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January 28, 2020

Docket Clerk
Marketing Order and Agreement Division, Specialty Crops Program, AMS
United States Department of Agriculture
1400 Independence Avenue SW, STOP 0237
Washington, DC 20250-0237

Re: Docket ID No: AMS-SC-19-0042; SC19-990-2 IR; Establishment of a Domestic Hemp Production Program; Document Number: 2019-23749

To Whom It May Concern,

The New York Farm Bureau (NYFB), New York State's largest general farm organization, appreciates the opportunity to submit these comments to the U.S. Department of Agriculture (USDA) regarding its Interim Final Regulations on the Establishment of a Domestic Hemp Production Program (Interim Final Regulations), which were published in the Federal Register on October 31, 2019. The 2014 Farm Bill had allowed for the growing of hemp, but only as part of a research pilot program. These new regulations will allow for the expansion of hemp production, but some commonsense changes are needed to ensure practicality for farmers while also maintaining oversight by USDA.

NYFB represents farmers across New York State that produce diverse crops including fruits, vegetables, grain crops, and now hemp. New York farmers have begun to grow hemp on their farms under the research pilot program but need further guidance as they move to grow hemp under the 2018 Farm Bill. NYFB's members are involved in virtually every facet of agricultural production and are directly affected by USDA's policies with respect to regulations on planting, growing, and harvesting of hemp.

Hemp production has the potential to offer significant new economic opportunities for New York's agricultural industry. During a time when numerous farms struggle to remain successful in a global marketplace, many have turned to alternatives for diversification of crops and products produced on their farms. Hemp and its products could provide another commodity for agriculture to expand and produce which in turn; helps boost the economy of New York State as a whole.

In 2018, the NYS Department of Agriculture and Markets[1] had more than 100 new research partners, with approximately 3,500 acres of New York farmland approved for hemp research, compared to 2,000 acres in 2017.[2] Not only does this show the growing interest in hemp in New York State, it also highlights the need to have regulations in place that are practical and meet the needs of farmers.

[1] https://www.agriculture.ny.gov/PI/PIHome.html
[2] https://www.agriculture.ny.gov/AD/release.asp?ReleaseID=3920

Different research institutions including Cornell University[3], State University of New York-Morrisville[4], Binghamton University, and State University of New York-Sullivan, as well as the partner farmers they are working with, have been conducting research on hemp including optimal growing conditions, fertilizer applications, and pest pressures which have led to the development of standards and best management practices for growing hemp. To fully take advantage of these practices, it is critical that producers have clear and workable regulations to grow hemp.

Hemp has more than 25,000 possible uses that make it a central ingredient in an array of products from paper, textiles, building materials, foods, and animal bedding. Hemp has many different uses, and the major market for hemp is as a food or supplement as it is rich in protein and Omega fatty acids and has a high fiber content. The clothing industry also produces apparel and accessories from hemp and hemp blended fabrics. Hemp can also be used for building materials, plant-based plastics, and paper products.

The passage of the Agriculture Improvement Act of 2018 (2018 Farm Bill) removed hemp, defined therein as the plant *Cannabis sativa* L. and any part of that plant with a delta-9-tetrahydrocannabinol (THC) concentration of not more than 0.3% on a dry weight basis, from the Controlled Substances Act, 21 U.S.C. § 801, *et seq*, and in so doing, effectively transferred the authority to regulate hemp from the Department of Justice to other relevant administrative agencies, including the USDA. This shift has led to a significantly increased interest in hemp production generally. Recognizing this interest, NYFB's goals are to further development of this crop as an additional tool for farmers, assist interested members in entering the industry, and educate the consumer and regulators on hemp and its applications.

NYFB appreciates USDA issuing an Interim Final Rule that went into effect upon publication, so that regulations are in place for the 2020 growing season and beyond. While NYFB believes that the Interim Final Rule provides guidance on a number of issues and uncertainties that have plagued the industry since the passage of the Farm Bill, there are areas in which the regulations could be revised or expanded upon to further support the industry. With that in mind, the NYFB respectfully submits these comments on the Interim Final Rule.

I. Historical Context

To appreciate the significance of the Interim Final Rule to the industry, some historical context is helpful. Hemp was grown throughout the United States during the 1800s, and the widespread use of hemp continued into the 1900s.

However, the Marihuana Tax Act of 1937, Pub. L. 75–238, 50 Stat. 551, largely ended hemp's prosperity in the United States when all use of the *cannabis sativa* L. plant was subjected to substantial taxes in an effort to discourage its use. Although hemp made a comeback during World War II in the U.S. Government's "Hemp for Victory" campaign, the end of the war saw hemp production quietly shut down again. Finally, with the passage of the Controlled Substances Act in 1970, any vestiges of the hemp industry in the United States were quashed.

Hemp began to reemerge from its period of dormancy with the passage of the 2014 Farm Bill (Pub. L. No. 113-79, 128 Stat. 649). Congress explicitly authorized state departments of agriculture and

[3] https://sips.cals.cornell.edu/extension-outreach/industrial-hemp/
[4] https://www.morrisville.edu/cannabis

universities to establish programs for the in-state cultivation of hemp to study its growth, cultivation, or marketing. However, use of hemp was limited to "research," and also required the hemp cultivation be permitted under the law of the state where the research will take place.

The passage of the Agriculture Improvement Act of 2018 (2018 Farm Bill) removed hemp, defined therein as the plant *cannabis sativa* L. with a delta-9-tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis, from the Controlled Substances Act, creating a significant opportunity for the industry to make a long-awaited comeback. Interest in the hemp industry has grown exponentially, and this commodity has the potential to serve as a valuable addition to a New York farmer's operation.

II. Issues Raised by Interim Final Rule

a. THC Testing

The 2018 Farm Bill defines hemp as "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." H.R. Rep. No. 115-1072 § 7129, *citing* 7 U.S.C. § 1639o. However, the Interim Final Regulations require that hemp be tested not only for delta-9 tetrahydrocannabinol (delta-9 THC), but also for THC acid (THCA). This approach has the potential to artificially cause a "hot crop" outside the definition of hemp, risking crop destruction even as the delta-9 THC level, as defined in the 2018 Farm Bill, is below the 0.3% threshold.

The "Total THC" approach sums the delta-9-tetrahydrocannabinol acid (THC acid, or THCA) and delta-9-tetrahydrocannabinol (delta-9 THC) content. THCA is an acidic cannabinoid that does not contain psychoactive properties. Delta-9 THC is a neutral cannabinoid, meaning it possesses psychoactive properties. THCA can convert to delta-9 THC through the process of decarboxylation, which can occur through exposure to heat or sunlight.[5] A plant testing for 0.3% or less of delta-9 THC, but also with a certain concentration of THCA, could feasibly be altered, through decarboxylation, to have a higher THC content.

Specifically, while the 2018 Farm Bill calls for THC concentration to be measured "using post-decarboxylation," the statutory provisions also explicitly allow for "other similarly reliable methods." There are reliable methods in which THC can be measured independently, including high-performance liquid chromatography. In requiring THCA to be measured, USDA has gone beyond what is statutorily required.

Many states, including New York State, with preexisting hemp regulations under the 2014 Farm Bill do not comply with the new Total THC testing standards. Despite the USDA's intention of providing clarity and standardization in testing methodologies, the reality of the Total THC approach creates further confusion and vulnerability for hemp farmers, which are currently complying with the 2014 Farm Bill's Hemp Research and Pilot Programs and within the 2018 Farm Bill's statutory requirement for testing delta-9 THC.

[5] The Interim Final Rule defines "decarboxylation" as "[t]he removal or elimination of carboxyl group from a molecule or organic compound." 7 C.F.R. § 990.1.

Additionally, the USDA Interim Final Rule requires testing for only a portion of the plant—the flower—which happens to be the portion with highest THC content, even though farmers harvest and process the entire plant. This means that the USDA tests prepare for a worst-case scenario of THC testing. THC levels fluctuate over time based on plant stressors and other factors. Without testing the entirety of the plant and requiring farmers to account for more than the statutorily required delta-9 THC levels, the Interim Final Rule requires hemp farmers to answer to the highest possible level of THC from a plant without ability to dilute THC after harvest or salvage crops. NYFB supports the required testing of a plant to include the flower, leaf, and stem from parts of the entire plant in equal proportion, as opposed to only the top third of the plant.

NYFB is sympathetic to the concerns of law enforcement. Accordingly, NYFB supports and understands the need to define a threshold level of THC to distinguish between legitimate hemp crops and marijuana. However, NYFB believes that a "Total THC" threshold of 0.3% will deter farmers growing hemp for use in CBD products from entering the market. NYFB supports hemp THC levels up to 1%, but also realizes a statutory change must happen in order to change the THC threshold.

The Interim Final Rule also does not afford any provisions for growers to salvage crops and allows only limited circumstances for retesting where crops exceed the established 0.3% THC threshold. This is a significant issue because crop insurance does not provide protections in these circumstances. The Interim Final Rule allows producers operating under USDA's hemp plan to request that their samples be retested "if it is believed the original delta-9 tetrahydrocannabinol concentration level test results were in error." 7 C.F.R. § 990.26(f). As a starting place, the USDA should consider requiring state plans to include corresponding provisions for retests. Further, NYFB encourages the USDA to consider adopting provisions that would enable farmers to salvage crops which a) do not exceed the established 0.3% THC threshold upon retest, and b) develop approaches for farmers to find economic use of crops that exceed the 0.3% THC threshold, such as requiring deconstruction of the flowers but allowing the rest of the plant to be used for fiber.

Finally, NYFB supports that the Interim Final Rule defines the "acceptable hemp THC level" as "the application of measurement of uncertainty to the reported delta-9 tetrahydrocannabinol content concentration level on a dry weight basis produces a distribution or range that includes 0.3% or less." The measurement of uncertainty helps to address the inherent statistical uncertainty that occurs in the testing process. This flexibility should be retained in the Final Rule. NYFB would request greater flexibility for the farmer through allowance of a "hot" crop to be utilized on the farm as a soil amendment or animal bedding.

b. **Safe Harbor Provision**

NYFB appreciates that the Interim Final Rule attempts to protect farmers from prosecution through inclusion of a "safe harbor" provision. Specifically, the Rule specifies that hemp producers do not commit a negligent violation if they produce plants that exceed the

acceptable hemp THC level and use reasonable efforts to grow hemp and the plant does not have a THC concentration of more than 0.5% on a dry weight basis.[6]

The USDA should work with the Department of Justice, DEA, and other agencies to come up with cohesive guidance and information regarding enforcement against hemp growers.

c. **15-Day Sampling Requirement**

The Interim Final Rule requires that samples for testing of hemp for THC concentration levels be collected within fifteen days of the anticipated date of harvest. The regulations go on to specify that state hemp programs must prohibit hemp farmers from harvesting their crop until the samples have been taken.

Given the reality of time and labor commitments for harvesting, the 15-day sampling requirement specified under the USDA's Interim Final Rule is unrealistic for hemp producers. To sample and harvest an entire crop within a 15-day period requires major financial investment with no guarantee of completed testing, placing hemp growers in a vulnerable position. In addition, the 15-day timeline also places additional burdens on the state regulating agencies that are tasked with sampling and testing hemp crops. If hemp crops approach harvest at the same time across the state, this put increased pressure on the state agencies and staff to complete testing in a timely manner which may not be achievable.

Because testing may not be completed within the 15-day timeline, hemp growers may harvest and prepare an entire crop that tests above the THC threshold and is, by definition, marijuana, which then must be destroyed. Additionally, if farmers wait on the testing to be completed and ensure that the crop tests at or below the acceptable THC level, they may be required to harvest their crop on an even shorter timeline than 15 days. This could require hiring extra laborers or purchasing of extra equipment.

This past year represented the one of the wettest years in history for many farmers across New York which prevented them from planting due to heavy rainfall. The same scenario is possible in the future for hemp. Farmers who are unable to complete harvest in a timely manner due to weather factors should not be punitively penalized. USDA should allow for a longer harvest period or waivers on a case by case basis in the case of adverse weather.

NYFB appreciates that the 15-day requirement attempts to provide clarity in testing and ensure that the hemp crop tested and the crop that is harvested are at the same THC level. But in reality, this creates extra hurdles and impacts the profits and bottom line for hemp farmers. The USDA should revisit this requirement in order to balance between testing at a standard to obtain adequate validation of THC levels and placing an unfair and expensive burden on farmers. Farm Bureau supports extending this 15-day requirement to testing the crop 45 days before harvest.

d. **Transportation**

[6] 7 C.F.R. § 990.29(c)

The Interim Final Rule states that "[n]o state or Indian Tribe may prohibit the transportation or shipment of hemp or hemp products lawfully produced…through the State or territory of the Indian Tribe".[7] However, as noted in two recent state court actions, Idaho and South Dakota have taken the position that they are able to interdict hemp travelling through their borders. *See Big Sky Scientific LLC v. Idaho State Police*, Case No. 19-CV-00040 (D. Idaho Feb. 2, 2019).

The uncertainty and need to litigate these cases could result in prosecution for drivers and the spoiling of hemp or hemp products as it is held up by state law enforcement. NYFB encourages the USDA to collaborate with the Department of Transportation, the Department of Justice, DEA, and states to develop a uniform and consistent approach to regulation of interstate hemp transportation.

e. **DEA Testing Lab Requirements**

USDA's interim regulations require that "testing is completed by a DEA-registered laboratory using a reliable methodology for testing the THC level." The DEA, through its website and other published material, does not specify locations for DEA-registered laboratories. The only available description of these laboratories provided by DEA notes that they are primarily located in states where marijuana is legal. Subsequent to USDA releasing the Interim Final Rule, USDA has added to its website a list of hemp testing laboratories who are registered with the DEA.[8]

As of January 27, this list shows that there are only 44 laboratories in 22 states. Having only 44 laboratories to service hundreds of hemp farmers will inevitably lead to testing delays and backlogs. New York State currently only has one DEA-certified lab, which is located in Suffolk County on Long Island, which is hundreds of miles away from many New York farmers who need to test their hemp crops. In addition, there is no indication by these labs that they have the manpower or interest in providing testing services. Traveling this distance to get their crops tested is not only time consuming but overly burdensome for farmers. Moreover, given the lack of an acceptable laboratory for testing THC levels in hemp in every state, hemp growers may be required to transport or ship untested samples of hemp plants across state lines to comply with USDA regulations. Of the six states that border New York (Connecticut, Massachusetts, New Jersey, Pennsylvania, Rhode Island, and Vermont), there are only two additional labs, one in New Jersey and one in Pennsylvania. Again, both of these labs are not within a close driving distance and involve crossing state lines with untested hemp.

In the process of transporting hemp samples to be tested, hemp farmers run the risk of sending hemp plants that contain or may test above 0.3% THC by dry weight, and therefore will have shipped marijuana across state lines. So, to comply with USDA's regulations, hemp producers may actually provide evidence to the DEA that they have committed a federal crime—transporting a controlled substance across state lines—and be at risk of prosecution.

[7] 7 C.F.R. § 990.63

[8] Hemp Analytical Testing Laboratories, USDA (Jan. 27, 2020), https://www.ams.usda.gov/rules-regulations/hemp/dea-laboratories.

In many states where hemp programs are in place under the 2014 Farm Bill, the states have required testing to be done by private labs with private certification, including ISO 17025 accreditation. ISO 17025 accrediting requires third-party assessors to evaluate the laboratory and its ability to produce precise, accurate test and calibration data. To maintain this accreditation, laboratories must be regularly reassessed to ensure that technical expertise is maintained.

Additionally, the regulations require laboratories to meet the AOAC International standard method performance requirements for selecting an appropriate method. With multiple methods meeting these requirements, and numerous other methods available that have managed to successfully test THC limits, the USDA should open testing requirements beyond just DEA laboratories. Limiting laboratories to only one form of registration will severely limit the availability and processing time for testing. NYFB requests that the USDA allow testing to take place in private labs, with third-party accreditation, such as ISO 17025, which ensures accuracy and technical expertise, to minimize the undue delay, burden, and cost on hemp cultivators.

In addition, NYFB recommends that USDA work with DEA to provide guidance on how a lab might become DEA-registered and provide farmers with strong assurances that DEA will expedite this process and ensure that an adequate fleet of labs are available for the 2020 season.

f. **Seed Certification**

USDA's final regulations omit a federal seed certification program. Under the 2014 Farm Bill's Hemp Research and Pilot Program, various States developed seed certification programs to help producers identify hemp seed that would work well in their specific geographical areas. USDA's choice not to include a federal seed certification program means that individual cultivators remain liable to the 0.3% delta-9 THC standard. A federal seed certification would be the best approach to support the industry, by providing clarity both to hemp farmers and seed cultivators. Without such a program, farmers risk investing in seed that produce plants that do not qualify as hemp under the THC standard.

The reasoning USDA gave for this omission was that the same seeds grown in different geographical locations and growing conditions can react differently. For example, the same seed used in one State to produce hemp plants with THC concentrations less than 0.3%, can produce hemp plants with THC concentrations of more than 0.3% when planted in a different State. USDA also noted that they have found the technology necessary to determine seed planting results in different locations is not advanced enough. While these issues are valid, the NYFB urges USDA to develop a federal seed certification program.

g. **Disposal**

For disposal of non-compliant crops, the Interim Final Rule requires that the DEA or another entity authorized to handle marijuana under the Controlled Substances Act will dictate the process for disposal. This will likely create unnecessary and costly burdens on both the farmers and the states and tribes managing hemp programs. Allowing simpler, more time

and cost-effective methods for disposal overseen by state agriculture departments and law enforcement agents would provide greater flexibility and minimize burdens on the regulators and farming community. Additionally, rather than dispose of 100% of a hot crop, NYFB supports alternative uses of a product that has tested in excess of the established 0.3% threshold so that a producer does not lose 100% of the significant investment incurred in planting and growing a hemp crop. These alternative uses could include fuel, textiles, fiber and building material products.

III. Interagency Cooperation

The Interim Final Regulations do not address the use of hemp products and CBD products as the 2018 Farm Bill preserved the authority of the U.S. Food and Drug Administration (FDA), which NYFB supports this authority but encourages USDA to work with FDA to develop scientifically-based regulations and guidance for consumable hemp products. The CBD market is the biggest market for hemp and without regulations from FDA, there is a potential to curtail hemp production and farmers' investment.

IV. Conclusion

NYFB appreciates the USDA's efforts to provide clarity and fill in regulatory gaps through promulgation of the interim regulations. NYFB supports the USDA's efforts to create an established domestic hemp production program that benefits New York farmers and others with an interest in the hemp industry. Thank you for your consideration of these comments.

Sincerely,

David Fisher
President, New York Farm Bureau