

October 6, 2016

The Honorable Thomas J. Vilsack
Secretary
United States Department of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250

Dear Secretary Vilsack,

I write today regarding the joint Statement of Principles on Industrial Hemp (Federal Register; Vol 81: no.156) (herein referred to as the “Joint Statement”) developed by the U.S. Department of Agriculture (USDA) in consultation with the Drug Enforcement Agency (DEA) and the Food and Drug Administration (FDA). I was directly involved with the drafting and inclusion of Section 7606 in the Agricultural Act of 2014 (P.L. 113-79), as well as Section 763 in the Consolidated Appropriations Act of 2016 (P.L. 114-113, Division A). First, I would like to thank your agency for authorizing industrial hemp pilot programs to compete for federal grant funding through the National Institute of Food and Agriculture (NIFA). I am encouraged that this federal support will help enhance the research that is already being conducted. That said, while I am pleased that the USDA has been responsive to my inquiries regarding federal funding opportunities for industrial hemp research, I am concerned that other aspects of the Joint Statement are at variance with federal law and will inhibit lawful research into the promise of industrial hemp.

As you may know, Kentucky leads the country in the growth and production of industrial hemp. In 2016, over 4,600 acres were approved for hemp production – 2,300 of which are confirmed planted. Further, ten of our state’s colleges and universities are participating in hemp research that could be impacted by certain findings within the Joint Statement. I have enclosed for your reference a letter from Dr. David W. Williams, Professor from the University of Kentucky Department of Plant and Soil Sciences and largely considered one of the lead researchers on industrial hemp. As his letter explains, interpretations in the Joint Statement could immediately curtail research being conducted throughout the state, and specifically at the University of Kentucky.

For example, the Joint Statement appears to narrow the definition of industrial hemp beyond what Congress explicitly prescribed in the Agricultural Act of 2014. The Joint Statement defines industrial hemp as “the plant *Cannabis sativa* L and any part or derivative of such plant, whether growing or not, that is used exclusively for industrial purposes (fiber and seed) with a tetrahydrocannabinols concentration of not more than 0.3 percent on a dry weight basis,” and that “includes all isomers, acids, salts, and salts of isomers of tetrahydrocannabinols.” Federal law, however, defines “industrial hemp” based only on the presence of delta-9

tetrahydrocannabinols and only when it is present in a “concentration of not more than 0.3 percent on a dry weight basis.” See 7 U.S.C. Section 5940(b)(2). Congress explicitly based the definition of industrial hemp on the presence of “delta-9 tetrahydrocannabinol,” as this compound is the primary psychoactive ingredient found in the cannabis plant. Furthermore, Congress did not include in this definition “all isomers, acids, salts, and salts of isomers of tetrahydrocannabinols” in cannabis plants as the Joint Statement does. According to Dr. Williams, under the guidance contained in the Joint Statement, “many of the varieties [of industrial hemp] currently under study at UK will very likely exceed the 0.3% limit.” “Denying access to these varieties due to the concentrations of non-THC cannabinoids would significantly impede” UK’s research, he concludes.

In addition, the Joint Statement appears to limit marketing research for industrial hemp products, again in contravention of federal law. The Joint Statement provides that “industrial hemp products may be sold in a State with an agricultural pilot program or among States with agricultural pilot programs, but may not be sold in States where such sale is prohibited.” Federal law, however, does not limit the ability to sell lawfully grown industrial hemp products only to states with agricultural pilot programs. It only requires that the products be from “industrial hemp that is grown or cultivated in accordance” with an authorized pilot program. See Section 763(2) of P.L. 114-113 (Division A). The importation of hemp products is legal in all fifty states. And as Dr. Williams notes, “[i]f it becomes illegal to sell processed hemp products except in states with pilot research programs and/or for profit (general commercial activity), it will almost certainly have a very negative impact on the evolving hemp industry” in this country.

Although the Joint Statement acknowledges that it “does not establish any binding legal requirements,” I am concerned that some of its pronouncements will inhibit or prevent lawful research into the potential of industrial hemp. Please review the issues that I and the University of Kentucky have raised and please consider revising your guidance to ensure that it conforms to federal law. I look forward to your prompt response and to continuing to work with the USDA to enhance and build on the important industrial hemp research that has taken place thus far.

Sincerely,



MITCH McCONNELL
U.S. SENATE MAJORITY LEADER

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Enclosure

cc: The Honorable Chuck Rosenberg, Acting Administrator of the Drug Enforcement Agency
The Honorable Robert M. Califf, MD, Commissioner of the Food and Drug Administration



University of Kentucky
College of Agriculture, Food
and Environment
Department of Plant and Soil Sciences
105 Plant Science Bldg.
Lexington, KY 40546-0312
P: 859-218-0709

2 September 2016

Honorable Mitch McConnell
Senate Majority Leader
United States Senate
317 Russell Senate Office Building
Washington, DC 20510

Dear Senator McConnell,

We are writing regarding the *Statement of Principles on Industrial Hemp* published jointly by the U.S. Department of Agriculture, Drug Enforcement Administration, and the Food and Drug Administration on 12 August 2016 (Federal Register; Vol. 81: no. 156). Interpreted literally, the principles could have significant impacts on industrial hemp research at the University of Kentucky, as well as other participants in the industrial hemp pilot research program administered by the Kentucky Department of Agriculture (KDA).

Our main concern arises from the wording of the paragraph defining industrial hemp. The paragraph reads: "The term "industrial hemp" includes the plant *Cannabis sativa* L. and any part or derivative of such plant, including seeds of such plant, whether growing or not, that is used exclusively for industrial purposes (fiber and seed) with a tetrahydrocannabinols (THC) concentration of not more than 0.3 percent on a dry weight basis. The term "tetrahydrocannabinols" includes all isomers, acids, salts, and salts of isomers of tetrahydrocannabinols".

By way of further explanation of the reason for THC being a key part of the definition, THC is a cannabinoid. Cannabinoids are a class of molecules derived from *Cannabis* plants. There are dozens of known cannabinoids, many of which might be useful drugs. The most common example of a potentially useful drug is cannabidiol (CBD). However, the most famous cannabinoid is the psychoactive molecule delta-9-tetrahydrocannabinol (THC). The presence or absence of THC is generally considered the specific factor that defines *Cannabis* plants as marijuana (> 0.3% THC) or industrial hemp (<= 0.3% THC). This is exactly the case within the 2014 Farm Bill.

Our largest concern is due to the use of the word 'isomer' in the definition. The simple definition of isomer from *Merriam-Webster* is: "one of two or more compounds, radicals, or ions that contain the same number of atoms of the same elements but differ in structural arrangement and properties". In the case of THC (<https://pubchem.ncbi.nlm.nih.gov/compound/Dronabinol>) and CBD (<https://pubchem.ncbi.nlm.nih.gov/compound/cannabidiol>), both have the chemical

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formula $C_{21}H_{30}O_2$, but they have different chemical structures and properties. We cannot know if it was the intent of the federal agencies to include simple isomers in their definition of industrial hemp, or if they were specifically referring to the more common isomers of delta-9-THC (e.g., delta-1- and delta-6-THCs).

If the agencies intended to include other simple isomer cannabinoids (e.g., CBD) in their definition of industrial hemp, then many of the varieties currently under study at UK will very likely exceed the 0.3% limit. While UK has not routinely analyzed research plant material for the concentrations of other cannabinoids besides THC, anecdotal evidence would indicate that many of the varieties grown for fiber and/or seed would likely contain levels of CBD well above the 0.3% limit. Denying access to these varieties due to the concentrations of non-THC cannabinoids would significantly impede our research efforts with industrial hemp, and be in contradiction to THC measurements and hemp definitions used by other countries. It would be most desirable to request clarification from the federal agencies on this issue. We recommend that the definition clearly refer to THC and not contain the ambiguity about other cannabinoids.

A second concern is related to the broad class of cannabinoids. As mentioned previously, there is extensive interest in other, non-THC cannabinoids (e.g., CBD) as nutraceuticals and/or pharmaceuticals. This is true in Kentucky and in other states with pilot research programs. Today, approximately 60% of the total acreage within the hemp pilot program in Kentucky is devoted to the production of CBD. If the federal agencies intend to regulate the levels of CBD in industrial hemp plants to a level at or below 0.3%, then we cannot guarantee Kentucky hemp would be in compliance. Strict adherence to the recently published principles would effectively make CBD production fully illegal. We also notice that the wording "...exclusively for industrial purposes (fiber and seed)..." seems to legally preclude other uses of hemp plants beyond fiber and seed. UK is not offering a position on this issue. Rather, we are attempting to provide useful information to you regarding the potential effects of the new principles on the evolving hemp industry in Kentucky. Clearly, voiding the use of 60% of the current crop would have a very negative impact on Kentucky's pilot program.

Lastly, we would also like to make sure you are aware of two potential issues that are not directly related to research at UK. In the next paragraph following the definition of industrial hemp, the new principles state "For the purposes of marketing research by institutions of higher education or State departments of agriculture (including distribution of materials) but not for the purpose of general commercial activity, industrial hemp products may be sold in a State with an agricultural pilot program or among States with agricultural pilot programs, but may not be sold in States where such sale is prohibited. Industrial hemp plants and seeds may not be transported across State lines". The two potential issues follow. First, hemp and other bast fibers along with hemp grain are being processed and sold by companies in Kentucky. If it becomes illegal to sell processed hemp products except in states with pilot research programs and/or for profit (general commercial activity), it will almost certainly have a very negative impact on the evolving hemp industry. The hemp industry, including processors in Kentucky, provide significant financial support for research activities. If we lose our processors, then we will lose our ability to move forward with research with industrial hemp grown for fiber and grain. Second, Kentucky is in an

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excellent position to become the national leader in certified hemp seed production and sales. Significant acreage in Kentucky is devoted to certified seed production this year. These efforts are still small on a relative scale, and most of the certified seed produced in Kentucky this year can likely be sold in Kentucky. But, if fully enforced, this new principle will greatly restrict the growth of the certified hemp seed industry. Furthermore, prohibiting the movement of seeds across state lines would prohibit replicated studies using the same seed lots with collaborating universities in different states. There doesn't immediately seem to be strong logic in allowing importation of hemp seeds from foreign countries, but restrict transport of hemp seeds among states. Again, clarification from the federal agencies on both of these issues would be highly desirable.

We appreciate the opportunity to present this information to you. Please do not hesitate to contact us if you have any questions or if you require additional information. Thank you sincerely and in advance for your thoughtful consideration of these issues.

Very truly yours,



D.W. Williams, Professor
UK Department of Plant and Soil Sciences

cc: Honorable Ryan Quarles, Commissioner, Kentucky Department of Agriculture
Dr. Nancy Cox, Dean, UK College of Agriculture, Food and Environment
Dr. Rick Bennett, Associate Dean, UK College of Agriculture, Food and Environment
Mr. Drew Graham, Assistant Dean, UK College of Agriculture, Food and Environment
Mr. Eric King, UK Director of Federal Relations

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UK College of Opportunity University