



Mr. Dean Kelch, Environmental Program Manager
California Department of Food and Agriculture Plant Health and Pest Prevention Services 2800
Gateway Oaks Drive, Suite 200
Sacramento, CA 95833
Transmittal Via E-mail: Dean.Kelch@cdfa.ca.gov

RE: Comments for Proposed Rulemaking of Title 3, California Code of Regulations, Sections 4935, 4940, 4941, 4942, 4943, 4944, 4945, 4946, 4950, and 4950.1

Dear Mr. Kelch,

The following comments are submitted in response to the solicitation for comments on the proposed CDFA industrial hemp regulations at 3 CCR Sections 4935, 4940, 4941, 4942, 4943, 4944, 4945, 4946, 4950, and 4950.1. My name is Herrick Fox, and I respectfully submit these comments on behalf of **Cultivaris Hemp LLC, 1150 Quail Gardens Dr., Encinitas, CA 92024.**

TABLE OF CONTENTS

Commenter’s statement of relevant professional experience, expertise and credentials..... 1
Introduction 2
Overview of Comments..... 2
Detailed Comments 4
 1. *Sampling Procedures*..... 4
 2. *Liquid Chromatography Factor / Post-decarboxylated THC* 7
 3. *15-Day Harvest Window* 9
 4. *Sampling of Flowers*..... 10

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 CDFA Regulations.

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 agricultural capacity-building and land management, including technical and managerial positions as well as senior legislative and policy positions at the sub-Cabinet level and in the US Senate Agriculture Committee. 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. My early career was focused on biological science, which included an Adjunct Faculty appointment in Statistics with SUNY College of Environmental Science & Forestry, post-graduate research on statistical models of biological 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 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.

Introduction

The CDFA industrial hemp regulations issued at 3 CCR 4935, 4940-4946 and 4950 contain 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.

Overview of Comments

We thus submit our comments on the CDFA Regulations, 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 formula used for sampling incorrectly applies the formula for determining sample size, resulting in a sample size that is far too low to produce meaningful statistical inferences at the precision level currently required under USDA's Interim Final Rule (7 CFR 990). Correct application of the formula requires that "N" in the denominator of the formula be expressed in units of plants, not acres. This consequently requires at least 230 plants to be sampled for each lot, which is admittedly 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. For this reason we recommend that the sampling direction 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 7 CFR §990.3(a)(3)(iii)(F).*
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 $\Delta 9$ -THC, thus overestimating the amount of $\Delta 9$ -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 $\Delta 9$ -THC and calculate the resulting THC Level using the formula [$\Delta 9$ -THC + (THCA x 0.877 x 0.3)]."*
3. 15-day Harvest Window: The direction that harvest be completed within 15 days of collecting samples is impracticable according to testing labs and farmers throughout the country, which is why we recommended that USDA revise its Interim Final Rule to allow for a 30-day testing window. In the meantime, CDFA Regulations should specify 15 *business* days for its window.
4. Sampling of Flowers: The direction that samples shall be taken from the top eight inches of the plant contradicts the scientific basis for the legal definition of hemp, overestimates the amount of $\Delta 9$ -THC in the plant, and renders non-compliance findings scientifically and legally unsupportable. It should be revised to require that samples be taken from *younger, upper leaves of plants*.

Thank you for this opportunity to provide substantive comment to the CDFA Regulations. Please do not hesitate to contact us 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 improve the regulations.

Sincerely,

Herrick S. Fox, CEO
Meristem Farms, LLC
rick@meristemfarms.com

Josh Schneider, CEO
Cultivaris Hemp, LLC
josh@cultivaris.com

Detailed Comments

1. Sampling Procedures

The direction for sampling, 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.”*

There are several problems with the CDFA Regulations’s treatment of sampling uncertainty. First, they effectively 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 one¹: 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 USDA’s sampling methodology, from which CDFA’s direction presumably derives, 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.

However, in the Codex Alimentarius sampling protocol cited by USDA as the basis for this guidance², we find this information:

¹ Moore and McCabe, 2003. Introduction to the Practice of Statistics. (New York: Freeman), 828 pp.

² Codex Alimentarius Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLS (CAC/GL 33-1999) – publication submitted with comment.

(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

n_0 = 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,³ 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.

To resolve these problems, the regulations 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 approach comports with USDA direction that no more than 1% of a lot exceeds the Acceptable Hemp THC level at 95% confidence.

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 CDFA Regulations currently provide correctly in its direction on Measurement Uncertainty concerning the accuracy of testing devices. 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 regulations will violate APA prohibitions 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 populations⁴. Based on this concept, a sample size of 30, selected at

³ Thompson, Steven K., 1992. Sampling. (New York: Wiley), 343 pp.

⁴ Gregoire and Valentine, 2008. Sampling Strategies for Natural Resources and the Environment. (Boca Raton: Chapman), 474 pp.



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 CDFA Regulations 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 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.

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 $[\Delta^9\text{-THC} + (\text{THCA} \times 0.877 \times 0.3)]$.*”⁵

The Regulations’ current approach for 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 2004⁶, Iffland et al 2016⁷), 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.

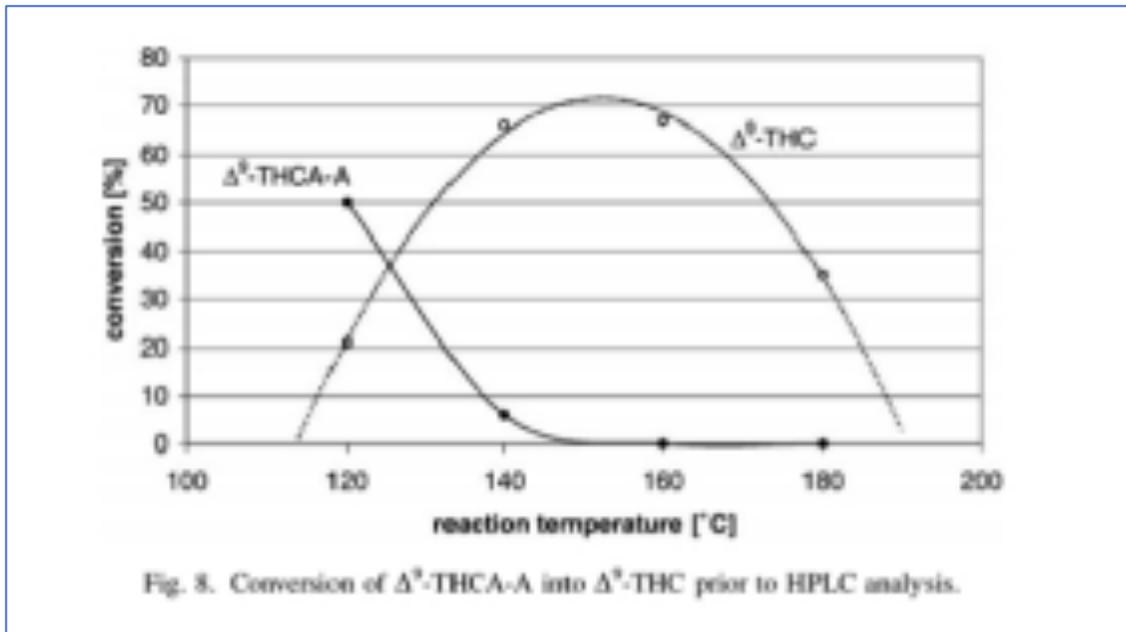


Figure 8 above, from Dussy et al, shows that a conversion rate of approximately 30% must be used in order to meet the Department’s burden of proof in sanctioning a crop as non-compliant. This is because decarboxylation converts THCA to Δ^9 -THC more than 50% of the time only above that level. Such a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

⁵ 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.

⁶ Dussy et al, 2004 – publication submitted with comment

⁷ Iffland et al, 2016 – publication submitted with comment

evidence⁸ and preponderance of evidence⁹ 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 methodology specified in the CDFA regulations assumes a rate of conversion higher than 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% 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 law¹⁰, such as disposal of a hemp lot pursuant to the CDFA Regulations. 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 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 risk¹¹ 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.¹², and it excludes 68% of all the varieties planted¹³.

⁸ Substantial evidence is generally recognized to be such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.

⁹ Preponderance of evidence is generally recognized as evidence establishing a probability greater than 50% that a claim is true.

¹⁰ 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.

¹¹ 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).

¹² HempExchange, 2019 – publication submitted with comment

¹³ 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. Therefore we have recommended that USDA revise its Interim Final Rule to allow for a 30-day testing window. In the meantime, CDFA Regulations should specify 15 *business* days for its window.

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 strictly limiting 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 requiring that samples shall be taken from the top eight inches of the plant 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 specify sampling of *younger, upper leaves*.

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 publication¹⁴ 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 CDFA Regulations, even by the relatively low standard of substantial evidence¹⁵ as required for sanctions under administrative law¹⁶, let alone by the higher preponderance of evidence standard¹⁷ 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

¹⁴ Small and Cronquist, 1976 – publication submitted with comment.

¹⁵ Substantial evidence is generally recognized to be such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.

¹⁶ 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.

¹⁷ Preponderance of evidence is generally recognized as evidence establishing a probability greater than 50% that a claim is true.