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Mr. William Richmond
Branch Chief, U.S. Domestic Hemp Production Program
Specialty Crops Program, Agricultural Marketing Service

Submitted electronically via www.regulations.gov

Re: September 8, 2020, Federal Register Notice – Interim Final Rule, Reopening of Comment Period on Domestic Hemp Production Program (Docket No. AMS–SC–19–0042)

Dear Mr. Richmond,

The following comments are submitted in response to the September 8th Federal Register notice reopening the comment period on the Interim Final Rule (IFR) for the Domestic Hemp Production Program. My name is Herrick Fox, and I respectfully submit these comments on behalf of Meristem Farms, LLC, of which I am Managing Member and serve as the Chief Executive Officer.

Meristem Farms is a Vermont-based grower, producer and distributor of hemp and hemp products for premium wellness markets throughout the U.S. and in other countries. We farm our proprietary hemp varieties on our own leased cropland and with partner farms in northern Vermont, we distribute hemp planting seeds and clean-stock clones nationwide and for export, and we produce and distribute hemp-derived specialty consumer products nationwide. We also serve our broader industry through policy leadership, compliance support and public-private collaboration to build equity and effective governance throughout the hemp value chain.

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Commenter's statement of relevant professional experience, expertise and credentials

As CEO and Co-founder of Meristem Farms, I led the company's bootstrapped development from its inception, and I hold primary responsibility to our investors and stakeholders for the company's overall financial viability and the continuous improvement of our production and distribution operations. In this capacity I have become intimately aware of the specific logistical, financial and regulatory challenges associated with the farming, processing, marketing and fulfillment of hemp and hemp products, particularly as experienced by smaller and independent farms. In addition, through my direct participation in the distribution and sale of hemp seeds and clean-stock clones from breeders and nurseries to brokers, independent farms and farming conglomerates, I have developed an equally deep understanding of the variability of hemp genetics and the specific problems and opportunities this presents to these various segments of the industry. Lastly, as one of very few—perhaps the only—of our industry's practitioners actively engaged in farming and production who has as extensive a background in USDA management, policymaking and regulatory procedures, I am frequently called upon to advise and consult with industry peers, State and Federal agency officials, Congressional staffs, trade associations and media outlets on a wide range of concerns and questions relating to these matters, which I provide as a public service to advance the industry at large. Due to the need for such support, and the ever-increasing scope of our company's business networks, this has availed me of a rare if not unique breadth of perspective on the real-world implications of regulatory decisions such as those within the IFR.

Finally, it is necessary to explain my prior professional experience because of the significant extent to which it informs the comments provided in this submission. Before I started Meristem, my 20+ years of post-graduate academic and professional experience included 15 years as a career USDA employee in technical, managerial and senior policy positions. In these capacities I developed extensive specialized expertise in several areas relating to these comments, including biological science, agronomy, statistical methods, public collaboration in regulatory policy, policy analysis, rulemaking, legislative affairs, and agricultural value-chain capacity building. Most recently, I served as a Deputy Director in USDA's Foreign Agricultural Service, leading a 40-employee division in agricultural capacity-building. Before that, I worked in the USDA Forest Service, first in land management on National Forests and later in policy and legislative affairs with senior agency and sub-cabinet officials, which included a year-long detail to the US Senate Committee on Agriculture to work on the 2014 Farm Bill. My early career was focused on biological science and forestry research, which included an Adjunct Faculty appointment in Statistics with SUNY College of Environmental Science & Forestry, post-graduate research on statistical models of forest growth and yield, and applied research in quantitative methods for land management decision-making. My relevant professional certifications include OPM/USDA Senior Executive Service Candidate Development Program, American University Key Executive Leadership Program, USDA Forest Service Senior Leader Program, and 7 USDA Certificates of Merit. My relevant academic credentials include a B.S. in Conservation and Resource Studies from U.C. Berkeley, a Master's in Forest Science from Yale University, and a Fulbright Research Fellowship in biological science and silviculture.

After recently leaving the marble and limestone caverns of Washington DC, I currently reside in the Green Mountains of Lamoille County, Vermont, where I continue to hone my gravity management skills with my wife and our three kids, except when we're busy chucking hemp.

Introduction

Hemp is as challenging to regulate as it is to produce, and USDA has confronted these challenges in drafting an Interim Final Rule (IFR) to implement the hemp authorities enacted in the 2018 Farm Bill. However, the rule was issued with substantive technical errors that contradict scientific evidence, overlook practical realities of real-world implementation, and apply statistical methods and hypothesis tests in such a way that exceeds the Department's statutory authority with respect to the legal definition of hemp. The Rule also overlooks less restrictive, yet easily administered regulatory alternatives that are equally or more valid for meeting the Department's statutory mandates.

Left uncorrected, these errors needlessly put farmers and other hemp businesses at immense financial risk. They also expose the Department to alleged violations of the Administrative Procedures Act (APA) for arbitrary and capricious rulemaking, for exceeding statutory authority, and for sanctions that fail to meet the agency's burden of proof according to APA-required evidentiary standards.

Fortunately, the Department has acknowledged many of these specific problems in its Federal Register announcement of the new comment period. This, along with its decision in February to delay enforcement of two other problematic provisions in response to substantive industry concerns from the industry, shows the Department has been listening and recognizes the need to address these outstanding issues. Such a constructive posture may yet enable the Department to incorporate the changes necessary to put the Rule, and the industry in general, on stable footing if it acts on the input it is requesting.

Urgent Appeal: extend or re-open the comment period and delay enforcement

However, the short window and timing of the current comment period came to some as a surprise, given the legitimate criticisms last year for issuing the IFR and a *post hoc* comment period at the end of October. These actions come right at harvest, when farmers are most vulnerable to market disruptions and least able to provide constructive feedback, and it precludes consideration of the copious information to be obtained from this year's harvest, which is the first to take place with the IFR in effect. Therefore, we recommend that USDA extend or re-open the comment period to allow scientists, practitioners and farmers to contribute information from this year's harvest, potentially filling critical knowledge gaps to correct the Rule.

The brevity of the window also limits the opportunity and usefulness of public collaboration opportunities, with farmers and other stakeholders, such as the field workshop convened by Meristem Farms and its industry partners in Litchfield, Michigan, on October 1-2, 2020. This workshop, which was held safely outdoors and open to the public, was conducted interactively with USDA AMS Hemp Program staff, state agency officials, and Congressional staffs who participated via remote video connection. It drew from a 'collaborative learning' model that has been used to engage with USDA Forest Service on complex rulemaking and land management decisions for many years, and found to be an effective and FACA-compliant vehicle for substantive exchange and shared problem-solving on complex regulatory matters. By all accounts the workshop was a success, providing all participants—including officials who connected remotely—with useful information exchange and improved understanding of the issues at hand. It served as a valuable source of input for this comment as well. Our company and our partners

stand ready to coordinate more workshops, interactively with USDA officials like this one was, whether during a formal comment period or not.

But whether or not the comment period can be adjusted to allow for new information from this season, confusion and consternation now reign with the IFR in its current form and we fear this year's impending harvest will yield a bumper crop of bankruptcies and lawsuits rather than fiber, flower and food. Therefore, we also urge USDA to delay enforcement of the IFR provisions relating to the problems that commenters (and now USDA itself) have identified—specifically those at §990.3(a)(2)(i), §990.3(a)(2)(ii), §990.3(a)(3), §990.25(b) and related references in other sections of the IFR—until the Final Rule is promulgated.

That the nation is reeling from wildfires, extreme weather, socioeconomic upheaval and the COVID pandemic should be reason enough to take such action. Moreover, in elaborating on the specific topics on which it seeks input in announcing the comment period, the Department is clearly hearing stakeholders' concerns and recognizing their importance. Given that, and USDA's own intent to protect farmers as stated in its Federal Register preamble to the IFR, we hope the Department will recognize the imperative to apply the precedent it set in February and delay enforcement of the remaining provisions that are of even greater concern. Such action is well within its administrative discretion and carries practically no risk or cost of any kind, whereas the alternative is to leave in place ill-advised Rule provisions that expose regulators to legal jeopardy, threaten to invalidate the Rule, and needlessly endanger farmers with financial ruin. With so little to gain and so much to lose by leaving these provisions in place, it's hard to imagine any reason not to delay their enforcement at this time. Which mistake would the Department rather make?

Comments on the IFR – Overview

The immediate relief provided by the above steps would aid immensely in the paramount task before USDA and its stakeholders, which is to improve upon the IFR with a Final Rule that lays a sound foundation for the industry's long-term viability while meeting the Department's statutory mandates. But nevertheless, we have redoubled our efforts to provide the most comprehensive and substantive input we can by the existing October 8th closing date.

Thus, we submit our comments on the IFR, first in summary immediately below, and then with more detailed explanation on #1 through #4 in the subsequent pages:

1. **Measurement of Uncertainty for Sampling:** The direction for sampling, if applied correctly, requires at least 230 plants to be sampled for each lot. This is impracticable and mandates a degree of precision that exceeds the Department's statutory authority for establishing non-compliance according to the legal definition of hemp. It should be revised to state: "*The method used for sampling must be random and sufficient at a confidence level of 95 percent that the average THC level of the lot falls within the confidence interval for the estimated average as calculated from the sample and its associated variance. The confidence interval shall be added to the Measurement Uncertainty to be reported in accordance with §990.3(a)(3)(iii)(F). In cases where the sample size required for the above approach is deemed by the permit holder to be impracticable, an alternative method shall be provided that must be random and sufficient at a confidence level of 95 percent that no more than fifty percent (50%) of the plants in the lot would exceed the acceptable hemp THC level.*"

2. Liquid Chromatography Factor / Post-decarboxylated THC: The direction for calculating post-decarboxylated THC contradicts scientific evidence by failing to account for THCA that does not convert to Δ 9-THC, thus overestimating the amount of Δ 9-THC and rendering non-compliance findings scientifically and legally unsupportable based on the Department's statutory authority. It should be revised to state: "The testing methodology must consider the conversion of THCA in hemp into Δ 9-THC and calculate the resulting THC Level using the formula [Δ 9-THC + (THCA x 0.877 x 0.3)]."¹
3. 15-day Harvest Window: The direction for sampling at §990.3(a)(2)(i) and elsewhere requires that harvest be completed within 15 days of collecting samples, which is impracticable according to testing labs and farmers throughout the country. It should be revised to state: "*Within 30 business days prior to the anticipated harvest of cannabis plants, samples from such cannabis plants must be tested for delta-9 tetrahydrocannabinol concentration level as described in §§ 990.24 and 990.25.*"
4. Sampling of Flowers: The direction at §990.3(a)(2)(i) and elsewhere requires that samples shall be taken from the flowers of the plants. This contradicts the scientific basis for the legal definition of hemp, overestimates the amount of Δ 9-THC in the plant, and renders non-compliance findings scientifically and legally unsupportable. It should be revised to state: "*...designated person shall collect samples consisting of younger, upper leaves from such cannabis plants...*"
5. Negligence: The timing of the comment period is particularly unfortunate given USDA's explicit request that comments on this issue include quantitative and qualitative data: with harvest just getting underway there is inadequate opportunity to collect data on this issue. Nevertheless, we recommend that the negligence threshold be set no lower than 5% THC. THC levels in hemp can fluctuate dramatically based on numerous genetic and climatic factors that are beyond farmers' control and thus cannot be ascribed to negligence. Any such threshold must therefore be sufficiently high, such that occurrences of criminal negligence and the required mens rea (i.e., guilty mind) are proven beyond a reasonable doubt. Since cannabis cultivated for marijuana production contains THC levels much higher than 5%, it would be difficult if not impossible to establish that a farmer negligently planted marijuana instead of hemp, let alone do so with culpable intent.
6. Sampling methodology: See discussion on "Sampling Uncertainty," above.
7. Sampling Agents: We believe that personnel qualified and trained in proper sampling techniques can be drawn from a variety of governmental and private-sector organizations; limiting such responsibilities to drug enforcement personnel is both unnecessary and inadvisable as the scarcity of such personnel would create additional bottlenecks for hemp

¹ The additional 0.3 factor for THCA→ Δ 9-THC conversion should not be confused with the 0.877 factor, which is used to account only for the difference in the mass of the two types of molecules, not the rate at which the one type of molecule converts to the other. Please see the detailed discussion on this item below for citation and rationale on the 0.3 factor.



production. We are also concerned that such responsibilities would detract from the ability of such personnel to address more pressing narcotics issues facing our society, such as the opioid epidemic. Finally, we observe that the 2018 Farm Bill explicitly tasked USDA with implementation of all regulations relating to the domestic production of hemp. Therefore, it would exceed agency authority for drug enforcement agency personnel to carry out such responsibilities.

8. Specialty Crops: USDA's current guidance on specialty crops establishes hemp to be a fiber crop, and thus ineligible for specialty crop funding. Yet over 75% of the hemp planted in the US is grown not for fiber production, but for flowers and other uses consistent with the statutory definition of specialty crops. A similar proportion of all US farms engaged in hemp cultivation grow the crop solely for this purpose. While it is true that in some cases the crop is indeed grown for fiber, and such cultivation is expected to increase in the coming years, USDA has established a precedent of dual-designation with its treatment of amaranth (designated a commodity if grown for grain production and designated a specialty crop if grown for leafy greens) and other multiple-use crops variously designated as specialty crops or not, depending on their use. This precedent can clearly be applied to hemp as well. Guidance from USDA AMS and NIFA staff indicates that the statutory definition of specialty crops leaves some agency discretion in making specialty-crop designations and that such decisions do not require legislation, rulemaking or other regulatory procedure. The usual practice for considering new specialty-crop designations typically entails a review of the horticultural and floricultural scientific literature for its treatment of the crop in question. However, such literature remains scarce for hemp as its broad cultivation for flower production is a relatively recent development. Nevertheless, USDA's current designation of hemp as solely a commodity (fiber) crop excludes all producers of hemp flower, and thus the overwhelming majority of hemp producers, including our company, from participating in the Specialty Crops Block Grant Program, Technical Assistance for Specialty Crops and other USDA support programs. We therefore request that the Final Rule clarify this issue by specifying a dual-designation of hemp as either a commodity or specialty crop, depending on its use, based on the growing body of evidence USDA has already collected concerning the prevalence of the crop's cultivation for flower production throughout the country.

Thank you for this opportunity to provide substantive comment to the USDA Rule on Domestic Hemp Production. Please do not hesitate to contact me at any time for further information, additional questions, assistance with public collaboration opportunities, or any other support we can provide to your critical efforts to update the Rule.

Sincerely,

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DETAILED RESPONSES TO ISSUES RAISED IN USDA’S 9/8/2020 NOTICE OF COMMENT PERIOD

1. Measurement of Uncertainty for Sampling

The direction for sampling at §990.3(a)(2)(ii), if applied correctly, requires at least 230 plants to be sampled for each lot, even those as little as 1000 plants (about 0.5 acres) in size. This is impracticable and mandates a degree of precision that exceeds the Department’s statutory authority for establishing non-compliance according to the legal definition of hemp. It should be revised to state: *“The method used for sampling must be random and sufficient at a confidence level of 95 percent that the average THC level of the lot falls within the confidence interval for the estimated average as calculated from the sample and its associated variance. The confidence interval shall be added to the Measurement Uncertainty to be reported in accordance with §990.3(a)(3)(iii)(F). In cases where the sample size required for the above approach is deemed by the permit holder to be impracticable, an alternative method shall be provided that must be random and sufficient at a confidence level of 95 percent that no more than fifty percent (50%) of the plants in the lot would exceed the acceptable hemp THC level.”*

There are several problems with the IFR’s treatment of sampling uncertainty. First, the “Sampling guidelines for hemp growing facilities” provided by the Department² actually specify a minimum sample size of 1 plant per acre, not the 230 as mentioned above. Unfortunately this specification is implausible, since no valid inference can be made about a population based on a sample size of one³: it would be akin to estimating the average height of residents in a neighborhood by measuring the height of one person.

A closer examination of the sampling methodology reveals how this error occurred. To reach this conclusion, the USDA guidelines provide this methodology:

$$n_o = \frac{\ln(1 - p)}{\ln(1 - i)}$$

where p is the confidence level to detect hemp plants having THC content greater than the acceptable hemp THC level and i is the proportion of hemp plants having THC content greater than the acceptable hemp THC level. The values for i are based on past experience in the same or similar growing areas.

4.3.3. The initial primary plants estimate is adjusted by the number of acres to calculate the minimum number of primary plants for composting as follows:

$$n = \frac{n_o}{1 + \frac{(n_o - 1)}{N}}$$

where n is the minimum number of primary plants to be selected for forming a composite sample, n_o is the initial number of primary plants, and N is the number of acres under cultivation.

² <https://www.ams.usda.gov/sites/default/files/media/SamplingGuidelinesforHemp.pdf>

³ Moore and McCabe, 2003. Introduction to the Practice of Statistics. (New York: Freeman), 828 pp.

However, in the Codex Alimentarius sampling protocol cited by USDA as the basis for this guidance⁴, we find this information:

(b) Where the number of primary samples indicated in Table 2 is more than about 10% of units in the total lot, the number of primary samples taken may be fewer and should be calculated as follows:

$$n = \frac{n_0}{1 + (n_0 - 1) / N}$$

where n = minimum number of primary samples to be taken

n₀ = number of primary samples given in Table 2

N = number of units, capable of yielding a primary sample, in the lot.

From the Codex formula, and as well established in statistical sampling practice,⁵ it is evident that n_0 and N must be expressed in the same units: for the purposes of USDA's protocol, these units are plants, not acres (if the sample units were acres, then every plant in the acre would have to be removed to comprise the sample unit). Thus, it is evident that the USDA guidance is the result of a factual error: in establishing the "N" in the denominator of the formula for determining sample size, USDA incorrectly uses acres rather than plants.

A second problem is the IFR's existing direction at §990.3(a)(2)(ii), specifying that a sample "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." Upon correct application of the Codex formula as outlined above, and if we assume a reasonable number of plants in a one-acre lot to be 2000 plants, then this formula returns a sample size of 260 plants. This is problematic because it would be unduly onerous to expect farms to sample 260 plants per acre, for both logistical and financial reasons.

Finally, the existing direction that the sample must establish whether no more than 1% of a lot is non-compliant exceeds the Department's statutory authority. By requiring such a sample, the Department effectively sanctions growers for non-compliance if as little as 1% of the lot can be deemed non-compliant. This does not meet the Department's requisite burden of proof to support an order to dispose of a hemp lot pursuant to the IFR, even by the relatively low standard of substantial evidence⁶ required by the Administrative Procedures Act for sanctions under

⁴ Codex Alimentarius Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLS (CAC/GL 33-1999) – publication submitted with comment.

⁵ Thompson, Steven K., 1992. Sampling. (New York: Wiley), 343 pp.

⁶ Substantial evidence means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.

administrative law⁷, let alone by the higher standard of preponderance of evidence⁸ required for civil cases or beyond a reasonable doubt as needed for criminal negligence.

To resolve these problems, the Rule must provide for an implementable methodology that can meet the requisite burden of proof using valid statistical methods. The more robust solution, requiring a sample size of no more than 30 plants per lot for 95% confidence, is to analyze the THC Level in each sampled plant, calculate the mean across the sample, and then produce a margin of error based on the sample variance. This margin of error can then be reported with the sample mean as the THC Level. If the margin of error includes values only greater than 0.3%, then a valid inference can be made that the lot is non-compliant.

This requirement, that the margin of error must include only values greater than 0.3% in order to find a lot non-compliant, is the approach that the IFR currently provides correctly in its direction on Measurement Uncertainty concerning the accuracy of testing devices at §990.3(a)(3)(iii)(F). Since the Controlled Substances Act and the Agricultural Market Act as amended by the 2018 Farm Bill define hemp as “*the plant 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,*” a THC Level reported with a margin of error that includes a value that is less than or equal to 0.3% must be considered to meet this definition. Thus, the same logic must be applied to a margin of error for sample uncertainty, or else the Rule will violate APA’s prohibition against inconsistent reasoning as well as exceed the Department’s authority with respect to the definition of hemp.

A sample size of 30 is sufficient to make valid inferences about a population mean without knowing its variance, based on the Central Limit Theorem, which is fundamental to statistical analysis of large biological populations⁹. Based on this concept, a sample size of 30, selected at random, will ensure that the variance within the sample is a valid estimate of the variance within the population, no matter how large the population may be. This enables one to make valid inferences about an entire hemp lot (such as a 95% confidence interval for a population mean) based on a sample, as long as the confidence interval is correctly applied as a margin of error in testing the null hypothesis that the lot is compliant, according to the legal definition of hemp and as the current IFR direction correctly provides for Measurement Uncertainty as noted above.

Indeed, with this approach, the importance of reporting the margin of error bears repeating, since the absence of such reporting threatens farms with false findings of non-compliance. Consider a realistic example where 5 plants from a lot test for the following THC Levels: 0.20, 0.20, 0.20, 0.20, 0.80: The mean THC level reported for this sample would be 0.32%, and if reported without a margin of error the crop would be deemed non-compliant and ordered for disposal. But if this level were reported with the properly calculated margin of error at 95% confidence, the result

⁷ 5 USC §556(d): The proponent of a rule or order has the burden of proof. A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence.

⁸ Preponderance of evidence is generally recognized as evidence establishing a probability greater than 50% that a claim is true.

⁹ Gregoire and Valentine, 2008. Sampling Strategies for Natural Resources and the Environment. (Boca Raton: Chapman), 474 pp.

would be $0.32\% \pm 0.21\%$, meaning that the actual THC Level is somewhere between 0.11% and 0.53%. Thus the lot would not be deemed non-compliant and it would be allowed into the market.

That said, some farms may prefer a lower-cost approach that is also statistically valid, but somewhat less precise. Such an option would be to test whether no more than 50% of the plants in a lot exceeds the Acceptable Hemp THC Level, which at a confidence level of 95% requires a sample size of 5 plants per lot. This is considerably less than the 30 plants required for a valid estimate of the mean THC Level as described above, and cardinally less onerous than the 260 plants that would be required to test whether no more than 1% of the plants exceed the Acceptable Hemp THC Level, as would be required with correct application of the current IFR direction.

In order to use this approach, each sampled plant must be tested and reported as a binary variable, either exceeding or not exceeding the Acceptable Hemp THC Level. If the proportion of sampled plants exceeding this Level is greater than 50%, then a valid inference can be made with 95% confidence that the population proportion is also greater than 50%. Because the method establishes whether more than 50% of the lot exceeds the Acceptable Hemp THC Level, it can provide both substantial evidence and a preponderance of evidence that the lot is non-compliant.

Since growing conditions and other circumstances vary greatly from one farm to the next, and since both methods are statistically valid, it is appropriate to provide farmers with the option of using either approach. The first approach, estimating the mean THC Level in the lot and reporting the margin of error, required our farm less than one labor hour to collect the sample of 30 plants on approximately 1.5 acres, at a cost of about \$2100 to conduct the test, given that testing labs generally charge around \$70 per individual test. The second approach, estimating whether more than 50% of a lot exceeds the Acceptable Hemp THC Level, requires less than 20 minutes to collect the sample and would cost as little as \$350 to conduct the test. Farmers that have more variable growing conditions and/or genetics may prefer the greater precision of the former approach despite the cost, whereas farmers that expect less variability may prefer the cost savings of the second approach. Either approach satisfies the burden of proof for establishing non-compliance as concerns sampling uncertainty, though the method for estimating the mean is more robust for establishing such proof to a standard higher than substantial evidence.

It is also worth noting that the preferability of one approach or another may depend on the amount and type of material to be sampled from each plant. For example, from our experience, a sampling protocol that calls for using only leaves or the outer two inches of a side branch from each sampled plant resulted in a total wet weight of no more than eight ounces for 30 samples, which many farms would consider an acceptable loss on the value of a lot. Were the sampling protocol to require a larger volume or higher-value material, such as is the case with the IFR's current flower-only sampling protocol (which we address below), the value lost would be considerably greater and potentially less acceptable to the farmer.

2. Liquid Chromatography Factor / Post-decarboxylated THC

The direction for calculating post-decarboxylated THC, at §990.3(a)(3) and elsewhere, contradicts scientific evidence by failing to account for THCA that does not convert to Δ^9 -THC, thus overestimating the amount of Δ^9 -THC and rendering non-compliance findings scientifically and legally unsupported based on the Department's statutory authority. It should be revised to state: "The testing methodology must consider the conversion of THCA in hemp into Δ^9 -THC and calculate the resulting THC Level using the formula [Δ^9 -THC + (THCA x 0.877 x 0.3)]."¹⁰

The Rule's use of 'Total Theoretical THC' in determining post-decarboxylation levels of Δ^9 -THC assumes that decarboxylation fully converts all THCA molecules solely to Δ^9 -THC and to no other substances. However, peer-reviewed research (Dussy et al 2004¹¹, Iffland et al 2016¹²), found the conversion rate to be most commonly as low as 30%, under no circumstances greater than about 70%, and that much of the remaining THCA converts to other cannabinoids or remains in ash. In fact, 100% conversion does not occur in any realistic setting.

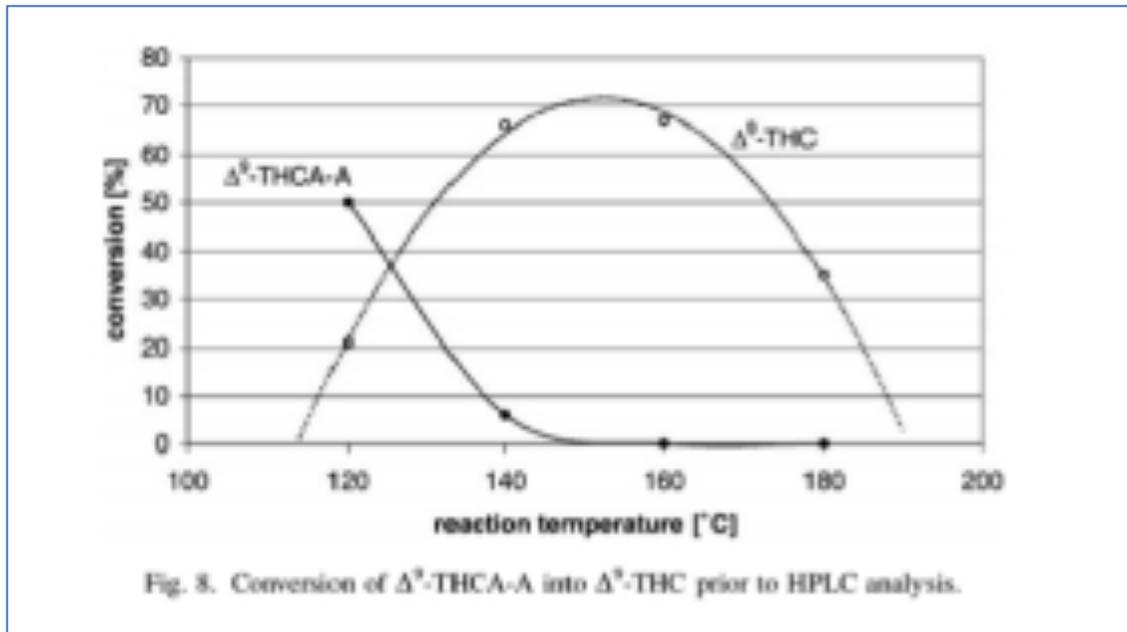


Figure 8 above, from Dussy et al, shows that a conversion rate of approximately 30% must be used in order to meet the Department's burden of proof in sanctioning a crop as non-compliant. This is because decarboxylation converts THCA to Δ^9 -THC more than 50% of the time only above that level. Such a delineation is necessary to meet a burden of proof to a standard of both substantial

¹⁰ The additional 0.3 factor for THCA→ Δ^9 -THC conversion should not be confused with the 0.877 factor, which is used to account only for the difference in the mass of the two types of molecules, not the rate at which the one type of molecule converts to the other.

¹¹ Dussy et al, 2004 – publication submitted with comment

¹² Iffland et al, 2016 – publication submitted with comment

evidence¹³ and preponderance of evidence¹⁴ that a crop is non-compliant, In other words, a THC level calculated to be more than 0.3% based on an assumption of 30% conversion would be supportable as indicating the crop contains more than 0.3% Δ9-THC, because in more than half of observed instances that would be true. In order to meet a higher standard of evidence, such as beyond a reasonable doubt as in the case of a criminal negligence ruling, a conversion rate considerably lower than 30% would be called for.

By contrast, the 100% rate in the 'Total Theoretical THC' method, specified by USDA, assumes a rate of conversion higher than most or all observed instances. As such it greatly inflates the amount of Δ9-THC produced and exceeds the Department's statutory authority. By assuming a 100% conversion rate, the Department effectively has no scientific basis to establish that a crop is non-compliant because there is no evidence to support such a conversion rate.

In place of this 100% assumption, some commenters recommend using a 70% or 75% conversion rate to properly account for decarboxylation. However, Figure 8 above demonstrates that this too is a maximum, and would thus fail to meet the Department's requisite burden of proof under the Administrative Procedures Act for sanctions under administrative law¹⁵, such as disposal of a hemp lot pursuant to the IFR. In other words, a THC level calculated to be more than 0.3% based on an assumption of 100% or 70% conversion would not be supportable by substantial evidence or a preponderance of evidence indicating that the crop contains more than 0.3% Δ9-THC, because only in less than half of all instances (and potentially in no instances) would that be true.

Finally because of this erroneous provision, our farm suffered over \$120,000 in losses, and many others have been similarly devastated, due to purchasers backing out of their contracts due to misperceptions of risk¹⁶ associated with theoretical estimates of THC rather than real data. It renders useless about 82% of the hemp flower and 74% of hemp biomass produced in the U.S.¹⁷, and it excludes 68% of all the varieties planted¹⁸.

¹³ Substantial evidence is generally recognized to be such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.

¹⁴ Preponderance of evidence is generally recognized as evidence establishing a probability greater than 50% that a claim is true.

¹⁵ 5 USC §556(d): The proponent of a rule or order has the burden of proof. A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence.

¹⁶ The promulgation of this limit in the rule has already devastated small- to medium-sized hemp farms as processors are backing out of their 2019 crop purchase contracts due to misperceptions of risk associated with marketing product derived from hemp in excess of the newly established limit. This is the case even though such hemp is fully compliant with applicable State and Federal law, and even though the USDA rule is explicitly inapplicable to hemp that was or is cultivated under the 2014 Farm Bill programs (which includes all hemp grown under in 2019 nationwide).

¹⁷ HempExchange, 2019 – publication submitted with comment

¹⁸ Orser, 2019 – publication submitted with comment

3. 15-Day Harvest Window

The direction for sampling at §990.3(a)(2)(i) and elsewhere requires that harvest be completed within 15 days of collecting samples, which is impracticable according to testing labs and farmers throughout the country. It should be revised to state: *“Within 30 business days prior to the anticipated harvest of cannabis plants, samples from such cannabis plants must be tested for delta-9 tetrahydrocannabinol concentration level as described in §§ 990.24 and 990.25.”*

In 2019, when most hemp in the country was being grown under regulations requiring a harvest window of a 28 or 30 calendar days, many farms—including our own—struggled to meet the required timeframe due to longer than expected waits to get test results back due to backlogs at the lab, inclement weather, broken-down equipment, labor shortages, etc. This was an all-too common experience with a 30-day window; imagine the same situation, but with a window half as long.

The 15-day window between testing and harvest is impracticable given testing-lab capacity as well as variable farming conditions and logistics. Even last year’s 28- or 30-day window proved difficult if not impossible for many farms, especially smaller and independent farms, like ours, that lack preferential access to vertically integrated testing labs, or to the labor and machinery needed to react quickly to changing conditions or complete 3-4 weeks’ worth of harvest work in just a week or two. Furthermore, many farms have no options but to mail their samples to labs in distant locations, which only adds to the time needed, especially where overnight USPS service is limited (UPS and FedEx have corporate policies prohibiting transport of hemp).

Lab capacity is unlikely to increase significantly in the coming years due to the seasonal nature of the demand, and labs could find themselves exposed to tort claims for causing farms to miss mandated deadlines. Increasing the window to 30 business days, and specifying this period to begin from the date samples are tested, rather than the date they are taken from the field, is the minimum that must be allotted for both farms and testing labs to be able to complete their work.

4. Sampling of Flowers

The direction at §990.3(a)(2)(i) and elsewhere requires that samples shall be taken from the flowers of the plants. This contradicts the scientific basis for the legal definition of hemp, overestimates the amount of Δ^9 -THC in the plant, and renders non-compliance findings scientifically and legally unsupported. It should be revised to state: “...*designated person shall collect samples consisting of younger, upper leaves from such cannabis plants...*”

It is well understood that the highest concentrations of all cannabinoids, including THC, are found in the flowering tops. However, the basis for the 0.3% Δ^9 -THC threshold was established by Small and Cronquist in their seminal 1976 publication¹⁹ for use in measuring THC in the leaves of young, vigorous plants—not flowers. Therefore, a sanction based on such a sample would likely be considered arbitrary and capricious and thus violate the Administrative Procedures Act. It would also fail to meet the Department’s requisite burden of proof for an order to dispose of a hemp lot pursuant to the IFR, even by the relatively low standard of substantial evidence²⁰ as required for sanctions under administrative law²¹, let alone by the higher preponderance of evidence standard²² for civil cases or beyond reasonable doubt for criminal negligence. Though some commenters maintain that sampling of whole plants would be adequately representative, such an approach is costlier and more complex for growers to implement while providing less support for findings of non-compliance given the Small and Cronquist study. Sampling should therefore be based on leaves (Small and Cronquist go on to specify younger, upper leaves of the plants), rather than flowering tops, in order for a non-compliance ruling to be supportable.

on a relative basis) result, depending on how such material is prepared: if the achenes and larger twigs are removed, THC concentrations are of course much higher.

It will be noted that we arbitrarily adopt a concentration of 0.3% Δ^9 -THC (dry weight basis) in young, vigorous leaves of relatively mature plants as a guide to discriminating two classes of plants. This is based on standard-grown material in Ottawa in gardens, greenhouses and growth chambers, and of course on our analytical techniques. Dr. C. E. Turner, who has conducted extensive chemical analysis of *Cannabis* at the University of Mississippi, has agreed (pers. com.) that this is a reasonable figure to discriminate two classes of plants. We

¹⁹ Small and Cronquist, 1976 – publication submitted with comment.

²⁰ Substantial evidence is generally recognized to be such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.

²¹ 5 USC §556(d): The proponent of a rule or order has the burden of proof. A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence.

²² Preponderance of evidence is generally recognized as evidence establishing a probability greater than 50% that a claim is true.