



October 8, 2020

**VIA ELECTRONIC FILING**

Docket Clerk  
Marketing Order and Agreement Division, Specialty Crops Program  
Agriculture Market Service  
U.S. Department of Agriculture  
1400 Independence Avenue, SW STOP 0237  
Washington, DC 20250

Re: Doc. No. AMS-SC-19-0042 SC19-990-2 IR; Establishment of a Domestic Hemp Production Program; Document Citation 85 FR 55363; Pages 55363-55366

To Whom It May Concern:

The American Trade Association for Cannabis and Hemp (“ATACH”) is a 501(c)6 trade organization that promotes the expansion, protection and preservation of businesses engaged in the legal trade of industrial, medical, and recreational cannabis-based and hemp-based products. ATACH has been named “Trade Association of the Year” and “Corporate Grassroots Organization of the Year” by *Campaigns & Elections* magazine. ATACH’s membership includes some of the most influential businesses as well as state, national, federal and international cannabis trade associations and organizations.

In September 2020, ATACH launched a Task Force to facilitate the harmonization of emerging cannabis-related laws and regulations and provide an industry response to marketplace issues surrounding CBD and other cannabinoids. The Task Force is led by legal compliance professionals from the country’s top hemp and marijuana operators, representatives from financial institutions and testing laboratories, in addition to medical experts and mainstream stakeholders. We submit this comment on behalf of our members to express our recommendations relating to the USDA’s Interim Final Rule (“IFR”).

This comment addresses two critical points: (1) the importance of USDA regulatory control over non-final “work-in-progress” hemp extract, and (2) industry challenges created by recent congressional legislation extending the grace period for states to be in compliance with the USDA’s hemp rules.

<https://attach.org/>

**I. USDA should retain regulatory control over non-final “work-in-progress” hemp extract.**

The Agricultural Improvement Act of 2018 (“AIA”) makes clear that the USDA has authority to regulate hemp cultivation within the United States. The statute also grants authority to the Food and Drug Administration (“FDA”) to regulate products intended for human consumption that contain hemp extracts or derivatives. General confusion in the industry remains, however, over which agency regulates the *process* of creating a final hemp product, otherwise known as non-final work-in-progress hemp extract.

The answer to this question lies within the definition of hemp, and combined with other provisions in the AIA, the Secretary of Agriculture is clearly granted the “sole authority” to issue federal regulations and guidelines relating to hemp production.<sup>1</sup>

The AIA defines hemp as:

The plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all *derivatives, extracts, cannabinoids*, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.<sup>2</sup>

(emphasis supplied).

Importantly, the definition of hemp expressly includes derivatives, extracts, and cannabinoids. “In other words, cannabinoids and derivatives of hemp are themselves hemp under the statute.”<sup>3</sup> Given that the Secretary of Agriculture shall have sole authority to issue federal regulations and guidelines that relate to the production of hemp (i.e., derivatives, extracts, and cannabinoids), it follows that the AIA mandates that only the USDA regulate the production of these derivatives, extracts, and cannabinoids. The Drug Enforcement Agency’s (“DEA”) recently issued Interim Final Rule<sup>4</sup> impermissibly frustrates the clear legislative intent behind the AIA by inserting an arbitrary standard to the production of hemp extracts.

ATACH urges the USDA to follow the plain language of the AIA and retain sole regulatory authority over non-final work-in-progress hemp extract. This was the intent of Congress as demonstrated in the House Committee Report on the AIA:

“In Sec. 297D, the Managers clarify that the Secretary has the sole authority to issue guidelines and regulations regarding the production of hemp. However, nothing in this

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<sup>1</sup> See AIA § 297D(b).

<sup>2</sup> 7 U.S.C. § 1639o(1).

<sup>3</sup> <https://cannabusiness.law/dea-just-dropped-a-bomb-on-the-hemp-industry-part-2-delta-8-thc/>

<sup>4</sup> See DEA Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51639.

subtitle shall affect or modify the authority granted to the Food and Drug Administration and the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262), including for hemp-derived products. The Secretary is required to consult with the Attorney General on the promulgation of regulations, but ultimately, the regulations shall only be issued by the Secretary of Agriculture. To ensure that the Secretary moves forward with issuing regulations in as timely a fashion as possible, the Secretary shall periodically report to Congress with updates regarding implementation of this title."<sup>5</sup>

Senator Mitch McConnell reiterated that the intent of the 2018 AIA was to remove the federal roadblocks facing hemp farmers and hemp-related product producers in America, stating on the Congressional Record that:

This farm bill also includes a bipartisan provision I crafted with Senator Wyden to legalize industrial hemp. At present, with just a few limited exceptions, our Federal Government bans domestic hemp production—never mind that this is a completely different plant than its illicit cousin, and never mind that consumers are already buying hemp products, everything from clothing to auto parts; they are just imported from foreign producers. Federal law has mostly prohibited our own farmers from getting in on the action. It is time to remove the roadblocks and let American farmers explore this growing market. This has long been a priority of mine. I championed hemp pilot programs in the 2014 farm bill. They have shown big success. It is time to take the next step.<sup>6</sup>

Despite the plain language of the AIA and absent clarification from the USDA, the DEA's IFR materially impedes the industry.

Regulating the production of a final product but not the final product itself is not a new concept for the USDA. The USDA currently oversees the "USDA Foods Further Processing" program, which permits state distributing agencies and school districts to contract with commercial food processors to convert raw or bulk USDA Foods into convenient end products.<sup>7</sup> Within this program, USDA regulates 38 different USDA Foods for further processing into defined processed end products. For example, USDA permits

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<sup>5</sup> H.R. Rep. No. 115-1072, at pg. 738.

<sup>6</sup> Senator McConnell, 164 Cong. Rec. S3929-05 (June 14, 2018).

<sup>7</sup> <https://fns-prod.azureedge.net/sites/default/files/resource-files/ProcessingFactSheet.pdf>

beef to be processed into charbroiled patties, crumbles or meatballs and permits tomatoes to be further processed into salsa, marinara sauce, meat sauce or ketchup.<sup>8</sup>

ATACH is asking the USDA to consider deploying the same basic oversight regime with non-final work-in-progress hemp extract. Understanding the scientific challenges of the manufacturing process of hemp extract, and in particular CBD, is critical to appreciate why the stated DEA position is untenable and why the USDA is best suited to regulate this process. As hemp biomass and subsequent material is processed and refined for its cannabinoid content, the weight of the non-final work-in-progress material decreases while the quantity of cannabinoids (including THC and CBD) remains constant. The percentage concentration of cannabinoids inevitably rises when measured against a material that weighs less than its original state, even though the quantity of cannabinoids remains the same. This non-final work-in-progress material is not intended for human consumption and legally remains hemp, despite the fact that the delta-9 THC percentage of intermediate processed material may fluctuate during processing.

Under the plain language of the AIA, the Secretary of Agriculture is required to regulate this exact type of production.

## **II. Legislation delaying the implementation of the AIA to 2021 must be used to safe harbor and develop clear guidance.**

The short-term spending bill signed into law by President Trump on October 1, 2020, should be used to safe harbor and develop clear guidance so the lawful commercialization of hemp will not be impeded. Although some states have enacted AIA-compliant hemp programs, 27 states are not operating under the AIA, but instead are operating under the less restrictive hemp program guidelines set forth in the 2014 Farm Bill.<sup>9</sup> Extending the grace period for states to update their hemp programs forces hemp industry participants to continue operating under a patchwork of state laws.

Maintaining this bifurcated regulatory regime for another year will have unintended consequences for the hemp industry, as participants operating in states with a 2014 Farm Bill program may not benefit from many of the key provisions of the AIA. For instance, the AIA expanded the definition of “hemp” to include derivatives, extracts and cannabinoids, and removed hemp from the definition of federally unlawful marijuana under the Controlled Substances Act. *See* AIA, §§ 10113, 12619.<sup>10</sup> These two alterations made clear that hemp was lawful, and specifically that hemp-derived products – an exploding market in the hemp industry – were permissible. The changes also improve the ability of hemp industry participants to access banking services.<sup>11</sup> It remains to be seen

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<sup>8</sup> *Id.* at pg. 2.

<sup>9</sup> A table showing states with unapproved hemp plans is annexed as Exhibit “A.”

<sup>10</sup> The definition of hemp in the 2014 Farm Bill only set limits on delta-9 THC, while the 2018 Farm Bill and USDA interim regulations measure “total” THC. 84 Fed. Reg. 58,524 (Oct. 31, 2019).

<sup>11</sup> *See, e.g.,* Financial Crimes Enforcement Network, *FinCEN Guidance Regarding Due Diligence Requirements under the Bank Secrecy Act for Hemp-Related Business Customers* 1 (2020) (“This clarification is intended to enhance the availability of financial services for, and the financial transparency of, hemp-related businesses in compliance with federal law.”); National Credit Union Administration,

whether hemp grown in 2021 under the 2014 Farm Bill will be entitled to the same banking access. This position creates issues for businesses should interim safeguards not be in place.

The AIA also explicitly permits the interstate transportation of hemp: “[n]o State or Indian Tribe shall prohibit the transportation or shipment of hemp or hemp products”. *Id.* at § 10114. This provision is crucial for hemp businesses interested in expanding into new territories, as there have been several instances where states without hemp programs have initiated enforcement actions against hemp businesses that have attempted to ship hemp products through their states.<sup>12</sup> Finally, the AIA included provisions to allow hemp farmers to secure crop insurance under the Federal Crop Insurance Act, just as they could for other agricultural commodities. *Id.* at §§ 11101; 11119.

This period presents an additional layer of uncertainty for hemp industry participants looking to expand their operations into new commercial markets or jurisdictions where additional guidance is required. For example, several states, including Illinois and New York, have issued regulations or governmental guidance explicitly permitting medical and adult-use marijuana businesses to purchase hemp for use in cannabis-infused products.<sup>13</sup> But neither Illinois nor New York have had their AIA-compliant hemp programs approved by the USDA. Thus, hemp businesses in these states are currently producing hemp compliant with the 2014 Farm Bill.

This is problematic because unlike the AIA, the 2014 Farm Bill definition of “hemp” does not include derivatives, extracts and cannabinoids, and the 2014 Farm Bill only set limits on delta-9 THC, while the USDA interim regulations interpreting the 2018 Farm Bill measures “total” THC. 84 Fed. Reg. 58,524 (Oct. 31, 2019). These differing definitions of “hemp” raise a question as to whether hemp produced in accordance with a state’s 2014 Farm Bill program would necessarily comply with the dictates of the IFR. If not, this poses a potential conflict to state programs and state-licensed marijuana and hemp industry participants for the usage of hemp materials in their products.

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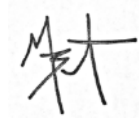
*Serving Hemp Businesses* (2019) (“Credit unions may provide the customary range of financial services for business accounts, including loans, to lawfully operating hemp-related businesses within their fields of membership.”).

<sup>12</sup> ATACH submitted an *amicus curiae* brief on this precise issue in *Big Sky Scientific LLC v. Jan Bennetts et al.*, 776 F. App’x 541 (9th Cir. 2019).

<sup>13</sup> N.Y. Comp. Codes R. & Regs. tit. 10, § 1004.11(n) (“a registered [medical marijuana] organization may use hemp, or extracts derived from hemp, grown and processed under the authority of the New York State Department of Agriculture and Markets in the manufacturing of medical marihuana products”); Ill. Dept. of Agriculture, *Illinois Department of Agriculture Policy Regarding Hemp and Hemp Derivatives in Medical and Adult-Use Cannabis Products* (2019) (“Cannabis business organizations licensed by the Illinois Department of Agriculture ... may use industrial hemp as an ingredient in cannabis-infused products offered for sale at licensed dispensaries in Illinois.”).

ATACH thanks the USDA for the opportunity to submit comments and looks forward to further discussion on these important issues facing the nascent hemp industry.

Sincerely,

A handwritten signature in black ink, appearing to read 'M. Bronstein', is centered on the page. The signature is written in a cursive, somewhat stylized font.

Michael Bronstein  
President and Co-Founder  
American Trade Association  
for Cannabis and Hemp

**EXHIBIT “A”**

<b>Unapproved States*</b>	<b>Status*</b>
Alabama	Under Review
Alaska	Drafting plan for USDA review
Arizona	Under Review
Arkansas	Under Review
California	Under Review
Colorado	Pending resubmission
Connecticut	Under Review
Hawaii	USDA Hemp Producer License
Idaho	Pending state legislation
Illinois	Pending resubmission
Indiana	Under Review
Kentucky	Under Review
Michigan	Under Review
Mississippi	USDA Hemp Producer License
Nevada	Under Review
New Hampshire	USDA Hemp Producer License
New Mexico	Under Review
New York	USDA Hemp Producer License
North Carolina	Will continue to operate under 2014 pilot
North Dakota	Under Review
Oklahoma	Under Review
Oregon	Under Review
Rhode Island	Will continue to operate under 2014 pilot
South Dakota	Under Review
Vermont	Under Review
Virginia	USDA Hemp Producer License
Wisconsin	Under Review

\* This information was extracted from <https://www.ams.usda.gov/rules-regulations/hemp/state-and-tribal-plan-review>.