





January 29, 2020

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

Re: State of Colorado Comments in Response to USDA Establishment of a Domestic Hemp Production Program, Interim Final Rule (IFR), Doc. No. AMS-SC-19-0042/SC19-990-2IR, published at 84 FED. REG. 58522 (Oct. 31, 2019).

Ladies & Gentlemen:

The State of Colorado thanks the United States Department of Agriculture (**USDA**), the Department of Justice (**DOJ**), and the Drug Enforcement Agency (**DEA**) for their efforts to advance the first national industrial hemp (**industrial hemp** or **hemp**) regulatory framework in generations and for the opportunity to comment on the IFR. Colorado has operated a robust and highly successful industrial hemp program for the past five years under the regulatory system enabled by the Agricultural Act of 2014 (the **2014 Farm Bill**). As an early mover state in hemp, we understand the pivotal role a workable regulatory structure plays in allowing a new industry to flourish and we appreciate the hard work your staff has undertaken to construct a framework for states to operate their own hemp programs.

However, the State of Colorado has identified key issues in the IFR that require significant modification. The State of Colorado therefore submits the following comments to improve the proposed regulatory system for hemp under the Agriculture Improvement Act of 2018 (the **2018 Farm Bill**). In particular, and as the nation's leading hemp-producing state, Colorado has identified the following critical and important IFR improvements that will allow our state and the national hemp industry to expand and thrive:

- Sampling Periods and Coverage;
- Lab Certification Requirements;

- Thresholds for Destruction and Negligence;
- Innovation;
- Disposal Protocols;
- Application Periods;
- Systemic Small/Disadvantaged Farmer Bias; and
- Banking and Insurance.

We understand that establishing a regulatory framework is a difficult task and we appreciate your willingness to consider the alternative approaches to regulating hemp as well as the legal issues set forth in this document.

As a background, Colorado was one of the first states to implement a hemp program, which has expanded to over 87,000 registered acres in 2019, with 5,539 unique registrations 2014-2019. We are confident Colorado can provide a unique and successful perspective on developing a regulatory environment that allows the industry to flourish.

To address requirements set forth in the 2018 Farm Bill and the IFR, the Colorado Department of Agriculture (**CDA**) partnered with leading state, local, and tribal agencies, as well as industry experts in cultivation, testing, research, manufacturing, banking, and marketing to establish a statewide initiative known as the Colorado Hemp Advancement and Management Plan (**CHAMP**). Through the CHAMP Initiative, about 150 stakeholders gathered for a public meeting on December 10, 2019, to share reactions and comments on the IFR. This meeting included hemp industry representatives, farmers, universities, local and state government agencies, law enforcement, and farming associations. Our comments and recommendations reflect the overarching themes expressed by these Colorado stakeholders. Moreover, our comments aim to make the IFR more workable, producer-friendly, and better-suited to address the needs of this nascent industry.

We have seen the emergence of a robust industrial hemp industry located throughout Colorado, including processing and manufacturing facilities, because our regulatory approach balances strict oversight with sensible economic and market considerations. We are enthusiastic about promoting the economic potential of this newly legal crop in both urban and rural communities. To ensure continued growth, it is critical that the IFR establishes a workable regulatory framework that allows farmers and other stakeholders to succeed. While the IFR provides a starting place for such a regulatory framework, several provisions are unnecessary, burdensome, and may potentially have a devastating impact on the Colorado hemp industry.

Importantly, the IFR does not recognize instability in hemp genetics and significant trait variations, including Δ -9 tetrahydrocannabinol (**THC**) concentrations. Despite such trait variations, the IFR includes rigid requirements for THC compliance, with steep penalties for growing noncompliant hemp, including crop destruction. The negative effects of regulatory incongruence in the IFR disproportionately affect farmers—especially new farmers and smaller farming operations. It is farmers whose investment is at risk, farmers who will be fined, farmers who may be criminally liable, and farmers who will pay the ultimate cost of propelling hemp genetics to stability.

Colorado's comments are intended to protect: (1) the significant investment our citizens and businesses have already made in hemp cultivation and laboratory operations; (2) our government and taxpayer investment in a well-serving regulatory system; and (3) our smaller or otherwise disadvantaged hemp farmers who will face additional risks if the IFR is implemented as written. The following comments set forth our key concerns and proposed amendments to the IFR.

Sincerely Yours,

Jared Polis Philip J. Weiser Governor Attorney General

Kate Greenberg Commissioner of Agriculture

Key Policy Concerns Presented by the IFR

The IFR creates a national commercial hemp program that unnecessarily limits established state and tribal hemp programs.¹ We urge the USDA to amend the IFR to reflect the comments set forth below.

1. Sampling Period and Coverage

The combination of a 15-day sampling period before harvest and 100 percent testing of registered lots will cause significant peak-demand concerns for governmental and government-certified resources.² We also note that the IFR prohibits harvesting hemp prior to receipt of official THC results.³ This proposal is unworkable for the CDA and Colorado farmers. In 2019, CDA sampled 23 percent (619) of all registered lots (2,712) within a 30-day window available to producers between sampling and harvesting. Under IFR requirements, Colorado will need to collect more than four times as many samples as were collected in 2019, but in half of the time. Hemp is primarily harvested in September and October in Colorado, and such a system would require over 100 sample collections and tests per working day based on figures from the 2019 growing season.⁴

Meeting the arbitrary sampling and harvesting deadlines in the IFR will require an extraordinary and impracticable level of effort and coordination to notify producers, schedule inspection dates, dispatch assignments to inspectors, collect and transport samples to labs, test samples, and issue a notice informing the outcome of the test result to the grower. As a result, Colorado, along with other states with large existing hemp industries, will need to substantially increase its field inspector workforce and resource allocations, and/or develop certified third-party sampling programs in an unrealistically short period of time. Colorado will likely elect to develop and administer a third-party sample collector certification program to meet this requirement, an issue further compounded by the need to work with

¹ Comments of the Montana Dep't of Agriculture dated Jan. 9, 2020, p. 1 (Montana Comment).

² See 7 C.F.R. §990.3(a)(2)(i) at IFR p.58556; 7 C.F.R. §990.3(a)(2) at IFR p.58556; see also Comments of Duckwater Shoshone Tribe dated Dec. 17, 2019, p. 5 (Duckwater Shoshone Comment); Comments of the Kansas Dep't of Agriculture dated Jan. 10, 2020, p. 2 (KDA Comment) (suggesting that "harvest be completed within a finite time frame following the issuance of a passing report of analysis to the licensee"); Comments of Senators Ron Wyden and Jeffrey Merkley dated Nov. 20, 2019, p. 1 (Wyden/Merkley Comment).

³ 7 C.F.R. §990.3(a)(2)(v) at IFR p.58556.

⁴ See also Montana Comment, p. 2-3 (noting variations in harvest seasons based on geography).

DEA-registered labs, which are notably limited in number, geographic availability, and ability to perform the large-scale services required of them under the IFR.⁵

If the IFR prevents producers from harvesting crops before receipt of a certified and compliant test result, it will create a bottleneck that could result in crop loss due to common environmental factors, such as early snow or frost or increasing THC expression at hemp maturity, without providing for the corresponding crop insurance protections. Yet, the IFR omits a remedy for farmers when labs cannot quickly and efficiently dispatch inspectors, collect samples, and process testing results. Simply put, farmers will face a significant risk of crop loss based not on their own planning and performance, but rather on the performance of the sampling and testing infrastructure, weather, and other environmental factors. The risk burden will be especially high for farmers in mountain and rural locations where sampling agents and testing facilities are not easily accessible and for farmers will be forced to pay for the production and destruction of crops that cannot be sold, creating a compounding punitive effect.

Weather in Colorado varies from season to season, which poses an issue for farmers who are harvesting hemp. In 2019, Colorado received an unusually early snowfall and a hard freeze on October 10, requiring many farmers to rush into harvest to save as much of their crop as possible. Those farmers would have been in direct violation of the IFR if they had been awaiting official test results. Farmers should not be forced to break the rules to save their crops and make a living. The first freeze date can vary from late August to early November in Colorado, depending on location and elevation.⁷ The IFR must consider the unique weather pattern in Colorado (and other states) that could prove to be devastating for our nations' hemp farmers and manufacturers.

Finally, the short 15-day window is incompatible with a common two-phase harvest technique where farmers first harvest the seeds and flower and then harvest the stalks of the hemp plant. This harvesting technique would require clarification on whether the "harvest date" is the date harvest begins or the date it ends. In light of the foregoing, the IFR's requirements for an unreasonably limited sampling period are arbitrary and capricious, and therefore violate the federal Administrative Procedure Act (**APA**).⁸

⁵ At present, only one DEA-certified lab appears on the USDA hemp lab directory page <u>https://www.ams.usda.gov/rules-regulations/hemp/dea-laboratories?field_state_tid=168</u>.

⁶ See Item 9, *infra*, regarding banking, financial services, and insurance.

⁷ The Old Farmer's Almanac, <u>https://www.almanac.com/gardening/frostdates/CO.</u>

⁸ 5 U.S.C. § 706(2)(A); see also *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 43 (1983) (holding that an agency's rulemaking is arbitrary and capricious, and therefore in violation of the APA, if

Recommendation: Allow 30 days between sampling and harvest.

We recommend for USDA to modify the IFR to allow for a 30-day period between sampling and harvest. This recommended 30-day period will decrease risk for farmers, samplers, testing labs, and CDA. Colorado currently provides producers with a 30-day window between identifying their planned harvest date(s) to CDA and their actual harvest date(s). During this 30-day period, CDA collects samples, transports samples to the lab, performs testing, and informs the grower of the THC test result. This 30-day period allows for much greater flexibility for CDA or certified entities to schedule sample collection and for producers to complete their harvest given unforeseeable environmental variables. CDA and hemp stakeholders favor this policy because it increases farmer compliance as well as accountability and quality of the program.⁹ The IFR requirement to test 100 percent of hemp lots within a 15-day period of harvest is simply unworkable and will cause increased costs, bottlenecks, and significant operational challenges given the current and expected scale of Colorado's hemp acreage.¹⁰

the agency fails to "examine relevant data," "consider an important aspect of the problem," or "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made").

⁹ Comments of Pala Band of Mission Indians dated Dec. 17, 2019, p. 1 (Pala Band Comment); Comment of Seminole Tribe of Florida dated Dec. 26, 2019, p.5 (Seminole Comment); see Comments of the California Farm Bureau Federation dated Jan. 17, 2020, p. 2 (Cal. Farm Bureau Comment); Comments of the South Carolina Department of Agriculture dated Dec. 20, 2019, p. 2 (SC Comment); Comments of the South Carolina Farm Bureau Federation dated Dec. 9, 2019, p. 1 (SCFB Comment); Comments of Butler Snow dated Dec. 23, 2019, p. 3 (Butler Snow Comment); Comments of Minnesota Department of Agriculture dated Jan. 2, 2020, p. 1, 4 (Minnesota Comment). We hereby incorporate the Minnesota Comment by this reference.

¹⁰ SC Comment, p. 2; see Comments of Dr. David Suchoff, N.C. State University, dated Dec. 27, 2019, p. 2 (Suchoff Comment) (noting that inclement weather may require earlier harvests in order to avoid crop destruction).

2. DEA Lab Certification Requirements

The IFR requires all THC testing to be performed and certified by DEA-registered laboratories.¹¹ As indicated above, this requirement at a minimum will significantly exacerbate existing testing bottlenecks. In 2019, the average testing turnaround period was eleven days at the CDA testing facility. This timeframe already presents compliance challenges if CDA were permitted to continue sampling and testing 23 percent of all registered lots (619 samples tested) as it completed last year. However, meeting the IFR's timeframe and the 100 percent testing requirement is untenable with CDA's current sampling and testing infrastructure. If testing requirements are increased to 100 percent of all registered lots (2,712 registered lots in 2019), CDA expects turnaround times to increase significantly, putting crops at risk as producers await test results prior to harvest. Further, a scarcity of qualified testing facilities will also likely drive up testing prices and transportation costs for producers, placing even more risk on the most vulnerable actors in the commercial hemp supply chain.¹² Officials from the Governor's Office and CDA met with the executives of Colorado's only known DEA certified lab, who noted that any state or tribal certified THC test lab should be permitted to test hemp as a part of this program because these labs have robust experience handling cannabis and administering THC potency tests.¹³

The requirement for DEA-registered labs overlooks the extensive investment and experience in THC testing facilities in jurisdictions with state-legalized cannabis like Colorado. Colorado currently has 13 THC testing facilities that are certified through a state program administered by the Colorado Department of Revenue (**DOR**) in consultation with the Colorado Department of Public Health and Environment (**CDPHE**). Under the program, all eligible testing facilities must be ISO 17025-certified (something USDA is explicitly seeking comment on)¹⁴, and controlling owners and all staff involved with cannabis must undergo background investigations. CDPHE also has established and documented requirements regarding inspections, regulatory and legal compliance, compliant analytical methods, and quality assurance.

At first glance, one might suggest that our established THC testing facilities should simply apply for DEA registration. However, as has been experienced by at least one of our state-certified labs, the DEA is reluctant to visit a state-certified testing laboratory that possesses non-hemp cannabis, much less grant

¹¹ 7 C.F.R. §990.3(a)(3)(i) at IFR p.58557. Seminole Comment, p.2 (noting the IFR requires use of DEA-approved labs, but the 2018 Farm Bill does not).

¹² See, e.g., Comments of the State of New Mexico dated. Jan. 16, 2010, p. 2, 4-5 (NM Comment).

 ¹³ Personal communication with Seth Wong, President, The Industrial Laboratories Company, Inc., January 22, 2020.

¹⁴ IFR pp. 58525 & 58529; see also 7 C.F.R. §990.3(a)(2)(v) at IFR p. 58557.

them registration. The CDA lab currently tests legal marijuana so it is questionable whether the state's own lab can be certified by the DEA. Such limitations unnecessarily exclude the most qualified laboratory operators in our state with specific expertise in plant THC content analysis from serving the commercial hemp industry.

Our existing certification program for laboratories is very similar in nature to the USDA's proposed Laboratory Approval Program described in the IFR.¹⁵ The state program ensures that only qualified laboratories that practice good laboratory procedure, have rigorous quality assurance and control protocol, and use only established methods performed on accepted equipment are able to acquire certification to participate in the program. The state performs regular on-site audits of labs in the program and administers a fee for participation.

CDA and Colorado hemp producers simply will not be able to comply with this requirement if a significant number of labs are unable to gain DEA certification or if the IFR does not permit testing of both marijuana and hemp at the same THC-testing labs.

Recommendation: Allow Use of State or Tribally Certified labs.

Considering that many jurisdictions have a limited number of DEA-registered labs, we encourage USDA to remove the requirement for DEA registration of THC testing laboratories and allow states and tribes the flexibility to develop their own programs to certify labs that are qualified to provide THC testing services to the commercial hemp industry.¹⁶ This is particularly important in jurisdictions that have legal cannabis and established certified laboratory programs. These programs can (and likely already do) follow the USDA's Laboratory Approval Program and DEA requirements for ISO 17025 and other technical requirements.

Such flexibility will allow state and tribal authorities to develop THC testing programs and facilities that most effectively and efficiently serve their industries, while maintaining the level of quality and reliability required by federal regulations.¹⁷ As an alternative, we suggest that the IFR language be changed to allow THC labs to request a written waiver from the DEA based on the marijuana testing activities the labs perform.

¹⁵ IFR p. 58525.

¹⁶ See Cal. Farm Bureau Comment, p. 2; Pala Band Comment, p. 1; Wyden/Merkley Comment, p. 1; SC Comment, p. 1-2; NM Comment, p. 4-5; SCFB Comment, p. 2, ¶ 5; Butler Snow Comment, p. 3.

¹⁷ See also Minnesota Comment, p. 2 (noting that the 2018 Farm Bill does not require sampling of all lots).

3. 0.3 Percent THC Threshold for Destruction

The IFR requires that all hemp crops testing over the "acceptable THC level" (0.3 percent), after accounting for a margin of uncertainty, must be destroyed.¹⁸ Following this directive in the IFR, the 2014 Farm Bill, and the 2018 Farm Bill, the State of Colorado has overseen the destruction of over 3,360 acres of hemp worth roughly \$115 million since 2014.¹⁹ Instead of sacrificing this investment, hemp testing above 0.3 percent for THC could be retained and put to productive use in the supply chain while still protecting public safety through simple policy changes. These policy changes will preserve value, increase returns, and protect jobs.

Colorado recommends several potential alternative policies that can retain value in the supply chain, including: (1) allowing post-harvest THC testing; (2) allowing hemp that tests over 0.3 percent THC into a separate industrial supply chain for non-consumable uses; (3) allowing THC remediation and destruction via processing; and (4) increasing the allowable THC amount in hemp to 1.0 percent. Avoiding needless destruction of valuable crop commodities is critically important to the survival of the hemp industry. Fortunately, there are several viable options to recapture this lost value in the industrial supply chain or through chemical remediation processes.

In 2019 alone, had the IFR requirements been implemented, crops on over 4,400 acres in Colorado would have been required to be destroyed at a value in excess of \$154 million. The Colorado hemp industry cannot sustain such losses. Moreover, much of this hemp tested between 0.3 percent and 1.0 percent THC, which indicates no intent by the producer to grow THC-heavy, psychoactive cannabis. Figure 1 below displays hemp test results in Colorado and associated acreage. If the rule were changed to allow hemp testing between 0.3 percent and 1 percent into the supply chain, only 289 acres would face destruction and total value loss. This policy change would preserve \$145 million in farmgate economic value.

¹⁸ 7 C.F.R. §990.3(a)(3)(i) at IFR p.58557; 7 C.F.R. § 990.27(a) at IFR p.58560-61; *see* Suchoff Comment, at p. 1-2 (noting that 0.3 percent was selected in an arbitrary manner); Butler Snow Comment, p. 2 (noting that the IFR diverges from the definition of hemp set forth in the 2018 Farm Bill and thus does not comply with the law).

¹⁹ See appendix for value calculation description.

Figure 1.		2019 Colorado Data		Scaled to 100% Sampling Coverage	
THC Test Results, Acreage and Value, 2019 and Scaled IFR	2019 THC		Total Economic		Total Economic
Projection	Test Results*	Acres**	Value	Acres**	Value
	<= 0.3	11,800	\$405,340,908	64,568	\$2,216,800,780
Note: * Figures are cumulative over 0.3%, i.e.,	> 0.3%	4,491	154,388,298	24,529	842,640,594
greater than 0.3% includes all acreage greater than 0.3%.	> 0.4%	2,654	91,192,443	14,492	497,610,333
** Includes indoor cultivation reported as	> 0.5%	1,560	53,562,013	8,512	292,205,585
square footage converted to acreage. Source: CDA; MPG Consulting LLC.	> 1.0%	289	9,943,681	1,579	54,239,600

If Colorado scales testing to cover 100 percent of hemp lots, CDA expects these figures to increase exponentially, as shown in the table above. If sampling and testing coverage is scaled to full coverage and the noncompliant rate remains the same as 2019 (17 percent), then we expect approximately 24,500 acres to face destruction—a farmgate value of \$842.6 million. Secondary economic effects are substantial in an industry-leading hemp state like Colorado where many processors and manufacturers are located. We currently estimate the total lost economic output associated with potential destruction to be approximately \$1.2 billion.²⁰ If the IFR permits producers to keep hemp between 0.3 percent and 1 percent in the supply chain, about \$789 million in direct farmgate value and \$1.1 billion in total economic output would be preserved. The appendix provides further details on this analysis. In short, the State of Colorado cannot express strongly enough the need to consider alternative use methods for cultivated hemp that tests in excess of 0.3 percent THC.

Colorado understands the need to protect against bad actors that may use a hemp license as cover to illegally grow and distribute high-THC cannabis. It would take a brash actor to pay the cost and go through the process of establishing a licensed hemp cultivation facility, only to engage in illicit marijuana cultivation. We have not identified a single prosecuted case of this type of fraudulent activity in Colorado since 2014. We understand that this may not be the case for all states or tribes (although an increasing number of states and tribes are legalizing various forms and uses of cannabis). However, in

²⁰ This calculation provides a quantification of the economic activity in downstream processing and sales functions that would be affected by destruction using RIMS II input/output multipliers obtained from the US Bureau of Economic Analysis. <u>https://apps.bea.gov/regional/rims/rimsii/</u>. A state-level Colorado proxy industry multiplier (1.0346, oilseed and grain farming, indirect/induced only) is used because hemp-specific multipliers are not available. Secondary impacts are calculated on lost potential sales revenue only (\$14,063/ac.) not total economic value. These figures are conservative because of the heavy concentration of hemp processing and manufacturing operations in Colorado.

Colorado, the IFR destruction threshold of 0.3 percent will effectively remove 24,000 acres of valuable hemp from the market that could be used for industrial applications.

The risk associated with this policy accrues solely to the farmer and not others in the supply chain. To take a broader perspective, it is the manufacturer and processor that must manage the THC levels of end-use products—the farmer is just a supplier of raw material. Only the farmer risks economic loss before there is an opportunity to effectively manage end-product THC content via extraction or dilution. THC compliance should and can be managed directly at the processor and manufacturer level of the supply chain. The state, of course, will maintain its ability to test crops to ensure there are no farmers willfully engaging in illegal activities.

There are several federal publications that provide unclear direction regarding THC levels at one percent. A Congressional Research Services paper has acknowledged that "[a] level of about 1% THC is considered the threshold for cannabis to have a psychotropic effect or an intoxicating potential."²¹ A DEA publication that provides guidance on determining marijuana from hemp indicates THC tests are inconclusive if below one percent, raising the question of whether the IFR is in conflict with DEA procedures.²² A final document shows the DEA lacking jurisdiction over hemp seeds and stalks, which contain just trace amounts of THC.²³ These documents relate to the following recommendations. The USDA can implement any of these recommendations to reduce the amount of hemp that would be destroyed under the current IFR requirements.

<u>Recommendation A: Allow harvest of crops between 0.3 percent and 1 percent THC contingent on</u> <u>entering a post-harvest testing protocol.</u>

In the event that pre-harvest testing indicates a level greater than 0.3 percent THC, the crop should not be allowed to be consumed or enter the stream of commerce unless post-harvest sampling and testing of the noncompliant lot by a CDA authorized agent reveals a content of 0.3 percent THC or

²¹ Cong. Res. Serv., *Defining Hemp: A Fact Sheet*, p. 3; <u>https://fas.org/sgp/crs/misc/R44742.pdf</u>.

²² DEA Analysis of Drugs Manual, p. 304 & p.309, <u>https://www.dea.gov/sites/default/files/2019-10/Forensics/ADM%20R4%202019 Public%20Posting Final2.pdf</u>.

²³ 21 U.S.C. § 802 (16)(B)(ii) ("The term "marihuana" does not include...the mature stalks of [hemp], fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination."), available at https://www.deadiversion.usdoj.gov/21cfr/21usc/802.htm.

less. Our experience is that the harvested and homogenized raw material tests at a significantly lower rate of THC than just the flower material. Sampling the entire harvested crop is also more representative of what enters the market for processing and ensures the lot is legal hemp. What's more, such an approach would reflect the exclusions set forth in 21 C.F.R. § 1308.35 that exempt certain hemp-related materials from the ambit of the Controlled Substances Act (**CSA**) and DEA jurisdiction.²⁴

<u>Recommendation B: Allow hemp testing between 0.3 percent and 1.0 percent THC to enter the</u> <u>industrial (non-consumable) supply chain.</u>

In the event that pre-harvest testing indicates a level greater than 0.3 percent THC, the crop will not be allowed to be consumed but may enter the stream of commerce for industrial uses only, including plastics, textiles, building materials, or other uses that do not allow for extraction or human or animal consumption. In this case, material transferred to a processor must be approved prior to leaving the registered land area and must be verified by CDA or CDPHE. Further, such an approach recognizes existing DEA exemptions for certain cannabis plant materials and related products within the CSA.²⁵

<u>Recommendation C: Allow hemp tested between 0.3 percent and 1.0 percent THC to enter a</u> remediation program where THC is extracted and disposed.

This recommendation would allow states and tribes to administer a remediation program for hemp with noncompliant levels of THC, where THC would be isolated and extracted through a chemical process for disposal. A state- or tribally-regulated THC remediation program could include specifically licensed processors. Producers that grow noncompliant hemp would be required to sell into the remediation program at below-market rates. Producers that grow hemp that must enter the remediation program on a repeated basis would be subject to penalty. Proceeds from the remediation program would be dedicated to social equity programs, workforce development, or other public programs.

²⁴ See Suchoff Comment, supra, at p. 2 (suggesting that the threshold should be increased to 1.0 percent); Montana Comment, supra, at p. 2.

²⁵ See 21 C.F.R. § 1208.35; see also Daniel Shortt, DEA Confirms It Cannot Regulate All Parts of the Cannabis Plant, CANNA LAW BLOG, May 29, 2018, <u>https://www.cannalawblog.com/dea-confirms-its-cannot-regulate-all-parts-of-the-cannabis-plant/</u>.

Recommendation D: Work with Congress to raise the allowable THC limit to 1 percent.

The USDA should work with Congress to re-define hemp in the CSA to raise the THC threshold from 0.3 percent to 1.0 percent. Genetics in most commercially grown crops in the U.S. have benefitted from centuries of breeding and seed certification practices that ensure stability of attractive traits, such as nutritional composition, drought resistance, and climate acclimation. Hemp seed varieties in the U.S. have not yet been bred to keep THC below the defined amount and such varieties likely will not be widely commercially available for some time. Commercially viable hemp crops in Colorado's altitudes often express greater than 0.3 percent THC if grown to maturity, and a matter of days can often mean the difference between cultivating a compliant and a noncompliant crop.

4. 0.5 Percent THC Threshold for a Negligent Violation

The IFR requires that farmers growing hemp testing over 0.5 percent THC, after accounting for a margin of uncertainty, be assessed a negligent violation and must complete a state- or tribally-administered corrective action plan.²⁶ This threshold for negligent violations is too low and will create needless violations and unduly harsh administrative actions for otherwise compliant farmers and for CDA. Colorado recommends modifying this THC threshold to 1.0 percent to foster a more efficient and compliant industry. Colorado's current negligence threshold is set at 1.0 percent and it functions effectively by balancing the need to protect public health with the goal of facilitating the development of a healthy hemp industry.²⁷

If the 0.5 percent negligence threshold in the IFR had been applied to Colorado's industrial hemp program in 2019, Colorado would have been required to issue 48 negligent violations, which represents 12 percent of registrations.²⁸ At Colorado's 1 percent threshold, there were only 11 violations, which constitutes only 3 percent of registrations testing over 1.0 percent. Figure 2 shows Colorado hemp test results by THC amount and associated registrations if the IFR had been applied directly during the 2019 growing season and scaled to 100 percent testing coverage.

²⁶ 7 CFR §990.6(b)(3) at IFR p.58558.

²⁷ See also Duckwater Shoshone Comment, p. 2.

²⁸ A registration is a unique land area planted with a unique hemp variety. A registration is similar to a lot where a registrant may have multiple registrations.

Figure 2. THC Test Results and Registrations, 2019 and Scaled IFR Projection

Note: * Figures are cumulative over 0.3%, i.e., greater than 0.3% includes all acreage greater than 0.3%.

Source: CDA

	Registrations			
тнс	2019	Scaled to		
Test Results*	Season	100% Coverage		
<= 0.3	398	1,694		
> 0.3%	221	940		
> 0.4%	102	434		
> 0.5%	48	204		
> 1.0%	11	47		

If 100 percent testing is implemented under the IFR, we expect over 200 negligent violations. Addressing this number of violations will be costly, difficult, and unsustainable for CDA's hemp regulatory program. CDA estimates a policy change to 1.0 percent would save over 150 farmers the financial and operational risk of accruing violations. The appendix provides further details on this analysis.

As mentioned in comment 3 above, there are many environmental variables out of the farmer's control that can influence THC expression, including temperature, precipitation, altitude, disease and pest pressure, and soil type. Administrative variables, like sampling and testing bottlenecks, can also create compliance risks for the farmer as THC expression increases as hemp matures. The genetically unstable varieties currently available to farmers also exacerbate the risk.

The negligence threshold at 0.5 percent will also create a difficult compliance situation for the plant breeding and seed production industries. Please refer to comment 8, below, for details relating to the application of IFR requirements on plant breeders and seed producers.

In light of these considerations, the 0.5 percent negligence threshold is arbitrary and capricious under the APA, especially when considered against the current regulatory backdrop where many states rely on the 1.0 percent threshold for determining negligence and the hard 0.3 percent threshold for FCIC coverage.

Recommendation: Raise the threshold for negligent violations to 1.0 percent THC

Given the environmental variables, genetic instability, potential for administrative bottlenecks and actual testing data presented, Colorado urges USDA to raise the negligence threshold to 1.0 percent THC.²⁹ The Colorado hemp program currently uses 1.0 percent as a threshold for negligence, which

²⁹ SCFB Comment, p. 2 ¶ 6.

resulted in the State issuing violations to only 3 percent of hemp registrations (11 registrations) in 2019.³⁰ If the IFR had been effective in 2019 as written, CDA would have been required to issue over four times the amount of negligent violations (48 violations). Simply put, the threshold for negligence in the IFR creates an unreasonable administrative burden on the program and may prevent farmers from being able to participate in the industry in the future.

5. Disposal Protocol

The IFR requires licensed DEA reverse distributors to take custody of, and destroy, all noncompliant hemp.³¹ CDA has effectively supervised destruction of 3,360 acres of hemp since 2014. Additionally, the DOR has a vetted protocol to destroy legal cannabis that, for example, fails required testing, is subject to administrative hold or administrative license action, or that is voluntarily surrendered and destroyed by the owner. Both programs have existed for over five years without DEA involvement. To date, there have been no reports of theft, diversion, or use of previously wasted hemp or marijuana in Colorado.

Under 21 C.F.R. § 1317.95(a), two employees of a DEA-licensed reverse distributor must be present to collect the noncompliant hemp and transfer it to a registered disposal location. Two employees must also be present to complete an on-site destruction.³² In 2019, 99 crops were ordered to be destroyed in Colorado. If testing of all crops is required, this number is likely to increase five- to ten-fold. Neither CDA nor DEA has the resources required to ensure that two employees are available to coordinate the destruction of potentially tens of thousands of acres of hemp in different locations across Colorado.

Colorado's current regulations require that any material ordered to be destroyed is prohibited from leaving the registered land area, entering the stream of commerce, or being used for human or animal consumption. Farmers must provide CDA with evidence of destruction and the most common form of destruction is grinding or discing into the soil. This program is working effectively and CDA is concerned that the IFR will restrict an already successful practice. The current practices are sufficient to ensure that noncompliant material does not enter the supply chain.

³⁰ See Pala Band Comment, p. 1; Cal. Farm Bureau Comment, p. 3.; Wyden/Merkley Comment, p. 3; SC Comment, p. 2; NM Comment, p. 3; Comments of Sen. Mike Braun and Rep. James R. Baird dated Dec. 16, 2020, p. 1 (Braun/Baird Comment).

³¹ 7 C.F.R. §990.3(a)(3)(iii)(E) at IFR p.58557.

³² 21 C.F.R. §1317.95(d).

Given the current and expected scale of the Colorado industry, it is not practical or responsible to require farmers to surrender custody of the crop to a third party for off-site destruction, or to require burning of crops for destruction. Noncompliant plant material can (and should) be incorporated into fields as it is a powerful soil remediator, which is good for farmland and aligned with Natural Resources Conservation Service soil health priorities.

Law enforcement agencies across the state, including the Colorado Bureau of Investigation, Colorado State Patrol, and numerous county sheriff and municipal police agencies, have commented to CDA that they have no interest in taking custody of and managing the destruction of entire noncompliant hemp crops.³³ Attempting to do so would be extremely resource-intensive and unreasonable when considering the responsibilities and priorities of law enforcement. Additionally, it would place law enforcement in an agricultural role that they are neither equipped nor trained to accept. ³⁴

<u>Recommendation A: Allow noncompliant hemp to be disposed of on-site using traditional</u> <u>agricultural practices under the supervision of state or tribal agriculture departments.</u>

Under the IFR, destruction of a single noncompliant hemp field will require significant time, manpower, and equipment for the collection, transportation, and destruction of the plant material. The expected scale of Colorado's hemp acreage is far too large to facilitate the transfer of custody of noncompliant hemp material for off-site destruction as required in the IFR. CDA intends to register with DEA as a reverse-distributor, but it will not be able to efficiently take custody of noncompliant hemp and perform the destruction with two employees per site or observe onsite destruction. Furthermore, the cost to farmers of paying for destruction by a third party is unnecessarily punitive, given the loss of crop value already experienced, as well as the divergent definition of marijuana set forth in 21 U.S.C. § 802(16)(B)(ii). CDA requests the flexibility to continue its current practice of requiring farmers whose hemp tests above the acceptable limit but below the Colorado's threshold for negligent activity to destroy hemp onsite and provide photo or video evidence to CDA for documentation, and to limit destruction of entire plants in a manner that ignores the definition of marijuana in the Controlled Substances Act.³⁵

³³ Personal communication between CDA, CBI, CSP and other local law enforcement agencies December 6, 2019.

³⁴ Accord, KDA Comment, p. 2 ("As currently written, these requirements will result in a poor use of law enforcement resources.").

³⁵ See Comments of Summit Lake Paiute Tribe dated Dec. 23, 2019, p. 1 (Summit Lake Paiute Comment) (suggesting that stalks and seeds should be exempt from disposal requirements); Duckwater Shoshone Comment, p. 7; Seminole Comment, p. 7; Cal. Farm Bureau Comment, 3-4; SCFB Comment, p. 2 ¶ 4.

<u>Recommendation B: Provide clarification on which disposal methods are compliant under DEA rule</u> and include on-site grinding/discing as an acceptable disposal method.

Current DEA rules do not provide clear guidance on compliant disposal methods that are appropriate for potentially large amounts of plant material.³⁶ Current rules seem to be more appropriate for disposal of pharmaceuticals and chemical-based illegal drugs and, perhaps most importantly, the IFR disposal requirement would be difficult to apply in an agricultural setting. Under current rules, incineration and 'chemical digestion' are explicitly allowable disposal methods. These methods do not seem efficient or environmentally sound. Grinding or discing of organic agricultural waste is a time-tested and soil-conscious disposal method, which should be available to producers.³⁷

6. Cumulative Effects and Systemic Bias Towards Disadvantaged Producers

The cumulative effect of key provisions of the IFR will raise real barriers to entry for small and disadvantaged farmers and could prevent these critically important producer groups from entering the hemp industry.³⁸ The cumulative effects of the IFR may unintentionally favor larger, more well-capitalized operations that can spread risk among multiple lots and locations and that will recover better from a financial loss associated with a noncompliant crop.

Under the IFR, a farmer must be certain that a hemp lot will test below 0.3 percent THC or face a total loss. If that crop tests above 0.5 percent THC, the farmer will also accrue a negligent violation on their record. A prudent farmer would cultivate multiple varieties and test multiple times as the plant matures to ensure compliance with this requirement, given the current unstable genetics of most hemp varieties and the environmental variables that affect THC expression. The following is a testing cost description from a current hemp program registrant:

> "The actual cost of testing to a cultivator consists of potency testing every week for the last 6 weeks of crop cycle. Each potency test is \$85 and at least 5 tests per week per variety would be needed to establish the variety potency growth curve to properly estimate the harvest date and ensure

³⁶ See 79 FED. REG. 53547-53548. <u>https://www.govinfo.gov/content/pkg/FR-2014-09-09/pdf/2014-20926.pdf</u>

³⁷ See also Pala Band Comment, p. 2 (urging for transformation of nonconforming plants into other materials); Summit Lake Paiute Comment at 2; Minnesota Comment, p. 3.

³⁸ See also Duckwater Shoshone Comment, p. 5 (noting disadvantages faced by some tribal producers); Seminole Comment, p. 5 (same).

compliance. The total cost for 4 varieties on 24 acres, with 5 plant samples per week for 6 weeks would be about \$10,200. The additional official test would add about \$700 on average per variety according to the IFR (Table 4, p.58545) for a total of **\$13,000** in this example."³⁹

This example shows that the costs borne by producers are significantly higher than the estimates shown in the IFR. The IFR does not include the full cost of testing, which would include diligent and repeated testing for weeks to ensure compliance. If one of those lots tests as noncompliant, then the same farmer must pay for disposal, which could add \$4,800 for an average 24-acre lot according to the IFR.⁴⁰ The total cost for this farmer would be \$17,800 in sampling, testing, and disposal costs in addition to the lost value of the crop. Any of these costs could be higher if the supply of labs, samplers, and disposal agents is constrained through the requirement of DEA certified labs.

CDA is also concerned that the IFR has an unintended, yet systemic bias against small farmers in rural locations, who will face increased risks and potentially increased costs if transportation costs are higher and transport takes longer than the averages shown above and in the IFR. The 15-day sampling requirement exacerbates this issue in a compounding, and cumulative effect. When Congress passed the 2018 Farm Bill legalizing the cultivation of hemp, it intended to create an opportunity for all family farmers to grow a new and exciting crop with high demand. The costs of inspection, sampling, and testing under the new regime risk driving family farmers from the market, and instead the IFR as written favors vertically integrated, venture capital-backed companies. We envision a regulatory framework that is supportive of farms of all sizes with different levels of capital investment. Specifically, Colorado wants the USDA to provide opportunities for small or disadvantaged farmers and provide them with a workable system to cultivate the first new and revolutionary crop to become available to them in decades.⁴¹

³⁹ Public comment from Judith Daniels, Ph.D., Soil Scientist., IFR Public Meeting, December 10, 2019, Broomfield, Colorado.

⁴⁰ IFR p.58546.

⁴¹ We also note that the USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. Further, in addition to veterans, the Secretary must "provide outreach and technical assistance to encourage and assist socially disadvantaged farmers and ranchers to own and operate farms and ranches and to participate in agricultural programs." See https://www.outreach.usda.gov/sdfr/. To the extent that the IFR discriminates against or otherwise fails to account for socially disadvantaged farmers or veterans, the IFR violates corresponding provisions of the USDA's enabling statutes and regulations.

Recommendation: Adopt more farmer-friendly policies in the IFR

Several IFR provisions have an adverse effect on small farmers and should be considered for amendment as recommended in prior comments:

- Sampling time frame (Comment 1);
- DEA Lab Certification Requirements (Comment 2);
- 0.3 percent THC Threshold for Destruction (Comment 3);
- 0.5 percent THC Threshold for Negligence (Comment 4); and
- Disposal protocol (Comment 5).

Taken together, the referenced IFR provisions will increase the cost of production and legal risk associated with growing hemp. CDA is concerned that these rules will cause small farmers to reconsider whether to enter the hemp market.

7. Implementation Timeframe

Under Section 7605(b) of the 2018 Farm Bill, the regulatory authority used by states and tribes to implement hemp pilot programs under the 2014 Farm Bill expires one year from the date USDA promulgates rules governing hemp production in the United States. On October 31, 2019, USDA published the IFR, which started the one-year countdown to the expiration of state and tribal authority under the 2014 Farm Bill pilot program.

This is problematic because Colorado, like many other states, intends to operate its industrial hemp program during the 2020 crop season pursuant to its existing regulatory authority under the 2014 Farm Bill. Many states, including Colorado, will face serious logistical hurdles and significant financial burdens in implementing a new statutory and regulatory scheme for cultivating and testing hemp prior to October 31, 2020, the date that USDA marks as the expiration of 2014 pilot program authority.

In view of this looming problem, we urge USDA to expeditiously explore mechanisms for extending the expiration date of the pilot program authority provided in the 2014 Farm Bill. All stakeholders, including USDA, CDA, program registrants, testing labs, banks and insurance providers, will benefit from an extra year to adapt to the new regulatory requirements under the IFR. The extra year will increase compliance rates and industry revenues while potentially limiting business and regulatory failure associated with the new state administered federal hemp program.

We acknowledge that delaying the 2018 Farm Bill implementation timeframe presents some logistical challenges, most notably the delay in Federal preemption of state authority to impede interstate transportation and commerce in hemp and hemp products. We suggest that the USDA work with Congress to amend the 2018 Farm Bill to preserve the interstate commerce protections and the state regulatory authority of the 2014 Farm Bill until October 31, 2021.

<u>Recommendation: USDA should extend the expiration date of the 2014 hemp pilot program by at</u> <u>least one year.</u>

We believe USDA could extend the expiration date in at least two ways. First, USDA could work with the United States Congress to amend the 2018 Farm Bill to extend the timeframe for states and tribes to operate hemp pilot programs pursuant to the authority of the 2014 Farm Bill. Such an extension could be effected through a technical amendment or attached as a rider to an appropriate reauthorization bill. Second, the IFR promulgation was an *administrative action* undertaken by USDA that initiated the one-year countdown to 2014 Farm Bill expiration. USDA may be able to extend or restart the one-year countdown by re-issuing or revising the IFR with a specific provision expressing intent to extend the one-year expiration provisions of 2018 Farm Bill Section 7605(b).

8. Innovation: Lack of Seed Certification and Separate Plant-Breeding Program

USDA is aware that most hemp varieties currently available are not regionally adapted and contain a significant amount of genetic variation. The IFR itself estimates that up to 40 percent of producers will provide samples testing high in THC content.⁴² Hemp genetics currently lack the stability of other certified seed and the USDA has, as of these comments, refrained from including the regulatory framework for a certified seed program or for seed breeding and research and development programs in the IFR.

This is a significant omission from the regulatory framework—CDA is concerned that this omission will stifle innovation and delay hemp genetics from achieving much needed stability. CDA feels strongly that there is a critical need to regulate hemp research and development differently than commercial production.

⁴² IFR p.58547 ("Using the same assumptions regarding the prevalence of noncompliant crops and the costs of disposal that were used in generating the estimates of hemp disposal reporting (and disposal) for State and Tribal programs, the 1,000 producers that will participate in the USDA Plan will generate 400 samples will test high for THC content").

Innovation in plant breeding is vital to improving the genetics available in the market. In many plant breeding programs, greenhouses or fields contain segregated populations of plant varieties with different characteristics. Thousands of plants are screened before a select few with desired traits are advanced for further breeding.

As a result, breeding programs may produce plants with noncompliant levels of THC during certain stages as desirable traits, *i.e.*, frost, drought or pest resistance, are identified and isolated. Successful plant breeders can isolate these desirable traits from THC production to ensure they are preserved.

It is unclear how plant breeders could comply with the IFR. It is difficult for a breeding program to be successful if plants with unwanted genetic traits, diseases, or pollination cannot be separated and destroyed until testing at maturity. In many cases, leaving all plants in the ground until flowering is not possible. The very nature of research and development could produce plants with THC in excess of 0.5 percent somewhat regularly, creating unnecessary and in some cases serious violations as researchers innocently search for desirable plant traits. The application of this negligence threshold to breeding research could stifle innovation and prevent genetic evolution.

Colorado's five years of experience regulating and advancing industrial hemp has identified the importance of allowing for research in plant varietal breeding, providing a hemp seed certification program, advancing the stabilization of genetics for THC expression, and understanding how environmental factors, disease, and insect pressure influence the expression of THC.

<u>Recommendation A: Regulate hemp seed breeding and research programs separately from</u> <u>commercial hemp production by providing different registration options.</u>

Colorado is committed to innovation in hemp breeding and research by registering institutions of higher education and private hemp research companies that meet predetermined criteria including thirdparty certification, prohibition of material entering the chain of commerce, limitation on plot size, and a waiver from destruction and reporting to USDA, within responsible limits.

CDA would administer a specific registration for breeding and research and development with regulations that are intentionally designed to accommodate and monitor plant-breeding activities.⁴³ Regulations will mandate that: (1) no research and development materials enter the stream of commerce;

⁴³ Accord, KDA Comment, p. 4.

(2) breeders will dispose of noncompliant plant material; and (3) seeds are exempt from destruction so that breeders can use seeds for segregation of desired traits in future generations.

Recommendation B: Recognize the importance and legitimacy of AOSCA Certified Seed.

Certified seed is an important protective program used by farmers across the world. Certified seed should be recognized by the USDA and hemp should be folded into certified seed programs across the U.S.⁴⁴ CDA currently recognizes 17 certified seed varieties. These seeds have completed the certification process for use in Colorado in accordance with AOSCA standards. Certified Seed varieties have undergone THC verification trials in five different geographical regions of Colorado, from elevation of 7,000 feet to the high plains of Eastern Colorado and the Colorado Plateau on the western border with Utah. Testing these certified varieties for THC occurs for at least three years following initial certification, during foundation and registered class development stages. Farmers that purchase and plant certified seed pay a premium for the reliability of stable, uniform genetics and low risk for noncompliant THC levels. CDA encourages all farmers to use certified seed when possible. In the future, CDA intends to use certified seed to streamline the testing program.

9. Banking/Insurance Non-alignment

Several Federal regulators have provided guidance to banks, credit unions, and insurance companies on hemp-related provisions in the 2018 Farm Bill. Select members of the Federal Financial Institutions Examination Council, for example, issued guidance on the intersection between hemp provisions in the 2018 Farm Bill and the Bank Secrecy Act (**BSA**).⁴⁵ Likewise, an office of the Farm Credit Administration urged Farmer Mac to adopt policies and procedures for secondary market transactions in mortgages involving hemp that would include an analysis of: (1) applicable Federal and state law; (2) hemp production conditions; (3) hemp crop marketing opportunities; and (4) appropriate underwriting standards, such as the creditworthiness and experience of the producer or processor.⁴⁶ USDA's own Risk

⁴⁴ See Montana Comment at p. 3.

⁴⁵ See, e.g., Board of Governors of the Fed. Res. Sys., et. al., Providing Financial Services to Customers Engaged in Hemp-Related Businesses (OCC News Rel. 2019-141, Dec. 3, 2019), available at https://www.occ.treas.gov/news-issuances/news-releases/2019/nr-ia-2019-141a.pdf.

⁴⁶ See also Fed. Dep. Ins. Corp. Adv. Committee on Community Banking, Depository Institutions and Hemp Customers (Oct. 10, 2019), available at <u>https://www.fdic.gov/communitybanking/2019/2019-10-10-supervision-part-ii.pdf</u>; Nat'l Credit Union Admin., *Regulatory Alert: Serving Hemp Businesses* (No. 19-RA-02, Aug. 2019),

Management Agency (**RMA**) also announced a pilot for a new crop insurance option for hemp growers in select states, albeit subject to certain restrictions tied to THC levels, crop production history, and participation in a 2014 Farm Bill research pilot.⁴⁷ Such guidance, however, presents several issues with respect to the authority of the USDA to interpret hemp provisions in the 2018 Farm Bill.

Section 297D(b) of the 2018 Farm Bill provides that the Secretary of Agriculture has "sole authority" to issue Federal regulations and guidelines "that relate to the production of hemp," subject to certain exclusions. Yet the foregoing guidance from banking and insurance regulators arguably relates to the production of hemp in the context of certain financial services. We therefore ask for clarity on the extent to which USDA intends to supersede, coordinate, or adopt guidance issued by other Federal agencies in relation to hemp production, in particular any interpretive limits that USDA expects to impose upon itself or other agencies with respect to the scope of USDA's authority to regulate hemp banking, insurance, and other financial service providers under the IFR or in the final regulations.

Similarly, the State of Colorado requests that USDA clarify the scope of Section 10114(a) of the 2018 Farm Bill as it relates to interstate banking, insurance, or financial services involving hemp and hemp products. To be sure, Section 10114(a) states that nothing in Title X of the 2018 Farm Bill prohibits the "interstate commerce of hemp and hemp products[.]" But it remains unclear whether interstate commerce in hemp and hemp products necessarily includes the payment for any hemp and hemp products through various methods, such as wires, checks, automated clearinghouse transactions, credit card or other financial transactions, including loan proceeds. We believe it to be fairly clear that the phrase "interstate commerce of hemp and hemp products" encompasses payments made for hemp and hemp products, but the legal opinion issued to Secretary Purdue on May 28, 2019, focused primarily on

available at https://www.ncua.gov/files/regulatory-alerts/19-RA-02-serving-hemp-businesses.pdf; Small Bus. Admin., Information Notice: Issuance of SOP 50 10 5(K) at p. 3 (Control. No. 5000-19004, Feb. 2019), available at https://www.sba.gov/sites/default/files/2019-02/Info%20Notice%20SOP%2050%2010%205K%205000-19004.pdf; Colorado Div. of Financial Services, Guidance: BSA Expectations Regarding Industrial Hemp (Apr. 4, 2019), available at https://drive.google.com/file/d/13G5iIroJC8Hke6gj9Jgivxs-sM5aw9Hu/view; see also Kansas Acting Bank Commissioner Tim Kemp, Memorandum (Jan. 17, 2019), available at http://www.osbckansas.org/banking/resources/marijuana_guidance.pdf.

⁴⁷ USDA, News Release, USDA Announces Pilot Insurance Coverage for Hemp Growers (Dec. 23, 2019), available at https://rma.usda.gov/News-Room/Press/Press-Releases/2019-News/USDA-Announces-Pilot-Insurance-Coverage-for-Hemp-Growers; see also RMA, Insurability of Hemp Under the Whole-Farm Revenue Protection Plan During the 2019 Crop Year, MGR-19-002 (Feb. 25, 2019).

interstate transport of hemp under § 10114(b) and not on the effect of § 10114(a) on financial transactions.⁴⁸

Finally, the IFR indicates that without the regulations included therein, "the banking industry is not willing to take the risk of accepting deposits or lending money to these businesses."⁴⁹ We found through the CHAMP, however, that the IFR alone may not resolve the hesitancy of banks to lend funds to hemp producers. Instead, CHAMP participants indicated that the absolute 0.3 percent THC limit for crop insurance coverage, as opposed to the more expansive thresholds used in the IFR, may inhibit hemp production loans due to the fact that bank underwriting for crop production loans examines the availability of crop insurance (or lack thereof) as a risk mitigation factor.⁵⁰ That is, it appears that the absolute limit of 0.3 percent THC content for crop insurance coverage, among other restrictions, may also limit expansion of hemp production in Colorado and other jurisdictions.⁵¹ What's more, it remains unclear whether the absolute 0.3 percent limit for crop insurance extends solely to the flower or to the plant as a whole.

Recommendation: Clarify Preemption of State Laws and Crop Insurance Issues

We ask the Agricultural Marketing Service (AMS) to clarify in the final hemp regulations or the IFR that the preemption language in Section 10114(a) encompasses interstate banking, financial services, and insurance transactions, as well as any state or tribal laws encompassing the same. We also ask AMS to work with RMA to harmonize acceptable hemp THC levels contemplated in the IFR with acceptable hemp THC levels contemplated in the IAR with acceptable hemp THC levels contemplated in RMA regulations for crop insurance. Finally, in light of the language set forth in Section 297D(b) of the 2018 Farm Bill indicating that the Secretary holds the sole authority to issue regulations and guidance in relation to hemp production, we urge the Secretary to establish a safe harbor from liability for financial services providers seeking to service hemp producers, as Sections 297D(b) and Section 10114(a) of the 2018 Farm Bill can be read to provide USDA with the authority to implement a

⁴⁸ Memorandum from Stephen A. Vaden, General Counsel, USDA to Secretary Sonny Perdue, *Legal Opinion on Certain Provisions of the Agriculture Improvement Act of 2018 Relating to Hemp*, pp. 6-10 (May 28, 2019), *available at <u>https://www.ams.usda.gov/sites/default/files/HempExecSumandLegalOpinion.pdf</u>.*

⁴⁹ IFR p. 58539.

⁵⁰ See Office of the Comptroller of the Currency, Comptroller's Handbook A-AL at 6, 10 (v. 1.3, Oct. 15, 2018) (including insurance policy requirements as part of loan policy and governance standards).

⁵¹ See Insurability of Hemp Under the Whole Farm Revenue Protection Plan During the 2019 Crop Year (Mgr. Bulletin No. MGR-19-002, Feb. 25, 2019), available at <u>https://www.ag-risk.org/FCICDOCU/MGRBUL/2019/M19002.pdf</u>.

hemp-specific version of the prior Strengthening the Tenth Amendment Through Entrusting States (**STATES**) Act of 2018 or the current Secure and Fair Enforcement (**SAFE**) Banking Act of 2019 for hemp producers holding licenses under a USDA-approved plan or from the USDA itself.

10. Lack of Guidance on Documentation Required for Transportation

Interstate commerce and the free flow of intermediate and finished products are important benefits of the newly federally legal status of hemp. We understand that USDA regulatory scope is somewhat limited relating to transportation, although a strong chain of custody and clear documentation of compliant material starts at the farmgate. The IFR⁵² and the 2018 Farm Bill⁵³ both address interstate commerce in broad terms, but neither provides a national-level documentation system for producers and law enforcement agencies to verify compliant hemp shipments. A national documentation system is needed to facilitate interstate commerce and national industry growth.

Recommendation: Develop national documentation requirements for hemp starting at harvest.

CDA urges USDA to work with sister agencies to develop documentation, symbols, seals and procedures to identify compliant hemp and hemp products throughout the supply chain. We request USDA to issue guidelines for the commercial transportation of hemp, starting at the farmgate. This would include:

- Requirements for how a hemp load is certified that meets the THC threshold prior to transportation;
- Requirements for uniform documentation verifying the validity of the cargo, for use during a roadside law enforcement stop;
- Specific packaging and labeling requirements ensuring an officer can verify the validity of the cargo; and
- Requirements for hemp loads to be sealed, similarly to other high-value cargo, to mitigate the potential introduction of contraband.

⁵² IFR p. 58534.

⁵³ § 10114.

A unique and secure chain of custody system with standard documentation is necessary to ensure unimpeded transport of hemp throughout the U.S. The IFR should be amended to provide language for documentation requirements and for cooperation with law enforcement, FDA and other agencies.

11. Application Period

The IFR requires a discrete application period that is active from August 1 to October 31 of each year. It also requires the 3-year licenses to expire on December 31. It is unclear in the IFR whether states operating under a state plan or tribes operating under an approved tribal plan must adhere to the same application window.

<u>Recommendation: Allow states and tribes operating under USDA-approved plans the flexibility to</u> <u>determine their own registration period.</u>

In Colorado's experience, there are a significant number of operations with year-round cultivation of hemp mostly for maintenance of mother clones and clonal propagation. We also expect to see more indoor breeding and tissue culture operations in the coming years. Having only one window of application cycle will create peak pressure on registration, resulting in potential delay. Therefore, CDA requests USDA to modify the IFR to allow a Colorado-appropriate application calendar and for the USDA to have a year-round rolling application cycle while still maintaining the year beginning on January 1.

Additional Legal Concerns

Colorado recognizes and supports the efforts of the Secretary and of AMS staff in seeking to provide legal certainty for participants in the hemp value chain. Nonetheless, the IFR presents several legal issues, in addition to those discussed above, that we identify below.

12. Failure to Comply with Notice and Comment Requirements under the Administrative Procedure Act

With regard to the IFR, the USDA did not comply with the notice and comment requirements set forth in the APA, nor it would seem did the USDA adhere to its own internal procedures for issuance of an interim final rule.⁵⁴ The USDA instead found that good cause existed to forego notice and comment

⁵⁴ See USDA Office of Budget and Program Analysis, Regulatory Decisionmaking Requirements 5, 25-26, F-3 (Mar. 14, 1997) (requiring submission of the IFR and required information to Congress), available at https://www.ocio.usda.gov/sites/default/files/docs/2012/DR1512-001_0.pdf; APA § 706(2)(D).

proceedings otherwise required under the APA for the IFR.⁵⁵ Such a finding follows the newly-worn path of sister agencies litigating similar departures from APA strictures.⁵⁶ To be sure, the APA permits an agency to forego formal notice and comment rulemaking procedures if the agency "for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest," but the justification in the IFR fails to meet this standard.⁵⁷

For example, the good cause exception "excuses notice and comment in emergency situations, or where delay could result in serious harm."⁵⁸ Yet USDA provided no description of any environmental or public health and safety threat that requires ignoring the APA's mandate to engage in notice and comment rulemaking. Instead, the IFR relies on the need for expeditious rulemaking and Congress' desire for the same.⁵⁹ Such a justification alone is insufficient on its face, especially in light of the amount of time between passage of the 2018 Farm Bill and publication of the IFR, as the USDA had ample time to publish an advanced notice-of-proposed rulemaking and to provide other opportunities for stakeholder input in the manner required by the APA.

In addition, the USDA's conclusion in the IFR that the public interest will be served by foregoing notice and comment procedures does not address a central prong in the good cause exception analysis: "whether providing notice and comment would be contrary to the public interest."⁶⁰ The public interest

⁵⁵ IFR p. 58553 (citing 5 U.S.C. 553(b)(B)) and p. 58554 ("Accordingly, the Administrator finds that, under the totality of the circumstances presented, there is good cause to forego notice and comment through the issuance of a notice and proposed rulemaking"); *but see Association of Private Sector Colleges & Universities v. Duncan*, 681 F.3d 427, 462-63 (D.C. Cir. 2012) (holding that an "agency violates the APA when it does not give notice of a regulation, thus depriving the public of the chance to comment on those provisions"); *Analysis Corp. v. Bowles*, 827 F. Supp. 20, 23 (D.D.C. 1993 ("Courts in th[e D.C.] circuit take a dim view of rule-making which has not been preceded by notice and comment").

 ⁵⁶ See generally, Miriam Stiefel, Invalid Harms, 94 WASH. L. REV. 927, 927-928 (2019) (citing California v. Azar, 911 F.3d 558, 570–71 (9th Cir. 2018); California v. HHS, 351 F. Supp. 3d 1267 (N.D. Cal. 2019)).

⁵⁷ 5 U.S.C. § 553(b)(B).

⁵⁸ Mack Trucks, Inc. v. EPA, 682 F.3d 87, 93 (D.C. Cir. 2012) (citations omitted); Jifry v. FAA, 370 F.3d 1174, 1179 (D.C. Cir. 2004) (a rule necessary to address "a possible imminent hazard to aircraft, persons, and property within the United States"); *Council of the S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981) (a rule was of "life-saving importance" to mine workers in the event of a mine explosion); *American Federation of Gov't Emp., AFL-CIO v. Block*, 655 F.2d 1153 (D.C. Cir. 1981) (a rule in response to a court order that was necessary to prevent confusion, economic harm, and disruption to an entire industry and its customers).

⁵⁹ Although Section 10113 of the 2018 Farm Bill states that the Secretary "shall promulgate regulations and guidelines to implement this subtitle as expeditiously as practicable," neither this provision nor any other in the statute expresses an intent by Congress to waive the notice-and-comment requirements of the APA.

⁶⁰ Mack, 682 F.3d at 95 ("The public interest prong of the good cause exception is met only in the rare circumstance when ordinary procedures—generally presumed to serve the public interest—would in fact harm that interest").

would have to be served—not harmed—by compliance with notice and comment rulemaking because states, like Colorado, could have provided critical input derived from on-the-ground experience with state-sponsored hemp programs. Moreover, compliance with § 553 would not defeat the purpose of the proposal, another instance in which foregoing notice and comment is appropriate.⁶¹ Rather, notice and comment under the APA would have provided USDA with the input it now seeks in the IFR.

Moreover, this is not a situation where the 2018 Farm Bill mandated the issuance of an IFR or explicitly stated that, in promulgating rules, the APA should not apply.⁶²

Thus, although Colorado recognizes and appreciates the need for certainty among hemp growers and other participants in the hemp value chain, it appears that none of the circumstances identified in the IFR appear to provide the necessary legal justification for the USDA to forego the notice and comment rulemaking required under APA § 553(c).⁶³ Rather than describing a regulatory, agricultural, or economic emergency sufficient to dispense with notice and comment rulemaking, the AMS identifies the need for certainty within sister branches of USDA or the Federal Crop Insurance Corporation (**FCIC**) among other reasons for skipping standard APA-related rulemaking processes.⁶⁴ Rather than serving the public interest, the IFR subverts it by precluding experienced stakeholders from shaping the regulatory scheme upon which their livelihoods depend.

In sum, we are concerned that the IFR violates APA § 553, as well as the USDA's own procedures for formulating interim final rules.

13. The IFR Fails to Respect the Non-Preemptive Intent of the 2018 Farm Bill

The IFR on its face recites the non-preemption principle enshrined in the 2018 Farm Bill, that is, the Congressional guarantee that there shall be no preemption of state or tribal laws related to hemp production that are more stringent than the hemp provisions in the federal statute.⁶⁵ Nevertheless, by

⁶¹ See Utility Solid Waste Activities Group v. EPA, 236 F.3d 749, 755 (D.C. Cir. 2001).

⁶² Jared P. Cole, Cong. Res. Serv., The Good Cause Exception to Notice and Comment Rulemaking: Judicial Review of Agency Action (R44356, Jan. 29, 2016), <u>https://fas.org/sgp/crs/misc/R44356.pdf</u>; IFR p. 58553 ("[T]he Act does not contain an express end-date by which such regulations and guidelines must be issued"); *Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998) (where the language of the Act required publication of an interim final rule and "specifie[d] procedures which differ from those of the APA").

⁶³ Cole, *supra* note 505059.

⁶⁴ IFR p. 58553-54.

⁶⁵ Compare 7 C.F.R. § 990.3(b)(1)(ii) with 7 U.S.C. § 1639p(a)(3)(A). See also Memorandum from Stephen A. Vaden, General Counsel, USDA to Secretary Sonny Perdue, Legal Opinion on Certain Provisions of the Agriculture

establishing in the IFR a range of specific regulatory measures that conflict with existing state rules, policies, and practices, and especially that conflict with the now time-tested approaches in Colorado, the IFR threatens to impose far more wide-ranging preemption than Congress intended. Thus, for example, there is simply no reason to believe that Congress intended through the hemp provisions in the 2018 Farm Bill to require the use of DEA-certified labs when states like Colorado have their own closely regulated testing facilities that have proven their effectiveness at testing cannabis plants, or that Congress intended to mandate a 100 percent sampling regime when states like Colorado have found that sampling at far lower rates is effective to protect the public and ensure compliance. Indeed, there is no language in the 2018 Farm Bill that points to either requirement, let alone a mandate for such requirements.⁶⁶ As a result, while the IFR purports to respect the principles of federalism and to allow the "laboratories of the states" to continue their efforts at innovation in this area, the IFR necessarily upsets the delicate federalism balance, trampling on states' ability to develop their hemp industries effectively.⁶⁷ Moreover, by continuing to include the DEA as a regulator for hemp via lab certifications and reverse distribution requirements, the IFR expressly contradicts Section 297D(b) of the 2018 Farm Bill, which provides the Secretary of Agriculture with "sole authority" to issue Federal regulations and guidelines that relate to the production of hemp, subject to the authority of the HHS Secretary and FDA Commissioner to promulgate Federal regulations and guidelines under those U.S. Food and Drug Administration laws.⁶⁸ That is, by requiring use of DEA-licensed labs for testing of hemp or DEA-licensed reverse distributors for destruction of hemp, the USDA impermissibly exceeded the statutory authority set forth in the 2018 Farm Bill by permitting the DEA to continue regulating cannabis through DEA licensing procedures.⁶⁹

Improvement Act of 2018 Relating to Hemp, at 13 (May 28, 2019), available at https://www.ams.usda.gov/sites/default/files/HempExecSumandLegalOpinion.pdf [Vaden Opinion].

⁶⁶ 7 U.S.C. § 1639p.

⁶⁷Gonzales v. Oregon, 546 U.S. 243, 270 (2006) ("the structure and limitations of federalism ... allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons")(citations omitted); *Younger v. Harris*, 401 U.S. 37, 44 (1971) (observing that the principles undergirding "Our Federalism" direct a federal system in which "there is sensitivity to the legitimate interests of both State and National Governments, and in which the National Government, anxious though it may be to vindicate and protect federal rights and federal interests, always endeavors to do so in ways that will not unduly interfere with the legitimate activities of the States."). *See also Bernhard v. Whitney National Bank*, 523 F.3d 546, 548 (5th Cir. 2008); *Bank of Am. v. City and Cty. of San Francisco*, 309 F.3d 551, 565 (9th Cir. 2002); *Bank One v. Guttau*, 190 F.3d 844, 850 (8th Cir. 1999); *Perkins v. Johnson*, 551 F. Supp. 2d 1246, 1255 (D. Colo. 2008). Compare 21 U.S.C. § 903.

^{68 7} U.S.C. § 1639r(b).

⁶⁹ See 5 U.S.C. § 706(2)(C).

Conclusion

We thank the USDA for developing the IFR and for providing an opportunity to comment on the rule. As mentioned above, our comments aim to protect our state's significant investment in hemp cultivation and laboratory operations; preserve our established regulatory system; and assist smaller or disadvantaged hemp farmers. We hope USDA will look to Colorado's five years of experience regulating and advancing industrial hemp for guidance on how the IFR may be improved to meet the needs of hemp stakeholders.

Appendix

This appendix provides an analysis illustrating how producers, registrations, acreage, and economic value would be affected if the IFR THC limits and testing requirements are implemented, utilizing actual data from our 2019 crop season.

In 2019, CDA tested 23 percent of all registrations (619). The "2019 Colorado Data" panel of Table A below illustrates the number of tests that fell within each level of THC content. It also details the number of unique producers in each THC category, as well as the total acreage. As an example, 398 registrations held by 369 unique producers provided samples that tested within the 0.3 percent THC content limit, representing 11,800 acres of hemp with a total economic value of \$405 million. Similarly, 221 registrations tested at greater than the 0.3 percent THC content limit, and so forth. The panel to the right, entitled "Scaled to 100% Sampling Coverage," illustrates the projected outcomes for 2019 if CDA had sampled and tested all registrations as required by the IFR.

Table A. Colorado Hem	p Test Result Distribution
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2019 Colorado Data			Scaled to 100% Sampling Coverage					
2019 THC	IC Total Economic			Total Econon			Total Economic	
Test Results*	Producers	Registrations	Acres**	Value	Producers	Registrations	Acres**	Value
<= 0.3	369	398	11,800	\$405,413,512	1,276	1,694	64,568	\$2,217,109,996
> 0.3%	209	221	4,491	\$154,460,821	723	940	24,529	\$842,923,678
> 0.4%	98	102	2,654	\$91,226,304	339	434	14,492	\$497,742,332
> 0.5%	45	48	1,560	\$53,574,180	156	204	8,512	\$292,254,674
> 1.0%	11	11	289	\$9,945,697	38	47	1,579	\$54,248,178

Notes: * Each figure for producers, registrations, etc. is cumulative and includes all samples that tested above the THC test result value in the left column. We assume that the distribution of test results for 100 percent of registrations would be the same as observed in 2019 actual testing.

**Reported acreage includes all indoor hemp cultivation, scaled from square feet to acres.

Source: CDA; USDA; MPG Consulting LLC.

Importantly, the economic value of hemp production as described in this analysis represents the value of all production inputs plus the potential value of the hemp material output itself. This is not a calculation of revenue or profit in the traditional accounting sense, but rather the total dollar value and economic activity that would be lost by the destruction of a producer's hemp crop. In other words, if a field tests greater than 0.3 percent THC, the value of all inputs used to produce the noncompliant hemp crop is lost and irretrievable <u>and</u> the producer loses all potential economic value of the hemp destroyed.

In order to estimate the economic value of noncompliant crops, we combine various figures from the IFR with Colorado-specific data to estimate the total economic value of a hemp crop, including all production inputs (*i.e.*, registration, sampling, and production costs) and the potential market value

of the hemp specifically. Table B, below, provides all assumptions and cost/revenue estimates utilized in our analysis.

Estimate	Description	Source				
	Economic Value Per Producer ¹					
\$54	Producer Background/Felony Check Cost	IFR Pg. 58546				
\$33	Producer FSA Reporting Cost per Producer	IFR Pg. 58547				
\$250	Producer Voluntary METRC Testing Access Cost per Year ¹	CDA				
\$337	Total Economic Value per Producer					
	Economic Value Per Registration/Lot ²					
\$10	Producer Application Time Cost per Registration	IFR Pg. 58545				
\$715	Producer Sampling & Testing Cost per Lot, Midpoint	IFR Pg. 58545				
\$14	Producer Disposal Reporting Cost per Disposal, per Lot	IFR Pg. 58546				
\$57	Lab Reporting Cost per Test per Lot	IFR Pg. 58547				
\$500	Application Fee per Registration	CDA Application				
\$85	Producer Voluntary METRC Cost per Test, per Lot ³	Industry Review				
\$1,965	Total Economic Value per Registration					
	Economic Value Per Acre ⁴					
\$14,063	Producer Revenue per Acre, Midpoint⁵	IFR Pg. 58541				
\$19,421	Producer Production Costs per Acre	IFR Pg. 58542				
\$591	Producer Opportunity Cost per Acre	IFR Pg. 58542				
\$200	Producer Disposal Cost per Acre	IFR Pg. 58546				
\$5	Application Fee per Acre	CDA Application				
\$34,280	Total Economic Value per Acre					

Table B. Assump	ptions for Derivin	g the Economic	Value of Hem	p Production
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2 Producers have variable costs that scale with the number of registrations and lots that they produce. Internal CDA cost estimates have established that each registration has an average of 1.5 associated lots.

3 Colorado producers have the option to enroll in the state's voluntary testing program that allows them unlimited hemp testing through Colorado's certified marijuana testing labs.

4 In order to simplify the analysis, we combined square footage into total hemp acres. As a result, our figures are conservative since indoor cultivation is more resource-intensive and yields a higher-value CBD product.

5 Revenue per acre is calculated by averaging the high and low estimates in the IFR. This is likely a very conservative estimate for the state of Colorado, where a larger share of hemp production is based around higher-value CBD production.

Source: USDA; CDA; MPG Consulting LLC.