

PERFORMANCE BASED SAMPLING: USDA FINAL RULE

INDUSTRIAL HEMP ADVISORY BOARD MEETING

APRIL 11, 2023

PERFORMANCE BASED SAMPLING

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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 noncompliant plants. Research institutions and producers growing hemp for research purposes shall also comply with the reporting requirements including reporting disposal of noncompliant 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](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.

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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.