
Portions of producer licenses issued by Plan ¹		Portion of total planted acreage or lots under USDA Plan ²		Reporting & recordkeeping hours per producer (required of all) ³		Reporting & recordkeeping hours per disposed lot ⁴		Hourly salary of a compliance officer ⁵
USDA Plan	State/Tribal Plans	15%		USDA Plan	State/Tribal Plans	USDA Plan	State/Tribal Plans	\$
20%	80%			2.14	2.25	0.42	0.25	57
Year	Producers ⁶			Noncompliant lots for disposal ⁷		Total reporting & recordkeeping hours ⁸		Total producer reporting & recordkeeping cost (millions) ⁹
	Total	USDA Plan	State/Tribal Plans	USDA Plan	State/Tribal Plans	USDA Plan	State/Tribal Plans	
2020	20,000	4,000	16,000	212	1,203	8,640	36,289	\$ 2.56
2021	22,000	4,400	17,600	258	1,463	9,514	39,953	\$ 2.82
2022	24,200	4,840	19,360	285	1,616	10,466	43,951	\$ 3.10
2023	26,620	5,324	21,296	303	1,715	11,508	48,330	\$ 3.41
2024	29,282	5,856	23,426	310	1,758	12,650	53,131	\$ 3.75
2025	32,210	6,442	25,768	326	1,846	13,908	58,422	\$ 4.12
Sources and notes:								
¹ Portions of the number of producers under the USDA Plan and the State and Tribal Plans in 2020; data from state departments of agriculture.								
² Portion of planted acreage in states operating under USDA Plan; planted acreage data from state departments of agriculture.								
³ See PRA section.								
⁴ See PRA section.								
⁵ Bureau of Labor and Statistics. Occupational Employment Statistics Survey. May 2019; see PRA section.								
⁶ See Table 2 for total producers; product of total producers and portions of producer licenses issued by Plan.								
⁷ Product of noncompliant lots in Table 8 and portions of total planted acreage or lots under USDA Plan versus State/Tribal Plans.								
⁸ Sum of the product of reporting & recordkeeping hours per producer and producers and the product of reporting & recordkeeping hours per disposed lot and noncompliant lots for disposal.								
⁹ Product of hourly salary of a compliance officer and the sum of total reporting & recordkeeping hours.								

In order to obtain a producer license, AMS requires that each producer, or key participant of a business entity, submit to a background check, or criminal history report, at least every three years. A key participant is a person with a direct or indirect financial interest in the hemp-

producing entity, including a chief executive officer, a chief operating officer, and a chief financial officer. The cost of a criminal history report conducted by the Federal Bureau of Investigation (FBI) is \$18 per record. For the purposes of this analysis, AMS assumes each producer license to represent three key participants. The total annual cost of a background check for three key participants every three years at minimum is \$18 per producer.

The producer net benefits of this rule to society are shown in Table 10. Subtracted from producer sales due to the rule are the opportunity costs of the land on which hemp is currently grown; sampling and testing costs; disposal of noncompliant acreage; reporting and recordkeeping burdens; and, annual background checks. The producer net benefits of this rule to society range from \$49 million in 2020 to \$357 million in 2025.

	2020	2021	2022	2023	2024	2025
Grower sales due to rule	\$ 75.51	\$ 133.34	\$ 200.38	\$ 276.78	\$ 326.88	\$ 499.46
Opportunity cost	\$ (20.05)	\$ (35.40)	\$ (53.20)	\$ (73.48)	\$ (86.78)	\$ (132.59)
Sampling & testing	\$ (3.20)	\$ (3.89)	\$ (4.30)	\$ (4.56)	\$ (4.67)	\$ (4.91)
Disposal of noncompliant material	\$ (0.30)	\$ (0.36)	\$ (0.40)	\$ (0.42)	\$ (0.43)	\$ (0.46)
Reporting & recordkeeping	\$ (2.56)	\$ (2.82)	\$ (3.10)	\$ (3.41)	\$ (3.75)	\$ (4.12)
Background checks	\$ (0.36)	\$ (0.40)	\$ (0.44)	\$ (0.48)	\$ (0.53)	\$ (0.58)
Net benefits	\$ 49.05	\$ 90.47	\$ 138.95	\$ 194.43	\$ 230.72	\$ 356.80

States, Indian Tribes, and USDA

States and Indian Tribes have the authority to establish fee structures to fund their hemp programs. As of the writing of this analysis, about half of the states with plans approved by USDA reported their programs as being full funded through user-fees. To estimate the cost of administering a hemp program, AMS calculated an average of the total fees charged to producers by these states, which reported as fully user-fee funded, to use as a proxy for the per producer cost of hemp program administration. The fees used to calculate this average included those with such designations as application fee, site registration fee, licensing fee, and others. The average did not include fees associated with sampling and testing as these were calculated separately in Table 7. AMS estimates an average cost per producer of hemp program administration of \$800 annually. AMS has no reason to believe that Indian Tribes or USDA will

be any more or any less efficient than states in program administration. AMS believes, therefore, that this figure is a suitable proxy for the cost of program administration to states, Indian Tribes, and USDA per producer who cultivates hemp as a result of this rule.

As discussed in the “Baseline Definition” section, 17 states opted to participate in the new hemp programs authorized by the 2018 Farm Bill in time for the 2020 growing season. These states represented 20 percent of both planted acreage nationwide and the number of producers nationwide. By applying this percentage to the total number of producers in each year, as shown in Table 2, AMS estimates the number of producers that will cultivate hemp due to this rule. The product of the number of producers due to this rule and the \$800 per grower proxy for administration costs results in program administration costs to States, Indian Tribes, and USDA of \$3 million in 2020 to \$5 million in 2025.

This rule places a reporting and recordkeeping burden on states and Indian Tribes as detailed in the PRA section of this rule. The total time required per state or tribe for reporting and recordkeeping is 25.25 hours annually. AMS assumes constant the number of states and Indian Tribes that will operate their own hemp programs at 100 in total from 2020 through 2025. In total, the time required of 100 states and Indian Tribes for 25.25 hours of reporting and recordkeeping is 2,525 hours. Applying the hourly salary of a compliance officer of \$57 to this total results in an annual cost to all states and Indian Tribes of reporting and recordkeeping of \$143,919, or \$1,439 per state or tribe.

The total administration costs to states, Indian Tribes, and USDA are calculated in Table 11. They include the costs to all three entities of program administration, and the costs of reporting and recordkeeping to states and Indian Tribes. Total administration costs to states, Indian Tribes, and USDA range from \$3 million in 2020 to \$5 million in 2025.

Table 11. Total costs to States, Indian Tribes, and USDA (millions)						
	2020	2021	2022	2023	2024	2025
Program administration	\$ (3.20)	\$ (3.52)	\$ (3.87)	\$ (4.26)	\$ (4.69)	\$ (5.15)
Reporting & recordkeeping	\$ (0.14)	\$ (0.14)	\$ (0.14)	\$ (0.14)	\$ (0.14)	\$ (0.14)
Total costs	\$ (3.34)	\$ (3.66)	\$ (4.02)	\$ (4.40)	\$ (4.83)	\$ (5.30)

Laboratories

This rule also places a reporting and recordkeeping burden on laboratories as they will be required to report on the results of samples tested for THC content to the entities administering the hemp programs. The PRA section of this rule estimates an annual reporting and recordkeeping requirement for laboratories of 0.58 hours per sampled and tested lot. As calculated in Table 7, the total number of lots to be sampled and tested in each year is 5,659 in 2020; 6,886 in 2021; 7,606 in 2022; 8,069 in 2023; 8,272 in 2024; and, 8,688 in 2025. Multiplying the total number of lots to be sampled and tested in each year by the annual reporting and recordkeeping requirement of 0.58 hours per sampled and tested lot and by the hourly salary of a compliance officer of \$57 results in the total annual costs to laboratories as shown in Table 12.

	2020	2021	2022	2023	2024	2025
Reporting & recordkeeping	\$ (0.19)	\$ (0.23)	\$ (0.25)	\$ (0.27)	\$ (0.27)	\$ (0.29)

Total Net Benefit

Producers, states, Indian Tribes, and USDA, and laboratories are the entities most likely to be impacted by this rule. For this reason, the net benefits or costs of this rule to these entities have been evaluated in this analysis. The total net benefits to society as a whole and their present values by year are shown in Table 13. The rule has a positive net benefit in every year, ranging from \$46 million in 2020 to \$351 million in 2025.

Entity	2020	2021	2022	2023	2024	2025
Producers	\$ 49.05	\$ 90.47	\$ 138.95	\$ 194.43	\$ 230.72	\$ 356.80
States, Tribes & USDA	\$ (3.34)	\$ (3.66)	\$ (4.02)	\$ (4.40)	\$ (4.83)	\$ (5.30)
Laboratories	\$ (0.19)	\$ (0.23)	\$ (0.25)	\$ (0.27)	\$ (0.27)	\$ (0.29)
Total	\$ 45.52	\$ 86.58	\$ 134.68	\$ 189.76	\$ 225.61	\$ 351.21
Present values of net benefits annualized at the given discount rates						
Discount rates	2020	2021	2022	2023	2024	2025
3%	\$ 45.52	\$ 84.06	\$ 126.95	\$ 173.66	\$ 200.45	\$ 302.96
7%	\$ 45.52	\$ 80.92	\$ 117.63	\$ 154.90	\$ 172.12	\$ 250.41

Alternatives

In developing this final rule, AMS considered several alternatives to the policies that were adopted. The first of these was related to methodologies for sampling. The methodologies considered include sampling and testing of all lots, as mandated in the IFR, sampling and testing based on risk, and sampling and testing based on performance. The latter of these was the sampling methodology that was chosen for the final rule as it results in the lowest total cost to producers. Performance-based sampling also grants flexibility to States and Indian Tribes in the development of sampling methodologies. In the IFR, AMS required sampling of every hemp lot, regardless of intended use; however, AMS has determined that compliance to this method would too greatly burden producers as well as program administrators, whose responsibility it would be to enforce it. AMS also considered requiring risk-based sampling, which would mandate minimum portions of sampling of lots by intended use. The portions of lots to be sampled by intended use that were considered were 50 percent of lots for cannabinoids, 10 percent of lots for fiber, and 10 percent of lots for grain. AMS currently lacks sufficient data to successfully carry out a risk-based sampling methodology that would be applicable to the varying growing regions nationwide; therefore, the risk-based sampling methodology was not chosen for this final rule. An analysis of these sampling methodologies is illustrated in Table 14.

Intended use	Portions to be sampled & tested based on methodology			Cost per lot of sampling & testing				
	All lots (IFR)	Risk-based	Performance-based (FR)					
Cannabinoids	100%	50%	USDA Plan acreage only	\$ 565				
Fiber		10%						
Grain		10%						
Year	Intended use	Total number of lots	Lots sampled & tested			Total cost of sampling & testing		
			IFR	Risk-based	Performance-based	IFR	Risk-based	Performance-based
2020	Cannabinoids	12,728	13,777	6,469	5,659	\$ 7,784,210	\$ 3,654,983	\$ 3,197,536
	Fiber	318						
	Grain	731						
2021	Cannabinoids	22,475	24,327	11,423	6,886	\$ 13,744,954	\$ 6,453,779	\$ 3,890,515
	Fiber	562						
	Grain	1,291						
2022	Cannabinoids	33,775	36,559	17,166	7,606	\$ 20,655,739	\$ 9,698,656	\$ 4,297,440
	Fiber	844						
	Grain	1,940						
2023	Cannabinoids	46,653	50,499	23,711	8,069	\$ 28,531,888	\$ 13,396,808	\$ 4,559,260
	Fiber	1,166						
	Grain	2,679						
2024	Cannabinoids	55,097	59,639	28,003	8,272	\$ 33,695,823	\$ 15,821,472	\$ 4,673,701
	Fiber	1,377						
	Grain	3,164						
2025	Cannabinoids	84,186	91,126	42,787	8,688	\$ 51,486,114	\$ 24,174,691	\$ 4,908,947
	Fiber	2,105						
	Grain	4,835						
Sources and notes: See Table 7 for calculations and references.								

Secondly, AMS considered retaining at 0.5 percent the limit for total THC content that would result in a negligent violation, as required in the IFR. Based on comments, however, AMS has determined this requirement to be too greatly burdensome to producers as factors beyond the control of the producer, such as seed genetics, weather and climate, may cause an increase in total THC-levels. By increasing the negligent violation threshold to 1.0 percent, AMS diminishes the risk to producers of incurring a negligent violation, which results in time and cost savings to producers and to program-administering entities.

Finally, AMS considered mandating a post-sample harvest window of 15 days, as required in the IFR. Based on comments and in consideration of the time required to complete sampling and testing activities, AMS has determined that requiring a 15-day post-sample harvest window would place undue strain on resources. AMS believes that the extension of the post-sample harvest window to 30 days will provide producers with a beneficial flexibility to adjust to unforeseen weather events and will accommodate complicated harvest processes.

Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (5 U.S.C. 601-612), AMS has considered the economic impact of this action on small entities. AMS prepared an initial regulatory flexibility act analysis presented with the interim final rule, and has now prepared this Final Regulatory Flexibility Act Analysis. AMS has determined that this rule will have a significant economic impact on a substantial number of small businesses because many small businesses will not be able to participate in the hemp market without this rule.

Need for Regulation

The rule is necessary to facilitate the domestic cultivation of hemp for sale into the market for hemp products by creating a set of minimum standards to ensure that hemp being produced under this program meets all statutory requirements. The rule establishes minimum requirements for States and Indian Tribes to obtain program approval and, for producers operating under the Federal program to obtain a license and meet operating requirements under that license. Without these provisions, it would not be possible to grow hemp legally.

Both the declassification of hemp, and the prohibition on interference with interstate transportation apply to hemp that is grown under an approved State or Tribal plan, or under a Federal license. As a result, this regulation facilitates provisions of the 2018 Farm Bill that would otherwise be self-implementing.

Overview of the Action

The 2018 Farm Bill granted regulatory authority of domestic hemp production to the State departments of agriculture, Tribal governments, and USDA. States and Indian Tribes wishing to operate their own programs must submit to USDA plans that include provisions for maintaining information regarding the land on which hemp is produced, for testing the levels of THC, for disposal of plants that do not meet necessary requirements, and for procedures to ensure compliance with the requirements of the new part, including background checks of all key participants. State and Tribal Plans must be approved by USDA. This rule outlines

requirements by which the USDA would approve plans submitted by States and Tribal governments for oversight of hemp production. The 2018 Farm Bill also directs USDA to develop a plan for use by hemp producers in States or Indian Tribes where no State or Tribal Plan has been approved and that do not prohibit the cultivation of hemp. These actions will promote consistency in regulations governing the legal production of hemp across the country.

Potentially Affected Small Entities

The Small Business Administration (SBA) defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than \$1 million. Unfortunately, very little data exists on hemp grower sales receipts. To conduct this analysis, however, AMS estimated prices per acre by intended use of hemp to find the acreage equivalent of \$1 million per intended use. AMS encountered data limitations due to the lack of reporting by States and Tribes that have not started implementing the 2018 Farm Bill provisions and the extension of the 2014 Farm Bill provisions which do not require reporting from States.

To this end, AMS utilized data on acreage by intended use from the Kentucky Department of Agriculture and the Montana Department of Agriculture. Together, Kentucky and Montana make up a large amount of domestic acreage and represent diversity in hemp planted by intended use. For the purpose of this analysis, therefore, AMS assumes that the combined planted acreage by intended use in Kentucky and Montana adequately represent the planted acreage by intended use across the United States.

For yield estimates, AMS compared the hemp enterprise budgets published by seven different academic institutions that represent the growing conditions across the country. Aside from these seven, AMS is unaware of any other hemp enterprise budgets published by an academic institution. AMS sourced 2019 and 2020 prices from the Jacobsen to estimate per-pound prices for cannabinoids, fiber, and grain of \$3.90, \$0.09, and \$0.53, respectively. The price for cannabinoids assumes 6 percent CBD content at \$0.65 per CBD percentage per pound.

Using these prices and yield estimates, AMS calculated a price per acre for each intended use of hemp, as shown in Table 15. From the estimates of price per acre by intended use, AMS calculated the equivalent of \$1 million in acres of hemp product per intended use. Of the 922 unique producers in the combined data from the Kentucky and Montana Departments of Agriculture, 97 percent reported acreage no greater than the amounts necessary to reach \$1 million, based on the estimated prices per acre. Assuming that these data are representative of the U.S. as a whole, then 97 percent of domestic producers of hemp would meet the SBA size standard of a small business of annual receipts of no greater than \$1 million.

Table 15. Calculation of the portion of producers considered to be small per SBA standards			
Intended use	Yield (lbs/acre) ¹	Price per lb ²	Price per acre ³
Cannabinoids	1,500	\$ 3.90	\$ 5,850
Fiber	8,000	\$ 0.09	\$ 720
Grain	1,200	\$ 0.53	\$ 636
Intended use	Acreage equivalent of \$1 million ⁴		Small producers
Cannabinoids	171		97%
Fiber	1,389		
Grain	1,572		
Sources and notes:			
¹ Hemp Enterprise Budgets from University of Kentucky, University of Tennessee, University of Georgia, North Dakota State University, Alabama A&M and Auburn Universities, Cornell University, and Penn State University.			
² The Jacobsen. Estimates based on 2019 and 2020 prices; for biomass, CBD% assumed to be 6%.			
³ Product of yield and price per lb.			
⁴ Quotient of \$1 million and price per acre by intended use.			

Alternatives Considered to Minimize Impacts of the Rule

In developing this final rule, due to comments received and experiences from the 2020 season, AMS considered several alternatives to the policies that were adopted. The first of these was related to methodologies for sampling. The methodologies considered include sampling and testing of all lots, as mandated in the IFR, sampling and testing based on risk, and sampling and testing based on performance. The latter of these was the sampling methodology that was

chosen for the final rule as it results in the lowest total cost to producers. Performance-based sampling also grants flexibility to States and Indian Tribes in the development of sampling methodologies. Some States currently have considered performance-based sampling under the 2014 Farm Bill. However, this information is not available and will need to be evaluated and approved by USDA as part of State and Tribal plans before it can be implemented under the 2018 Farm Bill program if States and Tribes decide to utilize this option. In the IFR, AMS required sampling of every hemp lot, regardless of intended use; however, AMS has determined that compliance to this method would too greatly burden producers as well as program administrators, whose responsibility it would be to enforce it. AMS also considered requiring risk-based sampling, which would mandate minimum portions of sampling of lots by intended use. The portions of lots to be sampled by intended use that were considered were 50 percent of lots for cannabinoids, 10 percent of lots for fiber, and 10 percent of lots for grain. AMS currently lacks sufficient data to successfully carry out a risk-based sampling methodology that would be applicable to the varying growing regions nationwide; therefore, the risk-based sampling methodology was not chosen for this final rule.

Secondly, AMS considered retaining at 0.5 percent the limit for total THC content that would result in a negligent violation, as required in the IFR. Based on comments, however, AMS has determined this requirement to too greatly burden producers as factors beyond the control of the producer, such as seed genetics, weather and climate, may cause an increase in total THC-levels. By increasing the negligent violation threshold to 1.0 percent, AMS diminishes the risk to producers of incurring a negligent violation, which results in time and cost savings to producers and to program-administering entities.

Finally, AMS considered mandating a post-sample harvest window of 15 days, as required in the IFR. Based on comments and in consideration of the time required to complete sampling and testing activities, AMS has determined that requiring a 15-day post-sample harvest window would place undue strain on resources. AMS believes that the extension of the post-

sample harvest window to 30 days will provide producers with a beneficial flexibility to adjust to unforeseen weather events and will accommodate complicated harvest processes.

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as “major,” as defined by 5 U.S.C. 804(2).

List of Subjects in 7 CFR Part 990

Acceptable hemp THC level, Agricultural commodities, Cannabis, Corrective action plan, Delta-9 tetrahydrocannabinol, Drugs, Dry weight basis, Hemp, Liquid chromatography, Laboratories, Marijuana.

For the reasons stated in the preamble, AMS revises 7 CFR part 990 to read as follows:

PART 990 – DOMESTIC HEMP PRODUCTION PROGRAM

Subpart A—Definitions

Sec.

990.1 Meaning of terms.

Subpart B—State and Tribal Hemp Production Plans

990.2 State and Tribal plans; General authority.

990.3 State and Tribal plans; Plan requirements.

990.4 USDA approval of State and Tribal plans.

990.5 Audit of State or Tribal plan compliance.

990.6 Violations of State and Tribal plans.

990.7 Establishing records with USDA Farm Service Agency.

990.8 Production under Federal law.

Subpart C—USDA Hemp Production Plan

990.20 USDA requirements for the production of hemp.

990.21 USDA hemp producer license.

990.22 USDA hemp producer license approval.

990.23 Reporting hemp crop acreage with USDA Farm Service Agency.

990.24 Responsibility of a USDA licensee prior to harvest.

990.25 Standards of performance for detecting total delta-9 tetrahydrocannabinol (THC) concentration levels.

990.26 Responsibility of a USDA producer after laboratory testing is performed.

990.27 Non-compliant cannabis plants.

990.28 Compliance.

990.29 Violations.

990.30 USDA producers; License suspension.

990.31 USDA licensees; Revocation.

990.32 Recordkeeping requirements.

Subpart D—Appeals

990.40 General adverse action appeal process.

990.41 Appeals under the USDA hemp production plan.

990.42 Appeals under a State or Tribal hemp production plan.

Subpart E—Administrative Provisions

- 990.60 Agents.
- 990.61 Severability.
- 990.62 [Reserved]
- 990.63 Interstate transportation of hemp.

Subpart F—Reporting Requirements

- 990.70 State and Tribal hemp reporting requirements.
- 990.71 USDA plan reporting requirements.

Authority: 7 U.S.C. 1639o note, 1639p, 1639q, 1639r.

Subpart A - Definitions

§ 990.1 Meaning of terms.

Words used in this subpart in the singular form shall be deemed to impart the plural, and vice versa, as the case may demand. For the purposes of provisions and regulations of this part, unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

Acceptable hemp THC level. When a laboratory tests a sample, it must report the total delta-9 tetrahydrocannabinol content concentration level on a dry weight basis and the measurement of uncertainty. The acceptable hemp THC level for the purpose of compliance with the requirements of State or Tribal hemp plans or the USDA hemp plan is when the application of the measurement of uncertainty to the reported total delta-9 tetrahydrocannabinol content concentration level on a dry weight basis produces a distribution or range that includes 0.3 percent or less. For example, if the reported total delta-9 tetrahydrocannabinol content concentration level on a dry weight basis is 0.35 percent and the measurement of uncertainty is ± 0.06 percent, the measured total delta-9 tetrahydrocannabinol content concentration level on a dry weight basis for this sample ranges from 0.29 percent to 0.41 percent. Because 0.3 percent is within the distribution or range, the sample is within the acceptable hemp THC level for the purpose of plan compliance. This definition of “acceptable hemp THC level” affects neither the statutory definition of hemp, 7 U.S.C. 1639o(1), in the 2018 Farm Bill nor the definition of “marihuana,” 21 U.S.C. 802(16), in the CSA.

Act. Agricultural Marketing Act of 1946.

Agricultural Marketing Service or *AMS*. The Agricultural Marketing Service of the U.S. Department of Agriculture.

Applicant. (1) A State or Indian Tribe that has submitted a State or Tribal hemp production plan to USDA for approval under this part; or

(2) A producer in a State or territory of an Indian Tribe that is not subject to a State or Tribal hemp production plan and who has submitted an application to USDA for a license under the USDA hemp production plan under this part.

Audit. An official inspection of an individual's or organization's accounts and paperwork or documentation by an independent body. An audit also refers to a compliance audit of States and Indian Tribes with approved hemp production plans by USDA to determine compliance with their approved plan, the regulations in this part, and the Act. For this part, audit relates to documentation related to authorities under the 2018 Farm Bill to produce hemp.

Cannabis. A genus of flowering plants in the family Cannabaceae of which *Cannabis sativa* is a species, and *Cannabis indica* and *Cannabis ruderalis* are subspecies thereof. Cannabis refers to any form of the plant in which the total delta-9 tetrahydrocannabinol concentration on a dry weight basis has not yet been determined.

Controlled Substances Act (CSA). The Controlled Substances Act as codified in 21 U.S.C. 801 *et seq.*

Conviction. Means any plea of guilty or nolo contendere, or any finding of guilt, except when the finding of guilt is subsequently overturned on appeal, pardoned, or expunged. For purposes of this part, a conviction is expunged when the conviction is removed from the individual's criminal history record and there are no legal disabilities or restrictions associated with the expunged conviction, other than the fact that the conviction may be used for sentencing purposes for subsequent convictions. In addition, where an individual is allowed to withdraw an original plea of guilty or nolo contendere and enter a plea of not guilty and the case is

subsequently dismissed, the individual is no longer considered to have a conviction for purposes of this part.

Corrective action plan. A plan proposed by a licensed hemp producer and approved by the governing entity for correcting a negligent violation or non-compliance with the applicable State, Tribal, or USDA hemp production plan, its terms, the applicable law(s), and/or this part. Also, a plan proposed by a State or Tribal government for correcting violations or non-compliances with USDA-approved State or Tribal hemp programs.

Criminal history report. The Federal Bureau of Investigation's Identity History Summary.

Culpable mental state greater than negligence. To act intentionally, knowingly, willfully, or recklessly.

Decarboxylated. The completion of the chemical reaction that converts THC-acid (THCA) into delta-9-THC, the intoxicating component of cannabis. The decarboxylated value is also calculated using a molecular mass conversion ratio that sums delta-9-THC and eighty-seven and seven tenths (87.7) percent of THC-acid $((\text{delta-9 THC}) + (0.877 * \text{THCA}))$.

Decarboxylation. The removal or elimination of carboxyl group from a molecule or organic compound.

Disposal. An activity that transitions the non-compliant product into a non-retrievable or non-ingestible form. Such activities include plowing, tilling, or disking plant material into the soil; mulching, composting, chopping, or bush mowing plant material into green manure; burning plant material; burying plant material into the earth and covering with soil.

Delta-9 tetrahydrocannabinol or THC. Delta-9-THC is the primary psychoactive component of cannabis. For the purposes of this part, delta-9-THC and THC are interchangeable.

Drug Enforcement Administration or DEA. The United States Drug Enforcement Administration.

Dry weight basis. The ratio of the amount of moisture in a sample to the amount of dry solid in a sample. A basis for expressing the percentage of a chemical in a substance after

removing the moisture from the substance. Percentage of THC on a dry weight basis means the percentage of THC, by weight, in a cannabis item (plant, extract, or other derivative), after excluding moisture from the item.

Entity. A corporation, joint stock company, association, limited partnership, limited liability partnership, limited liability company, irrevocable trust, estate, charitable organization, or other similar organization, including any such organization participating in the hemp production as a partner in a general partnership, a participant in a joint venture, or a participant in a similar organization.

Farm Service Agency or FSA. An agency of the United States Department of Agriculture.

Gas chromatography or GC. A type of chromatography in analytical chemistry used to separate, identify, and quantify each component in a mixture. GC relies on heat for separating and analyzing compounds that can be vaporized without decomposition.

Geospatial location. A location designated through a global system of navigational satellites used to determine the precise ground position of a place or object.

Handle. To harvest or store hemp plants or hemp plant parts prior to the delivery of such plants or plant parts for further processing. “Handle” also includes the disposal of cannabis plants that are not hemp for purposes of chemical analysis and disposal of such plants.

Hemp. The plant species *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a total delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

Immature plants. A cannabis plant that is not flowering.

Indian Tribe or Tribe. As defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

Information sharing system. The database that allows USDA to share information collected under State, Tribal, and USDA plans with Federal, State, Tribal, and local law enforcement.

Key participants. A sole proprietor, a partner in partnership, or a person with executive managerial control in a corporation. A person with executive managerial control includes persons such as a chief executive officer, chief operating officer, and chief financial officer. This definition does not include non-executive managers such as farm, field, or shift managers. This definition also does not include a member of the leadership of a Tribal government who is acting in their capacity as a Tribal leader except when that member exercises executive managerial control over hemp production.

Law enforcement agency. Any Federal, State, Tribal, or local law enforcement agency.

Liquid chromatography or LC. A type of chromatography technique in analytical chemistry used to separate, identify, and quantify each component in a mixture. LC relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid absorbent material to separate and analyze compounds.

Lot. A contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of cannabis throughout the area. The term lot also means the terms “farm,” “tract,” “field,” and “subfield” as these are terms used by FSA in 7 CFR 718.2 to define lot.

Marijuana. Or “marihuana”, as defined in the CSA, means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; 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. The term “marihuana” does not include hemp, as defined in section 297A of the Agricultural Marketing Act of 1946, and does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is

incapable of germination (7 U.S.C. 1639o). “Marihuana” means all cannabis that tests as having a THC concentration level of higher than 0.3 percent on a dry weight basis.

Measurement of Uncertainty (MU). The parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement.

Negligence. Failure to exercise the level of care that a reasonably prudent person would exercise in complying with the regulations set forth under this part.

Phytocannabinoid. Cannabinoid chemical compounds found in the cannabis plant, two of which are delta-9 tetrahydrocannabinol (delta-9 THC) and cannabidiol (CBD).

Plan. A set of criteria or regulations under which a State or Tribal government, or USDA, monitors and regulates the production of hemp.

Post-decarboxylation. In the context of testing methodologies for THC concentration levels in hemp, means a value determined after the process of decarboxylation that determines the potential total delta-9 tetrahydrocannabinol content derived from the sum of the THC and THCA content and reported on a dry weight basis. The post-decarboxylation value of THC can be calculated by using a chromatograph technique using heat, gas chromatography, through which THCA is converted from its acid form to its neutral form, THC. Thus, this test calculates the total potential THC in a given sample. The post-decarboxylation value of THC can also be calculated by using a liquid chromatograph technique, which keeps the THCA intact. This technique requires the use of the following conversion: $[\text{Total THC} = (0.877 \times \text{THCA}) + \text{THC}]$ which calculates the potential total THC in a given sample. See the definition for decarboxylation.

Produce. To grow hemp plants for market, or for cultivation for market, in the United States.

Producer. A producer as defined in 7 CFR 718.2 specifically of hemp.

Remediation. Remediation refers to the process of rendering non-compliant cannabis, compliant. Remediation can occur by removing and destroying flower material, while retaining stalk, stems, leaf material, and seeds. Remediation can also occur by shredding the entire plant into a biomass like material, then re-testing the shredded biomass material for compliance.

Reverse distributor. A person who is registered with the DEA in accordance with 21 CFR 1317.15 to dispose of marijuana under the Controlled Substances Act.

Secretary. The Secretary of Agriculture of the United States Department of Agriculture.

State. Any one of the fifty States of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and any other territory or possession of the United States.

State department of agriculture. The agency, commission, or department of a State government responsible for agriculture in the State.

Territory of the Indian Tribe. (1) All land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, including rights-of-way running through the reservation;

(2) All dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a State;

(3) All Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same; and

(4) Any lands title to which is either held in trust by the United States for the benefit of any Indian Tribe or individual or held by any Indian Tribe or individual subject to restriction by the United States against alienation and over which an Indian Tribe exercises jurisdiction.

Total THC. Total THC is the value determined after the process of decarboxylation, or the application of a conversion factor if the testing methodology does not include decarboxylation, that expresses the potential total delta-9 tetrahydrocannabinol content derived

from the sum of the THC and THCA content and reported on a dry weight basis. This post-decarboxylation value of THC can be calculated by using a chromatograph technique using heat, such as gas chromatography, through which THCA is converted from its acid form to its neutral form, THC. Thus, this test calculates the total potential THC in a given sample. The total THC can also be calculated by using a liquid chromatograph technique, which keeps the THCA intact. This technique requires the use of the following conversion: $[\text{Total THC} = (0.877 \times \text{THCA}) + \text{THC}]$ which calculates the potential total THC in a given sample.

Tribal government. The governing body of an Indian Tribe.

USDA licensee. A person, partnership, or corporation licensed under the USDA plant to grow hemp under the terms established in this part and who produces hemp.

Subpart B—State and Tribal Hemp Production Plans

§ 990.2 State and Tribal plans; General authority.

States or Indian Tribes desiring to have primary regulatory authority over the production of hemp in the State or territory of the Indian Tribe shall submit to the Secretary for approval, through the State department of agriculture (in consultation with the Governor and chief law enforcement officer of the State) or the Tribal government, as applicable, a plan under which the State or Indian Tribe monitors and regulates that production.

§ 990.3 State and Tribal plans; Plan requirements.

(a) *General requirements.* A State or Tribal plan submitted to the Secretary for approval must include the practice and procedures described in this paragraph (a).

(1) A State or Tribal plan must include a practice to collect, maintain, and report to the Secretary relevant, real-time information for each producer licensed or authorized to produce hemp under the State or Tribal plan regarding:

(i) Contact information as described in §990.70(a)(1);

(ii) A legal description of the land on which the producer will produce hemp in the State or territory of the Indian Tribe including, to the extent practicable, its geospatial location; and

(iii) The status and number of the producer's license or authorization in a format prescribed by USDA.

(2) A State or Tribal plan must include a procedure for accurate and effective sampling of hemp that includes the requirements in this paragraph (a)(2).

(i) Samples from cannabis plants must be collected within 30 days prior to the anticipated harvest, for total delta-9 tetrahydrocannabinol concentration level testing. Samples must be collected by a sampling agent. Producers may not collect samples from their own growing facilities.

(ii) Samples shall be obtained from the flowering tops of plants when flowering tops are present, and shall be approximately five to eight inches in length from the “main stem” (that includes the leaves and flowers), “terminal bud” (that occurs at the end of a stem), or “central cola” (cut stem that could develop into a bud) of the flowering top of the plant.

(iii) The method used for sampling must be sufficient at a confidence level of 95 percent that no more than one percent of the plants in each lot would exceed the acceptable hemp THC level and ensure that a representative sample is collected that represents a homogeneous composition of the lot. Alternatively, States and Tribes may adopt a performance-based method that meets the requirements in paragraphs (a)(2)(iii)(A) and (B) of this section.

(A) The alternative method must be part of the State or Tribe’s hemp plan and is subject to USDA approval.

(B) The alternative method must have the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to the alternative method will not test above the acceptable hemp THC level. The alternative method may consider one or more of the following factors:

(1) Seed certification process or process that identifies varieties that have consistently demonstrated to result in compliant hemp plants in that State or territory of the Indian Tribe;

(2) Whether the producer is conducting research on hemp;

(3) Whether a producer has consistently produced compliant hemp plants over an extended period of time; and

(4) Factors similar to those in this paragraph (a)(2)(iii)(B).

(iv) During a scheduled sample collection, the producer or an authorized representative of the producer shall be present at the growing site if possible.

(v) Sampling agents shall be provided with complete and unrestricted access during business hours to all hemp and other cannabis plants (whether growing or harvested), to areas where hemp is grown and stored, and to all land, buildings, and other structures used for the cultivation, handling, and storage of all hemp and other cannabis plants, and all locations listed in the producer license.

(vi) A producer shall not harvest the cannabis crop prior to samples being taken.

(vii) Sampling agents must be trained using USDA, State, or Tribal training procedures. States and Indian Tribes must maintain information, available to producers, about trained sampling agents.

(3) A State or Tribal plan must include a procedure for testing that is able to accurately identify whether the sample contains a total delta-9 tetrahydrocannabinol content concentration level that exceeds the acceptable hemp THC level. The procedure must include a validated testing methodology that uses post-decarboxylation or other similarly reliable methods. The testing methodology must consider the potential conversion of THCA in hemp into THC and the test result must report the total available THC derived from the sum of the THC and THCA content. Testing methodologies meeting the requirements of this paragraph (a)(3) include, but are not limited to, gas or liquid chromatography with detection. The total THC concentration level shall be determined and reported on a dry weight basis.

(i) Any test of a representative sample resulting in higher than the acceptable hemp THC level shall be conclusive evidence that the lot represented by the sample is not in compliance with this part and shall be disposed of or remediated in accordance with §990.27.

(ii) Samples of hemp plant material from one lot shall not be commingled with hemp plant material from other lots.

(iii) Laboratories conducting analytical testing for purposes of detecting the concentration levels of Total THC shall meet the following requirements:

(A) Laboratory quality assurance must ensure the validity and reliability of test results;

(B) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose), and that the laboratory can successfully perform the testing;

(C) The demonstration of testing validity must ensure consistent, accurate analytical performance;

(D) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part; and

(E) Effective disposal procedures for non-compliant samples that do not meet the requirements of this part.

(F) Measurement of uncertainty (MU) must be estimated and reported with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

(G) Sample preparation of pre- or post-harvest samples shall require grinding of sample to ensure homogeneity of plant material prior to testing. Sample preparation may follow a procedure described by USDA.

(H) After December 31, 2022, States and Indian Tribes shall require that only laboratories registered with the DEA may conduct testing under this section.

(4) A State or Indian Tribe shall require testing laboratories to comply with USDA reporting requirements in subpart F of this part. Laboratories shall only submit test results used to determine compliance with this part. Test results from informal testing conducted throughout the growing season shall not be reported to USDA.

(5) A State or Tribal plan must include a procedure to comply with the enforcement procedures in §990.6.

(6) A State or Tribal plan must include a procedure for the disposal or remediation of cannabis plants if the sample representing that plant tests above the acceptable hemp THC level.

(i) The disposal must be conducted either by using a DEA-registered reverse distributor or law enforcement; or on site at the farm or hemp production facility.

(ii) The State or Tribal plan must include procedures to verify the disposal or remediation of the cannabis plant. This may come in the form of in-person verification by State or Tribal representatives, or alternative requirements that direct growers to provide pictures, videos, or other proof that disposal or remediation occurred successfully. Disposal and remediation means are described at AMS's website.

(iii) If a producer elects to perform remediation activities, an additional sampling and testing of the post-remediated crop must occur to determine THC concentration levels.

(7) A State or Tribal plan must include a procedure for conducting annual inspections of, at a minimum, a random group of producers to verify that hemp is not produced in violation of this part.

(8) A State or Tribal plan must include a procedure for submitting the report described in §990.70 to the Secretary by the first of each month. If the first of the month falls on a weekend or holiday, the report is due by the first business day following the due date. All such information must be submitted to the USDA in a format that is compatible with USDA's information sharing system.

(9) The State or Tribal government must certify that the State or Indian Tribe has the resources and personnel to carry out the practices and procedures described in paragraphs (a)(1) through (9) of this section.

(10) The State or Tribal plan must include a procedure to collect and share information with USDA to support the information sharing requirements in 7 U.S.C. 1639q(d). The State or

Tribal government is responsible for reporting the information identified in paragraphs (a)(10)(i) through (iii) of this section with AMS. The State or Tribal hemp production plan must include the following:

(i) A requirement that producers report their hemp crop acreage to the FSA, consistent with the requirement in §990.7.

(ii) Assignment of a license or authorization identifier for each producer in a format prescribed by USDA.

(iii) A requirement that producers report the total acreage of hemp planted, harvested, and, if applicable, disposed or remediated. The State or Tribal government shall collect this information and report it to AMS.

(b) *Relation to State and Tribal law.* A State or Tribal plan may include any other practice or procedure established by a State or Indian Tribe, as applicable; *Provided*, That the practice or procedure is consistent with this part and Subtitle G of the Act.

(1) *No preemption.* Nothing in this part preempts or limits any law of a State or Indian Tribe that:

(i) Regulates the production of hemp; and

(ii) Is more stringent than this part or Subtitle G of the Act.

(2) *References in plans.* A State or Tribal plan may include a reference to a law of the State or Indian Tribe regulating the production of hemp, to the extent that the law is consistent with this part.

§ 990.4 USDA approval of State and Tribal plans.

(a) *General authority.* No later than 60 calendar days after the receipt of a State or Tribal plan for a State or Tribal territory in which production of hemp is legal, the Secretary shall:

(1) Approve the State or Tribal plan only if the State or Tribal plan complies with this part; or

(2) Disapprove the State or Tribal plan if the plan does not comply with this part. USDA shall provide the State or Tribe with written notification of the disapproval and the cause for the disapproval.

(b) *Amended plans.* A State or Tribal government, as applicable, must submit to the Secretary an amended plan if:

(1) The Secretary disapproves a State or Tribal plan and the State or Indian Tribe wishes to have primary regulatory authority over hemp production within its State or territory of the Indian Tribe; or

(2) The State or Indian Tribe makes substantive revisions to its plan or its laws which alter the way the plan meets the requirements of this part. If this occurs, the State or Tribal government must re-submit the revised plan for USDA approval. Such re-submissions should be provided to USDA within 60 days from the date that the State or Tribal laws and regulations are effective. Producers shall continue to comply with the requirements of the existing plan while such modifications are under consideration by USDA. If State or Tribal government laws or regulations in effect under the USDA-approved plan change but the State or Tribal government does not submit a revised plan within 60 days from the effective date of the new law or regulation, the existing plan is revoked.

(3) USDA approval of State or Tribal government plan shall remain in effect unless an amended plan must be submitted to USDA because of a substantive revision to a State's or Tribe's plan, a relevant change in State or Tribal laws or regulations, or approval of the plan is revoked by USDA.

(4) Upon USDA approval of a Tribal plan, an Indian Tribe may exercise jurisdiction and therefore primary regulatory authority over all production of hemp in its Territory regardless of the extent of its inherent regulatory authority.

(c) *Technical assistance.* The Secretary may provide technical assistance to help a State or Indian Tribe develop or amend a plan. This may include the review of draft plans or other informal consultation as necessary.

(d) *Approved State or Tribal plans.* If the Secretary approves a State or Tribal plan, the Secretary shall notify the State or Indian Tribe by letter or email.

(1) In addition to the approval letter, the State or Indian Tribe shall receive their plan approval certificate either as an attachment or via website link.

(2) The USDA shall post information regarding approved plans on its website.

(3) USDA approval of State or Tribal government plans shall remain in effect unless:

(i) The State or Tribal government's laws and regulations in effect under the USDA-approved plan change, thus requiring such plan to be revised and re-submitted for USDA approval.

(ii) A State or Tribal plan must be amended in order to comply with future amendments to Subtitle G the Act and this part.

(e) *Producer rights upon revocation of State or Tribal plan.* If USDA revokes approval of a State or Tribal plan due to noncompliance as defined in paragraph (b)(2) of this section and §990.5, producers licensed or authorized to produce hemp under the revoked State or Tribal plan may continue to produce for the remainder of the calendar year in which the revocation became effective. Producers operating in a State or Tribal territory with a revoked plan would have to apply to USDA for a license to continue producing.

§ 990.5 Audit of State or Tribal plan compliance.

The Secretary may conduct an audit to determine a State or Indian Tribe's compliance with their approved plan.

(a) *Frequency of audits.* Compliance audits may be scheduled, no more frequently than every three years, based on available resources. Audits may include an onsite-visit, a desk-audit, or both. The USDA may adjust the frequency of audits if deemed appropriate based on program

performance, compliance issues, or other relevant factors identified and provided to the State or Tribal governments by USDA.

(b) *Scope of audit review.* The audit may include, but is not limited to, a review of the following:

- (1) The resources and personnel employed to administer and oversee its approved plan;
- (2) The process for licensing and systematic compliance review of hemp producers;
- (3) Sampling methods and laboratory testing requirements and components;
- (4) Disposal and/or remediation of non-compliant hemp plants or hemp plant material practices, to ensure that correct reporting to the USDA has occurred;
- (5) Results of and methodology used for the annual inspections of producers; and
- (6) Information collection procedures and information accuracy (*i.e.*, geospatial location, contact information reported to the USDA, legal description of land).

(c) *Audit reports.* (1) Audit reports will be issued to the State or Tribal government no later than 60 days after the audit concludes. If the audit reveals that the State or Tribal government is not in compliance with its USDA approved plan, USDA will advise the State or Indian Tribe of non-compliances and the corrective measures that must be completed to come into compliance with the Act and regulations in this part. The USDA will require the State or Indian Tribe to develop a corrective action plan, which must be reviewed and approved by the USDA. The corrective action plan must include a reasonable date by which the State or Indian Tribe will correct make corrections. USDA will approve or deny the corrective action plan within 60 days of its receipt. USDA will conduct a second audit to determine if the State or Indian Tribe is in compliance with the corrective action plan and has corrected the non-compliances.

(2) If the USDA determines that the State or Indian Tribe is not in compliance after the second audit, the USDA may revoke its approval of the State or Tribal plan for one year or until the State or Indian Tribe becomes compliant whichever occurs later. USDA will not approve a

State or Indian Tribe's plan until the State or Indian Tribe demonstrates upon inspection that it is in compliance with all regulations in this part.

§ 990.6 Violations of State and Tribal plans.

(a) *Producer violations.* Producer violations of USDA-approved State and Tribal hemp production plans shall be subject to enforcement in accordance with the terms of this section.

(b) *Negligent violations.* Each USDA-approved State or Tribal plan shall contain provisions relating to negligent producer violations as defined under this part. Producers shall not receive more than one negligent violation per growing season. Negligent violations shall include:

(1) Failure to provide a legal description of land on which the producer produces hemp;

(2) Failure to obtain a license or other required authorization from the State department of agriculture or Tribal government, as applicable; or

(3) Production of cannabis with a total delta-9 tetrahydrocannabinol concentration exceeding the acceptable hemp THC level. Hemp producers do not commit a negligent violation under this paragraph (b)(3) if they make reasonable efforts to grow hemp and the cannabis (marijuana) does not have a total delta-9 tetrahydrocannabinol concentration of more than 1.0 percent on a dry weight basis.

(c) *Corrective action for negligent violations.* Each USDA-approved State or Tribal plan shall provide for the correction of negligent violations. Each corrective action plan shall include, at a minimum, the following terms:

(1) A reasonable date by which the producer shall correct the negligent violation.

(2) A requirement that the producer periodically report to the State department of agriculture or Tribal government, as applicable, on its compliance with the State or Tribal plan and corrective action plan for a period of not less than the next 2 years from the date of the negligent violation.

(3) A producer that negligently violates a State or Tribal plan approved under this part shall not as a result of that violation be subject to any criminal enforcement action by the Federal, State, Tribal, or local government.

(4) A producer that negligently violates a State or Tribal plan three times during a 5-year period shall be ineligible to produce hemp for a period of 5 years beginning on the date of the third violation.

(5) The State or Indian Tribe shall conduct an inspection to determine if the corrective action plan has been implemented as submitted.

(d) *Culpable violations.* Each USDA-approved State or Tribal plan shall contain provisions relating to producer violations made with a culpable mental state greater than negligence, including that:

(1) If the State or Tribal government determines that a producer has violated the plan with a culpable mental state greater than negligence, the State or Tribal government, as applicable, shall immediately report the producer to:

(i) The U.S. Attorney General; and

(ii) The chief law enforcement officer of the State or Indian Tribe, as applicable.

(2) Paragraphs (b) and (c) of this section shall not apply to culpable violations.

(e) *Felonies.* Each USDA-approved State or Tribal plan shall contain provisions relating to felonies. Such provisions shall state that:

(1) A person with a State or Federal felony conviction relating to a controlled substance may not participate in the plan and may not produce hemp under the State or Tribal plan for 10 years from the date of the conviction. An exception applies to a person who was lawfully growing hemp under section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940) before December 20, 2018, and whose conviction also occurred before that date.

(2) The State or Tribal plan shall define who is participating in the plan or program and is subject to the felony conviction restriction for purposes of paragraph (e)(1) of this section. To

determine whether a person is subject to the felony conviction restriction, the State or Tribe must obtain a criminal history report for that person. The State or Indian Tribe may require additional reports or checks as it deems necessary.

(3) For each license or authorization that the State or Indian Tribe issues, its plan must identify at least one individual as participating in the plan and for whom it will obtain a criminal history report to determine eligibility under paragraph (e)(1) of this section.

(f) *False statement.* Each USDA-approved State or Tribal plan shall state that any person who materially falsifies any information contained in an application to participate in such program shall be ineligible to participate in that program.

(g) *Appeals.* For States and Indian Tribes who wish to appeal an adverse action, subpart D of this part will apply.

§ 990.7 Establishing records with USDA Farm Service Agency.

All producers licensed to produce hemp under an USDA-approved State or Tribal plan shall report hemp crop acreage to FSA and shall provide, at minimum, the following information:

(a) Street address and, to the extent practicable, geospatial location for each lot or greenhouse where hemp will be produced. If an applicant operates in more than one location, or is producing under multiple licenses, production information shall be provided for each location.

(b) Acreage dedicated to the production of hemp, or greenhouse or indoor square footage dedicated to the production of hemp.

(c) License or authorization identifier in a format prescribed by USDA.

§ 990.8 Production under Federal law.

Nothing in this subpart prohibits the production of hemp in a State or the territory of an Indian Tribe for which a State or Tribal plan is not approved under this subpart if produced in accordance with subpart C of this part, and if the production of hemp is not otherwise prohibited by the State or Indian Tribe.

Subpart C—USDA Hemp Production Plan

§ 990.20 USDA requirements for the production of hemp.

(a) *General hemp production requirements.* The production of hemp in a State or territory of an Indian Tribe where there is no USDA approved State or Tribal plan must be conducted in accordance with this subpart, provided that the production of hemp is not prohibited by the State or territory of an Indian Tribe where production will occur.

(b) *Convicted felon ban.* A person with a State or Federal felony conviction relating to a controlled substance is subject to a 10-year ineligibility restriction on participating in and producing hemp under the USDA plan from the date of the conviction. An exception applies to a person who was lawfully growing hemp under section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940) before December 20, 2018, and whose conviction also occurred before that date.

(c) *Falsifying material information on application.* Any person who materially falsifies any information contained in an application for a license under the USDA plan shall be ineligible to participate in the USDA plan.

§ 990.21 USDA hemp producer license.

(a) *General application requirements--(1) Requirements and license application.* Any person producing or intending to produce hemp must have a valid license prior to producing hemp. A valid license means the license is unexpired, unsuspended, and unrevoked.

(2) *Application dates.* Applicants may submit an application for a license at any time.

(3) *Required information on application.* The applicant shall provide the information requested on the application form, including:

(i) *Contact information.* Full name, residential address, telephone number, and email address. If the applicant is a business entity, the full name of the business, the principal business location address, full name and title of the key participants, title, email address (if available), and employer identification number (EIN) of the business; and

(ii) *Criminal history report.* A current criminal history report for an individual, or if the applicant is a business entity, all key participants, dated within 60 days of the application submission date. A license application will not be considered complete without all required criminal history reports.

(4) *Submission of completed application forms.* Completed application forms shall be submitted to USDA.

(5) *Incomplete application procedures.* Applications missing required information shall be returned to the applicant as incomplete. The applicant may resubmit a completed application.

(6) *License expiration.* USDA-issued hemp producer licenses shall be valid until December 31 of the year three years after the year in which license was issued.

(b) *License renewals.* USDA hemp producer licenses must be renewed prior to license expiration. Licenses are not automatically renewed. Applications for renewal shall be subject to the same terms, information collection requirements, and approval criteria as provided in this subpart for initial applications unless there has been an amendment to the regulations in this part or the law since approval of the initial or last application.

(c) *License modification.* A license modification is required if there is any change to the information submitted in the application including, but not limited to, sale of a business, the production of hemp in a new location, or a change in the key participants under a license.

(d) *Licensing for research.* (1) Producers that produce hemp for research must obtain a USDA license. However, the hemp that is produced for research and does not enter the stream of commerce is not subject to the sampling requirements in §§ 990.24 and 990.26; provided that the producer adopts and carries out a USDA approved alternative sampling method that has the potential to ensure, at a confidence level of 95 percent, that the cannabis plant species *Cannabis sativa* L. that will be subject to this alternative method will not test above the acceptable hemp THC level.

(2) USDA licensees shall ensure the disposal of all non-compliant plants in accordance with § 990.27. Only research institutions registered with DEA to handle marijuana can keep hemp that tests over the 0.3 acceptable hemp THC level until the end of the study.

(3) USDA licensees shall comply with the reporting requirements in § 990.71 including reporting disposal of non-compliant plants.

§ 990.22 USDA hemp producer license approval.

(a) A license shall not be issued unless:

(1) The application submitted for USDA review and approval is complete and accurate.

(2) The criminal history report(s) submitted with the license application confirms that all key participants to be covered by the license have not been convicted of a felony, under State or Federal law, relating to a controlled substance within the past ten (10) years unless the exception in §990.20(b) applies.

(3) The applicant, if the applicant was previously or is currently licensed, submitted all reports required as a participant in the hemp production program by this part.

(4) The application contains no materially false statements or misrepresentations and the applicant has not previously submitted an application with any materially false statements or misrepresentations.

(5) The applicant's license is not currently suspended, if the applicant is currently licensed.

(6) The applicant is not applying for a license as a stand-in for someone whose license has been suspended, revoked, or is otherwise ineligible to participate.

(7) The State or territory of the Indian Tribe where the person produces or intends to produce hemp does not have a USDA-approved plan or has not submitted a plan to USDA for approval and is awaiting USDA's decision.

(8) The State or territory of the Indian Tribe where the person produces or intends to produce hemp does not prohibit the production of hemp.

(b) USDA shall provide written notification to applicants whether the application has been approved or denied. USDA shall provide written notification to applicants in a State or territory of an Indian Tribe that has submitted a plan to USDA and is awaiting USDA approval that their application is being returned.

(1) If an application is approved, a license will be issued.

(2) Licenses will be valid until December 31 of the year three after the year in which the license was issued.

(3) Licenses may not be sold, assigned, transferred, pledged, or otherwise disposed of, alienated or encumbered.

(4) If a license application is denied, the notification from USDA will explain the reason for denial. Applicants may appeal the denial in accordance with subpart D of this part.

(c) If the applicant is producing in more than one State or territory of an Indian Tribe, the applicant may have more than one license to grow hemp. If the applicant has operations in a location covered under a State or Tribal plan, that operation must be licensed under the State or Tribal plan, not the USDA plan.

§ 990.23 Reporting hemp crop acreage with USDA Farm Service Agency.

All USDA licensees shall report hemp crop acreage to FSA within 30 days of hemp been planted and shall provide, at a minimum, the following information:

(a) Street address and, to the extent practicable, geospatial location of the lot, greenhouse, building, or site where hemp will be produced. All locations where hemp is produced must be reported to FSA.

(b) Acreage dedicated to the production of hemp, or greenhouse or indoor square footage dedicated to the production of hemp.

(c) The hemp license number.

§ 990.24 Responsibility of a USDA licensee prior to harvest.

USDA licensees must:

(a) No more than 30 days prior to the anticipated harvest of cannabis plants, have a sampling agent collect samples from the cannabis plant for total delta-9 tetrahydrocannabinol concentration level testing.

(b) Have samples collected from the flowering tops of the plant by cutting the top five to eight inches from the “main stem” (that includes the leaves and flowers), “terminal bud” (that occurs at the end of a stem), ”or “central cola” (cut stem that could develop into a bud) of the flowering top of the plant. Sampling guidelines and training requirements for sampling agents are available from USDA. The method used for sampling must be sufficient at a confidence level of 95 percent that no more than one percent (1%) of the plants in the lot would exceed the acceptable hemp THC level. The method used for sampling must ensure that a representative sample is collected that represents a homogeneous composition of the lot.

(c) Have an authorized representative of the USDA licensee present at the growing site during a scheduled sample collection, if possible.

(d) Ensure that sampling agents are provided with complete and unrestricted access during business hours to all hemp and other cannabis plants, (whether growing or harvested), all hemp production and storage areas, all land, buildings, and other structures used for the cultivation, handling, and storage of all hemp and other cannabis plants, and all locations listed in the producer license.

(e) Not harvest the cannabis crop prior to samples being taken.

(f) Use post-harvest samples only for remediated biomass.

§ 990.25 Standards of performance for detecting total delta-9 tetrahydrocannabinol (THC) concentration levels.

Analytical testing for purposes of determining total THC in cannabis plants shall meet the standards in this section.

(a) Laboratory quality assurance must ensure the validity and reliability of test results.

(b) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose), and that the laboratory can successfully perform the testing.

(c) The demonstration of testing validity must ensure consistent, accurate analytical performance.

(d) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.

(e) Laboratory must have an effective disposal procedure for non-compliant samples that do not meet the requirements of this part.

(f) Measurement of uncertainty (MU) must be estimated and reported with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

(g) At a minimum, analytical testing of samples for total THC must use post-decarboxylation or other similarly reliable methods approved by the Secretary. The testing methodology must consider the potential conversion of THCA in hemp into THC and the test result must reflect the total available THC derived from the sum of the THC and THCA content. Testing methodologies meeting the requirements of this paragraph (g) include, but are not limited to, gas or liquid chromatography with detection.

(1) The total THC shall be determined and reported on a dry weight basis. Additionally, measurement of uncertainty (MU) must be estimated and reported with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

(2) Any sample test result exceeding the acceptable hemp THC level shall be conclusive evidence that the lot represented by the sample is not in compliance with this part.

(3) After December 31, 2022, USDA licensees may only use laboratories registered with the DEA to conduct testing under this section.

§ 990.26 Responsibility of a USDA producer after laboratory testing is performed.

(a) The producer shall harvest the crop no later than thirty (30) days after the date of sample collection.

(b) If the producer fails to complete harvest within thirty (30) days of sample collection, a second pre-harvest sample of the lot shall be required to be submitted for testing.

(c) Harvested lots of hemp plants shall not be commingled with other harvested lots or other material.

(d) Lots that meet the acceptable hemp THC level may enter the stream of commerce.

(e) Lots that do not meet the acceptable hemp THC level are subject to §990.27.

(f) Any producer may request additional pre-harvest testing if it is believed that the original total delta-9 tetrahydrocannabinol concentration level test results were in error. Additional testing may be conducted by the laboratory that conducted the initial test, or another laboratory.

§ 990.27 Non-compliant cannabis plants.

(a) Cannabis plants exceeding the acceptable hemp THC level constitute marijuana, a schedule I controlled substance under the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.*, and producers must either use a DEA-registered reverse distributor or law enforcement to dispose of non-compliant plants or ensure the disposal of such cannabis plant on site at the farm or hemp production facility.

(b) Producers must notify USDA of their intent to dispose of or remediate non-conforming plants and verify disposal or remediation by submitting required documentation.

(c) If a producer elects to perform remediation activities, an additional sampling and testing of the post-remediated crop must occur to determine THC concentration levels.

§ 990.28 Compliance.

(a) *Audits.* USDA licensees may be audited by the USDA. The audit may include a review of records and documentation, and may include site visits to farms, fields, greenhouses,

storage facilities, or other locations affiliated with the producer's hemp operation. The audit may include the current crop year, as well as any previous crop year(s). The audit may be performed remotely or in person.

(b) *Frequency of audit verifications.* Audit verifications may be performed once every three (3) years unless otherwise determined by USDA. If the results of the audit find negligent violations, a corrective action plan may be established.

(c) *Assessment of producer's hemp operations for conformance.* The producer's operational procedures, documentation, recordkeeping, and other practices may be verified during the audit verification. The auditor may also visit the production, cultivation, or storage areas for hemp listed on the producer's license.

(1) *Records and documentation.* The auditor shall assess whether required reports, records, and documentation are properly maintained for accuracy and completeness.

(2) [Reserved]

(d) *Audit reports.* Audit reports will be issued to the producer no later than 60 days after the audit is concluded. If USDA determines through an audit that the producer is not compliant with the Act or this part, USDA shall require a corrective action plan. The corrective action plan must include a reasonable date by which the producer will correct the negligent violation. USDA will approve or deny the corrective action plan within 60 days of its receipt. Producers operating under a corrective action plan must also periodically report to USDA on their compliance with the plan for a period of not less than two calendar years following the violation. The producer's implementation of a corrective action plan may be reviewed by USDA during a future site visit or audit. If additional instances of noncompliance occur, USDA may revoke the producer's USDA license for one year or until the producer becomes compliant whichever occurs later.

§ 990.29 Violations.

Violations of this part shall be subject to enforcement in accordance with the terms of this section.

(a) *Negligent violations.* Hemp producers are not subject to more than one negligent violation per calendar year. A hemp producer shall be subject to enforcement for negligently:

(1) Failing to provide an accurate legal description of land where hemp is produced;

(2) Producing hemp without a license; and

(3) Producing cannabis exceeding the acceptable hemp THC level. Hemp producers do not commit a negligent violation under this paragraph (a) if they make reasonable efforts to grow hemp and the cannabis does not have a total THC concentration of more than 1.0 percent on a dry weight basis.

(b) *Corrective action for negligent violations.* For each negligent violation, USDA will issue a Notice of Violation and require a corrective action plan from the producer. The producer shall comply with the corrective action plan to cure the negligent violation. Corrective action plans will be in place for a minimum of two (2) years from the date of their approval. Corrective action plans will, at a minimum, include:

(1) The date by which the producer shall correct each negligent violation;

(2) Steps that will be taken to correct each negligent violation; and

(3) A description of the procedures that will demonstrate compliance must be submitted to USDA.

(c) *Negligent violations and criminal enforcement.* A producer who negligently violates this part shall not, as a result of that violation, be subject to any criminal enforcement action by any Federal, State, Tribal, or local government.

(d) *Subsequent negligent violations.* If a subsequent negligent violation occurs while a corrective action plan is in place, a new corrective action plan must be submitted with a heightened level of quality control, staff training, and quantifiable action measures.

(e) *Negligent violations and license revocation.* A producer that negligently violates the license 3 times in a 5-year period shall have their license revoked and be ineligible to produce hemp for a period of 5 years beginning on the date of the third violation.

(f) *Culpable mental state greater than negligence.* If USDA determines that a licensee has violated the terms of the license or of this part with a culpable mental state greater than negligence:

(1) USDA shall immediately report the licensee to:

(i) The U.S. Attorney General; and

(ii) The chief law enforcement officer of the State or Indian territory, as applicable, where the production is located; and

(2) Paragraphs (a) and (b) of this section shall not apply to culpable violations.

§ 990.30 USDA producers; License suspension.

(a) USDA may issue a notice of suspension to a producer if USDA or its representative receives some credible evidence establishing that a producer has:

(1) Engaged in conduct violating a provision of this part; or

(2) Failed to comply with a written order from the USDA-AMS Administrator related to negligence as defined in this part.

(b) Any producer whose license has been suspended shall not handle or remove hemp or cannabis from the location where hemp or cannabis was located at the time when USDA issued its notice of suspension, without prior written authorization from USDA.

(c) Any person whose license has been suspended shall not produce hemp during the period of suspension.

(d) A producer whose license has been suspended may appeal that decision in accordance with subpart D of this part.

(e) A producer whose license has been suspended and not restored on appeal may have their license restored after a waiting period of one year from the date of the suspension. If the license was issued more than three years prior to the date of restoration, the producer shall submit a new application and criminal history report to USDA.

(f) A producer whose license has been suspended may be required to provide, and operate under, a corrective action plan to fully restore their license.

§ 990.31 USDA licensees; Revocation.

USDA shall immediately revoke the license of a USDA licensee if such licensee:

- (a) Pleads guilty to, or is convicted of, any felony related to a controlled substance; or
- (b) Made any materially false statement with regard to this part to USDA or its representatives with a culpable mental state greater than negligence; or
- (c) Is found to be growing cannabis exceeding the acceptable hemp THC level with a culpable mental state greater than negligence or negligently violated this part three times in five years.

§ 990.32 Recordkeeping requirements.

(a) USDA licensees shall maintain records of all hemp plants acquired, produced, handled, disposed of, or remediated as will substantiate the required reports.

(b) All records and reports shall be maintained for at least three years.

(c) All records shall be made available for inspection by USDA inspectors, auditors, or their representatives during reasonable business hours. The following records must be made available:

- (1) Records regarding acquisition of hemp plants;
- (2) Records regarding production and handling of hemp plants;
- (3) Records regarding storage of hemp plants; and
- (4) Records regarding disposal and remediation of all cannabis plants that do not meet the definition of hemp.

(d) USDA inspectors, auditors, or their representatives shall have access to any premises where hemp plants may be held during reasonable business hours.

(e) All reports and records required to be submitted to USDA as part of participation in the program in this part which include confidential data or business information, including but

not limited to information constituting a trade secret or disclosing a trade position, financial condition, or business operations of the particular licensee or their customers, shall be received by, and at all times kept in the custody and control of, one or more employees of USDA or their representatives. Confidential data or business information may be shared with applicable Federal, State, Tribal, or local law enforcement or their designee in compliance with the Act.

Subpart D—Appeals

§ 990.40 General adverse action appeal process.

(a) Persons who believe they are adversely affected by the denial of a license application under the USDA hemp production program may appeal such decision to the AMS Administrator.

(b) Persons who believe they are adversely affected by the denial of a license renewal under the USDA hemp production program may appeal such decision to the AMS Administrator.

(c) Persons who believe they are adversely affected by the revocation or suspension of a USDA hemp production license may appeal such decision to the AMS Administrator.

(d) States and Indian Tribes that believe they are adversely affected by the denial of a proposed State or Tribal hemp plan may appeal such decision to the AMS Administrator.

§ 990.41 Appeals under the USDA hemp production plan.

(a) *Appealing a denied USDA-plan license application.* A license applicant may appeal the denial of a license application.

(1) If the AMS Administrator grants an applicant's appeal of a licensing denial, the applicant will be issued a USDA hemp production license.

(2) If the AMS Administrator denies an appeal, the applicant's license application will be denied. The applicant may request a formal adjudicatory proceeding within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(b) *Appealing a denied USDA-plan license renewal.* A producer may appeal the denial of a license renewal.

(1) If the AMS Administrator grants a producer's appeal of a licensing renewal denial, the applicant's USDA hemp production license will be renewed.

(2) If the AMS Administrator denies the appeal, the applicant's license will not be renewed. The denied producer may request a formal adjudicatory proceeding within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Formal Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(c) *Appealing a USDA-plan license termination or suspension.* A USDA hemp plan producer may appeal the revocation or suspension of a license.

(1) If the AMS Administrator grants the appeal of a license termination or suspension, the producer will retain their license.

(2) If the AMS Administrator denies the appeal, the producer's license will be terminated or suspended. The producer may request a formal adjudicatory proceeding within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Formal Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(d) *Filing period.* The appeal of a denied license application, denied license renewal, suspension, or revocation must be filed within the time-period provided in the letter of notification or within 30 business days from receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the AMS Administrator. The decision to deny an appeal of a license application or renewal, or suspend or terminate a license, is final unless a formal adjudicatory proceeding is requested within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(e) *Where to file.* Appeals to the Administrator must be filed in the manner as determined by AMS.

(f) *What to include.* All appeals must include a copy of the adverse decision and a statement of the appellant's reasons supporting why the decision was not proper or made in accordance with applicable program regulations in this part, policies, or procedures.

§ 990.42 Appeals under a State or Tribal hemp production plan.

(a) *Appealing a State or Tribal hemp production plan application.* A State or Indian Tribe may appeal the denial of a proposed State or Tribal hemp production plan by the USDA to the AMS Administrator.

(1) If the AMS Administrator grants a State or Indian Tribe's appeal of a denied hemp plan application, the proposed State or Tribal hemp production plan shall be established as proposed.

(2) If the AMS Administrator denies an appeal, the proposed State or Tribal hemp production plan shall not be approved. Prospective producers located in the State or territory of the Indian Tribe may apply for hemp licenses under the terms of the USDA plan. The State or Indian Tribe may request a formal adjudicatory proceeding be initiated within 30 days to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(b) *Appealing the suspension or termination of a State or Tribal hemp production plan.* A State or Tribe may appeal the revocation by USDA of an approved State or Tribal hemp production plan.

(1) If the AMS Administrator grants a State or Indian Tribe's appeal of a State or Tribal hemp production plan suspension or revocation, the associated hemp production plan will remain in place and effective.

(2) If the AMS Administrator denies an appeal, the State or Tribal hemp production plan will be suspended or revoked as applicable. Producers located in that State or territory of the Indian Tribe may continue to produce hemp under their State or Tribal license until the end the calendar year in which the State or Tribal plan's disapproval was effective or when the State or

Tribal license expires, whichever is earlier. Producers may apply for a USDA license under subpart C of this part unless hemp production is otherwise prohibited by the State or Indian Tribe. The State or Indian Tribe may request a formal adjudicatory proceeding be initiated to review the decision. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Rules of Practice Governing Formal Adjudicatory Proceedings, 7 CFR part 1, subpart H.

(c) *Filing period.* The appeal of a State or Tribal hemp production plan suspension or revocation must be filed within the time-period provided in the letter of notification or within 30 business days from receipt of the notification, whichever occurs later. The appeal will be considered “filed” on the date received by the AMS Administrator. The decision to deny a State or Tribal plan application or suspend or revoke approval of a plan, is final unless the decision is appealed in a timely manner.

(d) *Where to file.* Appeals to the Administrator must be filed in the manner as determined by AMS.

(e) *What to include in appeal.* All appeals must include a copy of the adverse decision and a statement of the appellant's reasons supporting why the decision was not proper or made in accordance with applicable program regulations in this part, policies, or procedures.

Subpart E—Administrative Provisions

§ 990.60 Agents.

As provided under 7 CFR part 2, the Secretary may name any officer or employee of the United States or name any agency or division in the United States Department of Agriculture, to act as their agent or representative in connection with any of the provisions of this part.

§ 990.61 Severability.

If any provision of this part is declared invalid or the applicability thereof to any person or circumstances is held invalid, the validity of the remainder of this part or the applicability thereof to other persons or circumstances shall not be affected thereby.

§ 990.62 [Reserved]

§ 990.63 Interstate transportation of hemp.

No State or Indian Tribe may prohibit the transportation or shipment of hemp lawfully produced under a State or Tribal plan approved under subpart B of this part, under a license issued under subpart C of this part, or under 7 U.S.C. 5940 through the State or territory of the Indian Tribe, as applicable.

Subpart F—Reporting Requirements

§ 990.70 State and Tribal hemp reporting requirements.

(a) *State and Tribal hemp producer report.* Each State and Indian Tribe with a plan approved under this part shall submit to USDA, by the first of each month, a report providing the contact information and the status of the license or other authorization issued for each producer covered under the applicable State and Tribal plans. If the first of the month falls on a weekend or holiday, the report is due by the first business day following the due date. The report shall be submitted using a digital format compatible with USDA's information sharing systems, whenever possible. The report shall contain the information described in this paragraph (a).

(1)(i) For each new producer who is an individual and is licensed or authorized under the State or Tribal plan, the report shall include the full name of the individual, license or authorization identifier, Employee Identification Number (“EIN”) of the business entity, business address, telephone number, and email address (if available).

(ii) For each new producer that is an entity and is licensed or authorized under the State or Tribal plan, the report shall include full name of the entity, the principal business location address, license or authorization identifier, and the full name, title, and email address (if available) of each employee for whom the entity is required to submit a criminal history report.

(iii) For each producer that was included in a previous report and whose reported information has changed, the report shall include the previously reported information and the new information.

- (2) The status of each producer's license or authorization.
- (3) The period covered by the report.
- (4) Indication that there were no changes during the current reporting cycle, if applicable.

(b) *State and Tribal hemp disposal or remediation report.* If a producer has produced cannabis exceeding the acceptable hemp THC level, the cannabis must be disposed of or remediated. States and Tribes with plans approved under this part shall submit to USDA, by the first of each month, a report notifying USDA of any occurrence of non-conforming plants or plant material and providing a disposal or remediation record of those plants and materials. This report would include information regarding name and contact information for each producer subject to a disposal or remediation during the reporting period, and date disposal or remediation was completed. If the first of the month fall on a weekend or holiday, reports are due by the first business day following the due date. The report shall contain the information described in this paragraph (b).

- (1) Name and address of the producer.
- (2) Producer license or authorization identifier.
- (3) Location information, such as lot number, location type, and geospatial location or other location descriptor for the production area subject to disposal or remediation.
- (4) Disposal or remediation completion date.

(5) Total acreage.

(c) *Annual report.* Each State or Indian Tribe with a plan approved under this part shall submit an annual report to USDA. The report form shall be submitted by December 15 of each year and contain the information described in this paragraph (c).

- (1) Total planted acreage.
- (2) Total harvested acreage.
- (3) Total acreage disposed and remediated.

(d) *Test results report.* Each producer must ensure that the laboratory that conducts the test of the sample(s) from its lots reports the test results to USDA. Informal testing conducted throughout the growing season for purposes of monitoring THC concentration do not need to be reported to USDA. The test results report shall contain:

(1) Producer's license or authorization identifier.

(2) Name of producer.

(3) Business address of producer.

(4) Lot identification number for the sample.

(5) Name of laboratory and, no later than December 31, 2022, the DEA registration number of laboratory for testing.

(6) Date of test and report.

(7) Identification of a pre-harvest or post-harvest retest.

(8) Test result.

§ 990.71 USDA plan reporting requirements.

(a) *USDA licensing application.* USDA will accept applications on a rolling basis.

Licenses will be valid until December 31 of the year three years after the license is issued. The license application will be used for both new and renewal applicants. The application shall include:

(1) *Contact information.* (i) For an applicant who is an individual, the application shall include full name of the individual, Employee Identification Number (“EIN”) of the business entity, business address, telephone number, and email address (if available).

(ii) For an applicant that is an entity, the application shall include full name of the entity, the principal business location address, and the full name, title, and email address (if available) of each key participant of the entity.

(2) *Criminal history report.* As part of a complete application, each applicant shall provide a current Federal Bureau of Investigation's Identity History Summary. If the applicant is a business entity, a criminal history report shall be provided for each key participant.

(i) The applicant shall ensure the criminal history report accompanies the application.

(ii) The criminal history report must be dated within 60 days of submission of the application submittal.

(3) *Consent to comply with program requirements.* All applicants submitting a completed license application, in doing so, consent to comply with the requirements of this part.

(b) *USDA licensee disposal and remediation form.* USDA licensee conducts a disposal or remediation activity, that licensee must report the activity on the appropriate form to USDA no later than 30 days after the date of completion of disposal or remediation activity. The report shall contain the information described in this paragraph (b).

(1) Name and address of the producer.

(2) The USDA licensee's USDA license number.

(3) Geospatial location, or other valid land descriptor, for the production area subject to disposal or remediation.

(4) Date of completion of disposal or remediation.

(5) Signature of the USDA licensee or authorized representative

(c) *USDA licensee annual report.* Each USDA licensee shall submit an annual report to USDA. The report form shall be submitted by December 15 of each year and contain the information described in this paragraph (c).

(1) USDA licensee 's license number.

(2) USDA licensee 's name.

(3) USDA licensee 's address.

(4) Lot, location type, geospatial location, total planted acreage, total acreage disposed and remediated, and total harvested acreage.

(d) *Test results report.* Each USDA licensee must ensure that the laboratory that conducts the test of the sample(s) from its lots reports the test results for all samples tested to USDA. Informal testing conducted throughout the growing season for purposes of monitoring THC concentration do not need to be reported to USDA. The test results report shall contain the information described in this paragraph (d) for each sample tested.

- (1) USDA licensee 's license number.
- (2) Name of the USDA licensee.
- (3) Business address of the USDA licensee.
- (4) Lot identification number for the sample.
- (5) Name of testing laboratory.
- (6) Date of test and report.
- (7) Identification of a pre-harvest or post-harvest retest.
- (8) Test result.

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