Comments on USDA Agricultural Marketing Service's Interim Final Rule on Establishment of a Domestic Hemp Production Program

Published in Federal Register at 84 FR 58522-58564 on October 31, 2019.

Agency/Docket Numbers: Doc. No. AMS-SC-19-0042 and SC19-990-2 IR

Original deadline to comment was December 30, 2019 and was extended by USDA AMS on December 17, 2019 to be not later than January 29, 2020. https://www.ams.usda.gov/content/usda-extends-us-domestic-hemp-production-program-interim-final-rule-comment-period-january.

Submitted To: Docket Clerk, Marketing Order and Agreement Division
Specialty Crops Program, AMS, USDA
1400 Independence Avenue SW, STOP 0237
Washington, DC 20250-0237
Fax: (202) 720-8938

Submitted by: David Frankel, Attorney
Frankel Law Group APC
770 L Street, Ste. 950
Sacramento, CA 95814
info@frankel.law
916-250-0215

Submitted on January 29, 2020 via regulations.gov**.**

Specific Commenters:

Frankel Law Group APC ("FLG") on behalf of itself and the following interested parties: Earth Matters (HI), Go Farm Hemp, LLC (NV/CO), Halcyon Holdings, LLC (KY), Mantis Growth Investments (NV), Peak Products Corporation (OR), and Sports Science CBD (NV).

All of the foregoing persons and entities are referred to individually herein as a "**Commenter**" and collectively, as the "**Commenters**." Each of the Commenters is actively engaged in lawful commerce in industrial hemp and/or industrial hemp products (including commodities) in the United States and/or in lawful commerce in support of commerce in industrial hemp products and commodities.

SUMMARY

The U.S. Department of Agriculture ("**USDA**")'s Agricultural Marketing Service ("**Agency**") has issued an interim final rule ("**Interim Rule**") to establish a new part specifying the rules and regulations to produce hemp as mandated by Section 10113 of Public Law 115-334, the

Agriculture Improvement Act of 2018 (the "**2018 Farm Bill**"), which amended the Agricultural Marketing Act of 1946 ("**AMA**"). The Interim Rule is set forth as Part 990 - Domestic Hemp Production Program, 7 CFR §§ 990.1 et seq. (the "**Hemp Regulations**").

Section 10113 of the 2018 Farm Bill added to the AMA Subtitle G (sections 297A through 297D of the AMA) ("**Subtitle G**"). The USDA collected thousands of public comments on a proposed rule and states that "USDA is committed to issuing the final rule expeditiously after reviewing public comments and obtaining additional information during the initial implementation. This interim final rule will be effective for two years and then be replaced with a final rule."

Thus, the final USDA Interim Rule is final and was immediately effective on October 31, 2019 and is to remain in effect until October 1, 2021 unless otherwise decided by the Agency or a court of competent jurisdiction. The Interim Rule outlines provisions for the USDA to approve plans submitted by States and Indian Tribes for the domestic production of hemp.[1] It also establishes a Federal plan for producers in States or territories of Indian Tribes that do not have their own USDA-approved plan. The program includes provisions for maintaining information on the land where hemp is produced, testing the levels of delta-9 tetrahydrocannabinol, disposing of plants not meeting necessary requirements, licensing requirements, and ensuring compliance with the requirements of the new part. The Interim Rule does not allow remediation of 'hot' hemp but does impose testing protocols that are prohibitively expensive.

Commenters understand that the Administrator recognizes the value of public comment to refine the IFR and will keep an open mind as to any and all comment submissions. All written comments timely received will be considered before a final determination is made on this matter. 84 FR 58554.

Based on a finding of "Good Cause" with which Commenters disagree, the Agency has made the Interim Rule immediately effective for two years while retaining the discretion to make changes in its sole and absolute discretion. In doing so, the Agency has usurped the role of Congress and has exceeded its authority as discussed below.

The Agency should modify the Interim Rule as necessary to maintain orderly conditions for marketing industrial hemp as an agricultural commodity; to provide an orderly flow of the supply thereof and to avoid unreasonable fluctuations in supplies and prices; and to avoid a disruption of the orderly marketing of industrial hemp as a commodity.

The Agency should revise the Interim Rule to remove the disruptive impacts noted in this Comment.

---

[1] Pursuant to Subtitle G, the term "hemp" means the plant 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.

Specific Comment of Kentucky Hemp Company Halcyon Holdings, LLC

Re: KY Hemp Concerns regarding the USDA IFR and regulation of hemp farming

Dear Sir or Madam,

We are writing you today to share our concerns about the USDA interim final rule (IFR) issued on October 31, 2019. Hemp farming in Kentucky is still in its early stages and federal regulation of our farmers could have a serious detrimental impact on the Kentucky hemp industry if certain aspects are not addressed. We have reviewed the IFR and see a number of issues of concern we want to share with you. We hope that you will take these concerns seriously and work with us to get the USDA to make improvements to the IFR as soon as possible.

Testing of THC for compliance is a serious concern. Our farmers invest thousands of dollars to grow hemp and all of that investment is at risk if a crop is found to be out of compliance with the law. We appreciate the flexibility the IFR measurement of uncertainty (MU) provides on THC testing. Labs can calculate the MU for the testing process and provide some margin of error to determine an acceptable THC level in a tested crop. However, we are concerned that the variations of THC levels within the crop can be significant and this must be taken into account to ensure that a crop won't be destroyed on the basis of a sampling process that only selects a tiny fraction of plant population. THC levels can spike due to various reasons including stress, fertilization inputs and weather. THC levels can also vary due to inconsistencies in non-certified plant genetics that are prevalent in high CBD varieties. For example, the USDA sampling procedure specifies taking a single plant sample when testing 1 acre or less. Given that a 1-acre hemp field would have anywhere from 2,000 to 30,000 plants, a single plant is a tiny fraction of the crop and is insufficient to provide a fair and accurate average of THC levels across the crop.

We recommend USDA conduct or fund a study to determine MU of the sampling process. This is needed so that we can accurately report the MU resulting from the sampling process. Until this study is conducted, we recommend that USDA provide flexibility on acceptable THC levels by using a reasonable estimate of THC level variations.

After discussions with experienced Kentucky hemp farmers, it is clear that allowing only 15 days between sampling and harvest is inadequate and unworkable. Crop harvesting cannot begin until the test results are received or the farmer risks paying for harvest on a crop that must be disposed. This means, in the best-case scenario, that 7 or more days will pass before the test results will be available given the large number of hemp samples that will need to be tested during a short window of time.

In addition, our farmers have indicated that harvesting can take weeks due to the use of labor-intensive hand harvesting. Weather can also delay harvesting as the crop must be dry before harvesting. We recommend that USDA regulations allow for at least 30 days between sampling and harvest.

We are also concerned that IFR sampling procedure specifies only testing the top 1/3 of the plant. This does not result in an accurate measurement of the average THC levels in the plant because materials from the lower portion of the plant contain lower levels of THC than the top portions. In order to get an accurate average THC level, sampling must occur at the top, middle and bottom of the plant and the sample must be homogenized before lab testing.

The IFR requires all non-compliant plant material to be destroyed. However, the Farm Bill states nothing about destruction. In fact, the Farm Bill only requires <u>disposal</u> of non compliant plants or plant material. The Farm Bill specifically states:
"(2) CONTENTS.—A State or Tribal plan referred to in paragraph (1)—
"(A) ***shall only be required to include****—*
...
"(iii) a procedure for the ***effective disposal*** *of—*
"(I) plants, whether growing or not, that are produced in violation of this subtitle; and "(II) products derived from those plants;

Congress did not intend to require destruction of hemp above the limit under the provisions of the Controlled Substances Act ("**CSA**") or it would have said so. The CSA requires incineration of plant material and special storage requirements that will place an undue burden on producers. We recommend that USDA allow states to oversee disposal in any way that ensures that flower material is rendered non-viable.

We disagree with the decision that a delta-9 THC test result greater than 0.5% THC will automatically be considered "negligence." We believe Congress intended "negligence" to be consistent with traditional legal interpretations of that term based on what a reasonably prudent person would due under like circumstances - not an arbitrary number.

We urge you to protect Kentucky hemp farmers by advocating for negligence to be determined by state departments of agriculture based on the facts and circumstances.

We hope that you will listen to our concerns and make these changes to the proposed rule. We look forward to hearing back from you. Sincerely, Halcyon Holdings, LLC.

This comment is joined in by the other Commenters.

SPECIFIC COMMENTS:

Unauthorized Regulations Not Authorized by Statute Are Invalid

Nothing in the 2018 Farm Bill authorizes the USDA to implement and set in stone for two years its own standards and create new requirements. The Interim Rule is arbitrary and capricious and violates applicable law.

Pursuant to 5 USC 553(e), Commenters request that the Interim Rule be repealed effective immediately and replaced with a rule that does not disrupt the orderly flow of industrial hemp commodities or otherwise create unnecessary risk to hemp producers and other hemp companies.

There are ten states that have opted to delay submission of a plan to USDA and, rather, to continue under the 2014 Farm Bill programs that are in place in those states.[2] The other hemp states will be hobbled by the Interim Rule.

This a great distortion in the United States hemp market by favoring the hemp farmers in the ten States that are 2014 Farm Bill compliant and can bring in their harvest by October 31, 2020. By creating a rule that allows similarly situated hemp farmers in different states to be treated differently, the Agency has violated the Equal Protection Clause of the United States Constitution and the Administrative Procedure Act (5 USC 551 *et seq*.) ("**APA**").

Had the Agency properly evaluated the Interim Rule in the context of thousands of existing public comments and the existing industrial hemp market under the 2014 Farm Bill, it would have not issued a rule as extremely disruptive to the market for industrial hemp products in the United States as is the Interim Rule.

The creation of distortions in the orderly flow of industrial hemp commodities is contrary to the expressed intention of the Agency which it stated as follows: "[t]his interim rule will help expand production and sales of domestic hemp, benefiting both U.S. producers and consumers." 84 FR at 58523.

Further, the squelching of the commercial hemp industry by imposition of unnecessary and/or unduly expensive Hemp Regulations and/or the imposition of Hemp Regulations that unnecessarily increase commercial risk to US hemp producers is against the statutory

[2] Arkansas, Kentucky, Maine, Maryland, Minnesota, Missouri, New Mexico, North Dakota, Vermont, and Wisconsin.

authorization of the AMA.[3] Further, it puts US hemp producers at a disadvantage compared to their international counterparts in Europe, Canada, China, Australia and South America.

That the entire hemp industry should be promoted, and chain of production should be considered, by the Interim Rule is supported by Sections 297B(a)(2)(v) and 297C(a)(2)(C) and (a)(2) (E) which refer to the 'producing' of hemp, not just the 'cultivation' of hemp; and Section 297B(e)(2)(A)(iii) which refers to violations involving 'producing Cannabis sativa L. with a delta-9 tetrahydrocannabinol concentration of more than 0.3% on a dry-weight basis.'

The focus in those Sections is on the entire production process, not just the cultivation process.

Since the production of hemp includes cultivation and post-cultivation processing and since it is common outside the United States to remediate 'hot' hemp by post-cultivation processing, it was a critical mistake for the Agency to issue the Interim Rule without any post-cultivation opportunity for remediation as part of the production process. The Agency's failure here will cost United States hemp producers millions if not billions of dollars.

The Hemp Regulations in the Interim Rule (see Section 990.1 definition of "Produce") provide that to 'produce' hemp is to do so 'for market' in the United States which indicates that post-cultivation processing of 'hot' hemp to prepare it for market would be included in a reasonable interpretation of Subtitle G and could have been included in the Hemp Regulations. However, there is no provision in the Interim Rule for remediation of 'hot' hemp.

Distortions in Hemp Industry and Commercial Markets Caused by Rulemaking

Section 297B(a)(2)(A)(ii) and Section 297C(a)(2)(B) state the procedure for testing that uses post-decarboxylation or other similarly reliable methods, the "delta-9 tetrahydrocannabinol concentration levels of hemp produced…." A well known and regularly used method for testing cannabis, in those states in which it is legal, is HPLC - "High-performance liquid chromatography or HPLC." (See Hemp Regulations §990.1 definition of HPLC.) Congress knew about HPLC when it passed the 2018 Farm Bill. Therefore, HPLC must be interpreted as being one of the "similarly reliable methods" referred to in Section 297B((a)(2)(ii) and Section 297C(a)(2)(C).

---

[3] See 7 USC §601 "It is declared that the disruption of the orderly exchange of commodities in interstate commerce impairs the purchasing power of farmers and destroys the value of agricultural assets which support the national credit structure and that these conditions affect transactions in agricultural commodities with a national public interest, and burden and obstruct the normal channels of interstate commerce."

See also 7 USC 602 re: Congressional policy to cause USDA to establish and maintain orderly conditions for marketing agricultural commodities including hemp; to provide an orderly flow of the supply thereof and to avoid unreasonable fluctuations in supplies and prices; and to avoid a disruption of the orderly marketing of any commodity if the regulation of such commodity has been initiated during a marketing year on the basis of a need to effectuate the policy of the AMA.

By mandating only post-decarboxylation and imposing the factor with respect to THCA, the Agency has changed drastically the risk/reward analysis for hemp cultivators. The impact of the rule is that a much higher percentage of hemp tests will test 'hot.' Because there is no remediation contemplated by the Interim Rule and, therefore, no federally recognized remediation for the next two years, the nascent industrial hemp market will be knee-capped; it could die on the vine, so to speak.

Likewise, the Interim Rule re-integrates the U.S. Drug Enforcement Agency (DEA) into hemp regulation despite the general trend against treating cannabis as an unlawful drug in the United States; and industrial hemp even less so. The mere presence of minuscule amounts of THC should not, in and of themselves, give rise to a regulatory need to be licensed by the DEA as a testing lab.

There are only 44 DEA licensed testing labs. It would be impossible for the tens of thousands of licensed hemp producers to be serviced by a few dozen testing labs. While eventually a DEA licensed testing lab sub-industry could evolve, such would take time and during that time, the United States hemp industry will languish. From a practical standpoint, the imposition of the DEA license requirement, which is not supported by Subtitle G in any way, creates an tight pinch-point that will artificially depress the industry. All this is contrary to the AMA, Subtitle G and the Agency's mandates.

The imposition of the requirement for industrial hemp testing labs to be licensed by the DEA in case of 'hot' tests is arbitrary and capricious and invalid under the APA and applicable law. The damages caused to the United States industrial hemp industry will be monumental, albeit difficult to prove, and the harm will be irreparable and should be enjoined.

The Hemp Regulations (particularly including Section 990.3(a)(2) and Section 990.24 thereof) contain testing and sampling protocols that have the effect of squelching this nascent industry.[4] These include:

* requiring samples from the top 1/3 of the plant instead of requiring a representative sample of the plant's from top, middle and bottom.

* requiring uniformity within too narrow parameters, when it is known that different cultivars perform differently in different geographic areas and that it is difficult if not impossible to predict with certainty the THC results within the newly imposed measurements of uncertainty.

* requiring testing within 15 days of harvest.

[4] Indeed, the Agency states in the that it expects at least a $4,000,000 loss to hemp producers in 2020 due to the Interim Rule.

* requiring DEA licensed labs when there are known to be about 44 such labs in the United States that are expected to service over the more than 17,500 hemp licensees (under 2014 programs) and the tens of thousands of federally licensed hemp producers.

* The definitions and testing protocols conspire to increase risk of loss which will discourage hemp farms from investing substantial sums (up to $35,000/acre for some hemp farmers). Such increased risk of loss is likely to scare hemp producers from cultivating hemp and will further distort the market.

* No-commingling lots - overly burdensome; no legitimate governmental interest; not rational

* Implication of 21 CFR 1317.15 DEA Regulations contrary to USDA having sole authority

* Overbearing on Tribal Authority and States' Federalism to require state/tribal forms of licenses to be in a format prescribed by USDA -

Section 990.24 USDA Regulatory Impositions:

* Testing and protocols unfair and expensive

Section 990.25(b) - total THC issue not in furtherance of Subtitle G.

* should have also approved HPLC without THCA conversion factor-

Section 990.26 - burdensome on hemp producers:

Section 990.27 - no opportunity for remediation; on what authority does the USDA revert back to DEA regulations (see reference to 21 CFR 1317.15)?

Section 990.32 - burdensome to record all hemp plants individually -

Section 990.60 - naming agents brings DEA back into the hemp market -

Section 990.70 - implying DEA regulations re disposal -

The Agency estimates that due to its burdensome regulations, about 20% of the 2020 hemp crop will test as 'hot' hemp. See Footnote 14 to the Interim Rule as published in the Federal Register.[5]

Lack of Regulation Concerning Remediation Amounts to Taking Without Due Process or Just Compensation

It is common in Italy for hemp farmers there to pay a post-harvest processor to reduce the levels of THC in the hemp crop from the Italian maximum field inspection standard of 0.6% THC to

[5] "There is no way to know for certain how many samples will test beyond the 0.3 percent threshold for THC on a dry-weight basis; however, based on information discussions with States that have a hemp program under the 2014 Farm Bill, AMS estimates that 20 percent of lots per year will produce cannabis that tests high for THC content." 84 FR at 58564.

the legal threshold for commerce in Europe of 0.2% THC. The fact that so-called 'hot' hemp (i.e., non-psychoactive hemp that tests above the regulatory threshold which is somewhat arbitrary and varies internationally from 0.2% to 1.0% THC) may be remediated in a scientifically verifiable and repeatable manner means that Section 297B(a)(2)(iii) must be read to allow for the remediation of 'hot' hemp before the disposal procedures are implemented. To do otherwise causes great risk and distorts the entire commercial market for hemp which is the opposite of Congressional intent in adopting Subtitle G.

The USDA should allow farmers to remediate THC levels in 'hot' hemp by allowing them to (through sunlight/time etc.) degrade the THC levels in their hemp until they are suitable for sale. If farmers are allowed to remediate 'hot' hemp prior to sale, they'll still be able to utilize most currently available genetic stock, while simply adding a processing requirement to ensure hemp of required THC levels is being sold.

Allowing such activities will actual foster further economic growth rather than constrain it as will be the case under the Interim Rule.

Objection to "Good Cause" Determination

The Agency has taken the position that pursuant to the Administrative Procedure Act (APA), notice and comment are not required prior to the issuance of a final rule because the Agency has found "notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." (5 U.S.C. 553(b)(B)).

The Agency is making it much more complicated and 'complex' than it needs to be. United States' hemp farmers found a way to do this during the 19th Century and during the "Hemp for Victory" program years during World War II without so much complexity that there is warranted an exception that would allow the Agency to impose the Interim Rule without prior notice and comment. Commenters disagree and object to the Agency's finding of Good Cause.

Commenters assert that it was arbitrary and capricious and for the Agency to simply dispense with the statutory requirements of public notice and comment and its actions in finding such 'Good Cause' to avoid public comment and impose the Interim Rule immediately violates applicable law.

Section 990.22(b)(3) - Prohibition on transfer or liens on licenses is burdensome - restricts capital raising and small business financing further hamstringing hemp companies/ producers

Section 990.22(b)(3) states "Licenses may not be sold, assigned, transferred, pledged, or otherwise disposed of, alienated or encumbered."

There is no reason to restrict the transfer or encumbering of a License keeping in mind that most federal licenses are transferable. If there is no problem transferring nuclear licenses then what is the problem transferring a hemp license?

If a hemp company is sold, then Section 990.22(b)(3) would cloud the sale. If a hemp company takes out a loan, and the bank desires collateral, the value of the license, or the need to transfer the license in connection with a foreclosure, is necessary in order to allow for the free flow of financial capital into and out of the hemp industry. Failure to allow for transfers or liens on licenses restricts the access to capital at the very time when the industry needs capital the most.

Combined with the overly restrictive regulations and increased risks described in this Comment, the Interim Rule may likely be a 'death blow' to the industry in direct contravention of the Congressional Intent in passing the Subtitle G.

FLG Comment re: Mid-Season Drop Dead Date: Distortion Caused by Drop Dead Date of October 31, 2020 Instead of December 31, 2020

After Oct. 31, 2020, all hemp producers in the U.S. must be licensed by the USDA or by a state or tribe administering a USDA-approved hemp production plan, including those who were producing under the 2014 pilot program. Any hemp harvested after Oct. 31, 2020, is subject to the sampling, testing and other requirements in the interim final rule published Oct. 31, 2019. The mid-season drop dead further increases risk to farmers and the industry.

Comment re: Unreasonable Search & Seizures

To the extent that the Interim Rule allows for 24/7 unannounced "inspection" by law enforcement, it violates the 4th Amendments prohibition against unreasonable search and seizure and gives law enforcement unfettered investigatory authority inconsistent with industrial hemp's removal from the CSA.

To be constitutional, any inspection must be "pursuant to a general inspection program based on reasonable legislative or administrative standards derived from neutral sources." *Marshall v. Barlow's, Inc.*, 436 U.S. 307, 320-21 (1978).

Use of TOTAL THC

Section 990.1 of the Hemp Regulations contains a definition of the word "Decarboxylated" as follows:

> *Decarboxylated.* The completion of the chemical reaction that converts THC-acid (THC-A) 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*. (Emphasis added.)

The foregoing definition does more than define a technical term used in Subtitle G.

It creates a ***new*** rule that is **not** contemplated by Subtitle G; namely, a rule that creates a new legal term "Decarboxylated Value" which is stated as being equal to a conversion formula of Delta-9 THC % + (0.877) x THC-A % to equal a "Total THC" as converted amount for purposes of comparing to the statutory legality threshold of 0.3% Delta-THC on a dry weight basis.

Here, the Agency makes up new law that is not supported by Subtitle G and is contrary to Congressional intent and contrary to the Congressional Policy in the AMA to avoid disruptions to the orderly market and flow of commodities such as hemp.

Testing Protocols Are Disruptive to Industry and May Be Punitive

Testing of hemp to determine compliance with the 0.3% THC limit should not be done post-decarboxylation. Doing so will make it significantly harder for hard-working hemp farmers to produce legal hemp.

The current testing requirements are already sufficient to ensure no psychoactive effects will be elicited from smoking the plant material. The current available genetics would make it incredibly difficult for farmers to comply with the regulations.

The timeline for testing should be amended. Farmers absolutely need a 30 day or more prior to harvest testing window, 15 days is not enough time to harvest.

Not a sufficient supply of DEA licensed labs to test the US hemp crop.

Conclusion

For all of the foregoing reasons, Commenters urge the Agency to not throw the baby out with the bathwater. The Interim Rule should be immediately modified to be effective only until December 31, 2020 with modifications to remove the problematic regulations.

Testing protocols, restrictions and the DEA licensing aspects of the Interim Rule should be removed as should all parts of the Interim Rule that are disruptive or distort the market for industrial hemp as a commodity.

The Agency should modify the Interim Rule as described in this Comment and as necessary to maintain orderly conditions for marketing industrial hemp as an agricultural commodity; to provide an orderly flow of the supply thereof and to avoid unreasonable fluctuations in supplies and prices; and to avoid a disruption of the orderly marketing of industrial hemp as a commodity.

FLG and the Commenters appreciate the opportunity to submit comments on the Interim Rule.