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**MEMORANDUM** September 23, 2016

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**Subject:** Joint DEA/USDA/FDA "Statement of Principles on Industrial Hemp"

**This memorandum was prepared to enable distribution to more than one congressional office.**

This memorandum reviews recent U.S. agency administrative actions that address cultivation and research activities regarding industrial hemp, and highlights some of the questions and concerns that have been voiced in the U.S. hemp industry about these policies.

In August, 2016, the U.S. Drug Enforcement Administration (DEA) issued three major decisions on marijuana and industrial hemp.[1] Regarding marijuana, DEA announced it was rejecting a petition to reschedule marijuana (affirming its continued status as an illegal Schedule I controlled substance).[2] It also announced it was making certain policy changes regarding authorized marijuana cultivators for research.[3] Regarding industrial hemp, DEA issued a joint statement with the U.S. Department of Agriculture (USDA) and the Department of Health and Human Service's Food and Drug Administration (FDA) on the principles on industrial hemp. This memorandum addresses some of the issues related to the joint DEA/USDA/FDA statement regarding industrial hemp only: It does not discuss issues regarding recreational and/or medical uses of marijuana. Marijuana and industrial hemp are both of the plant species, *Cannabis sativa,* but hemp is genetically distinct from marijuana and is further distinguished by its use and chemical makeup as well as by differing cultivation practices in its production.[4]

Clarification regarding DEA's position on industrial hemp has been much anticipated by many in Congress and in the U.S. hemp industry, given continued uncertainty despite provisions supporting the cultivation of hemp enacted in the Agricultural Act of 2014 ("farm bill").[5] The joint DEA/FDA/USDA statement provides guidance to "individuals, institutions, and states" on a number of issues pertaining to

[1] For more information, see CRS Legal Sidebar WSLG1667, *DEA Will Not Reschedule Marijuana, But May Expand Number of Growers of Research Marijuana*.

[2] For more information on marijuana's current status and on rescheduling, see also CRS Report R43034, *State Legalization of Recreational Marijuana: Selected Legal Issues*, and CRS Legal Sidebar WSLG1423, *The Legal Process to Reschedule Marijuana*.

[3] For other related information, see: J.A. Gilbert, Jr. and L.K. Houck, "DEA Issues a Trifecta of Significant Marijuana and Industrial Hemp Decisions, Including Rejecting Rescheduling for Legitimate Medical Use," FDA Law blog (of Hyman, Phelps & McNamara, P.C), August 12, 2016, http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2016/08/dea-issues-a-trifecta-of-significant-marijuana-and-industrial-hemp-decisions-including-rejecting-res.html.

[4] For more information, see CRS Report RL32725, *Hemp as an Agricultural Commodity* .

[5] P.L. 113-79, §7606 (7 U.S.C. 5940).

the growing and cultivation of industrial hemp. The joint statement's guiding principles are provided in the **Appendix**.

Although some in the U.S. hemp industry—such as the Hemp Industries Association (HIA)—are encouraged by parts of the joint statement, they have expressed concerns about other aspects of the statement.[6] In addition, although the joint statement explicitly says it "does not establish any binding legal requirements," this still raises questions about whether guidance in the statement could influence future DEA policies and enforcement action regarding industrial hemp cultivation and marketing.

## Joint Statement of Principles on Industrial Hemp

The joint DEA/USDA/FDA "Statement of Principles on Industrial Hemp" has generated interest in Congress since it states that it is intended "to inform the public how Federal law applies to activities associated with industrial hemp that is grown and cultivated in accordance with Section 7606 of the Agricultural Act of 2014"... "so that individuals, institutions, and States that wish to participate in industrial hemp agricultural pilot programs can do so in accordance with Federal law."[7]

Section 7606 of the Agricultural Act of 2014 ("farm bill") legalized the growing and cultivation of industrial hemp for purposes of agricultural or other academic research, if grown and cultivated by an institution of higher education or state department of agriculture and if allowed under state laws where the institution or state department of agriculture is located. The farm bill also established a statutory definition of "industrial hemp" as "the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."[8]

In the joint statement, the three federal agencies—DEA, USDA, and FDA—acknowledge that the 2014 farm bill provision regarding industrial hemp "left open many questions regarding the continuing application of Federal drug control statutes to the growth, cultivation, manufacture, and distribution of industrial hemp products, as well as the extent to which growth by private parties and sale of industrial hemp products are permissible."[9]

The 2014 farm bill also "did not remove industrial hemp from the controlled substances list." Federal law continues to restrict hemp-related activities that were not specifically legalized under the farm bill provision, which did not amend requirements under the Controlled Substances Act of 1970 (CSA)[10] regarding the manufacture and distribution of "drug products" containing controlled substances. The farm

[6] See, for example: HIA, "Leading National Trade Association for Industrial Hemp Products Issues Response to Joint USDA & DEA Statement of Principles on Industrial Hemp," August 17, 2016; and HIA press release dated August 15, 2016 (https://www.thehia.org/HIAhemppressreleases/4196924).

[7] 81 *Federal Register* 156: 53395-53396, August 12, 2016. See also DEA's website: http://www.deadiversion.usdoj.gov/fed_regs/rules/2016/fr0812_4.htm.

[8] P.L. 113-79, §7606 (7 U.S.C. 5940). The provision was included as part of the research title of the law. Alternatively, the statutory definition of marijuana at 21 U.S.C. §802 states:

> (16) The term "marihuana" means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, 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.

[9] 81 *Federal Register* 156: 53395-53396, August 12, 2016.

[10] 21 U.S.C. §801 *et seq*.

bill provision also did not amend the Federal Food, Drug, and Cosmetic Act (FFDCA)[11] regarding the approval process for new drug applications.

The joint statement restates the 2014 farm bill's requirement that hemp be grown and cultivated "in accordance with an agricultural pilot program... established by a State department of agriculture or State agency... in a State where the production of industrial hemp is otherwise legal under State law."[12] It further notes that "state registration and certification of sites used for growing or cultivating industrial hemp" were not addressed in the 2014 farm bill, and recommends that "such registration should include the name of the authorized manufacturer, the period of licensure or other time period during which such person is authorized by the State to manufacture industrial hemp, and the location, including Global Positioning System coordinates, where such person is authorized to manufacture industrial hemp."[13]

## Selected Guidance/Clarification

Among the noted aspects of the joint DEA/USDA/FDA statement is clarification by the federal agencies about who is able to grow or cultivate industrial hemp as part of a state's agricultural research pilot program, and the applicability of USDA research and other programs to support industrial hemp. Other aspects of the joint statement, however, have raised concerns regarding how the federal agencies view the statutory definition of industrial hemp and also possible restrictions on the sale of industrial hemp products and the importation of viable seed for growing and cultivation. Each of these is discussed in the following sections.

### Clarification Regarding Who Can Grow/Cultivate Hemp

The joint statement acknowledges that the 2014 farm bill authorized "State departments of agriculture, *and persons licensed, registered, or otherwise authorized by them*" and "institutions of higher education[14] *or persons employed by or under a production contract or lease with them*" (italics added) to grow or cultivate industrial hemp as part of an agricultural pilot program in accordance with the 2014 farm bill provision. This seemingly clears up previous confusion regarding the potential participation of private farmers licensed or under contract with authorized state Departments of Agriculture and institutions of higher learning.

### Clarification Regarding USDA Research Support for Hemp

The joint statement clarifies that institutions of higher education and other authorized participants "may be able to participate in USDA research or other programs to the extent otherwise eligible for participation in those programs." This seemingly addresses questions raised in November 2015 by some members of Congress, as part of a letter sent to USDA requesting clarification on the extent to which federal funds may be used to support research on industrial hemp.[15]

Additional background information is provided in CRS Report RL32725, *Hemp as an Agricultural Commodity*. See section titled "Administrative Actions Regarding Industrial Hemp Research."

[11] 21 U.S.C. §301 *et seq*.

[12] 81 *Federal Register* 156: 53395-53396, August 12, 2016.

[13] Ibid.

[14] Although not defined in the 2014 farm bill, the joint statement defines "institutions of higher education" according to the Higher Education Act of 1965, §101 of (20 U.S.C. §1001).

[15] Letter to USDA Secretary Tom Vilsack signed by 37 Representatives and 12 Senators, November 20, 2015.

## Confusion Regarding the Definition of Industrial Hemp

Some in the hemp industry worry that the joint statement reinterprets the statutory definition of industrial hemp to cover fiber and seed only, excluding flowering tops, which they believe is covered by the farm bill definition.[16] The flowering heads of the plant have the greatest cannabinoid content.[17]They also worry that the joint statement expands upon inherent restrictions to the statutory definition in that it broadly highlights the term tetrahydrocannabinols (THC), which is defined to include "all isomers, acids, salts, and salts of isomers of tetrahydrocannabinols," whereas the statutory definition in the 2014 farm bill specifies delta-9 tetrahydrocannabinol (delta-9 THC), the dominant psychoactive cannabinoid of cannabis.

The definition in the joint statement might be considered more inclusive of certain tetrahydrocannabinol concentrations or THC isomers other than delta-9 THC. While THC is the primary psychoactive ingredient in cannabis, there are multiple THC isomers and variants (e.g., delta-8 THC, among multiple possible other variations).[18] Among the isomers of THC, properties may vary but not all have been well-characterized.[19] The interaction between THC and other non-THC cannabinoids in the cannabis plant is also not well known. (See text box for additional background information.)

Some remain confused by this interpretation and the relationship between THC and other cannabinoids, such as cannabidiol (CBD),[20] which some say may contradict information in other DEA documentation.[21] It remains unclear whether the joint DEA/USDA/FDA statement is contrary to the statutory definition in the 2014 farm bill, and whether it either requires consideration of or alternatively excludes consideration of other cannabinoids, such as CBD, which is generally considered to be non-psychoactive.

Other hemp producing countries have based their industrial hemp definition of THC more broadly (i.e., are not specific to delta-9 THC). Also, some countries specifically consider all parts of the plant, including leaves, stalks, flowers, and seeds. For example, Canada's hemp regulations define industrial hemp as:[22]

> the plants and plant parts of the genera *Cannabis*, the leaves and flowering heads of which do not contain more than 0.3% THC w/w [% weight per weight], and includes the derivatives of such plants and plant parts. It also includes the derivatives of non-viable cannabis seed. It does not include plant parts of the genera *Cannabis* that consist of non-viable cannabis seed, other than its derivatives, or of mature cannabis stalks that do not include leaves, flowers, seeds or branches, or of fibre derived from those stalks.

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[16] See, for example: HIA, https://www.thehia.org/HIAhemppressreleases/4196924. See also: J. Beckerman, Hemp Ace International, "The Curious Legal Status of CBD & Industrial Hemp-Derived Cannabinoids" webinar, September 13, 2016.

[17] Institute of Medicine, Marijuana and Medicine: Assessing the Science Base, J.E. Joy, S.J. Watson, Jr., and J.A. Benson, Jr. (editors), 1999.

[18] Other identified isomers of THC, such as delta-1 THC and delta-6 THC, may be related to delta THC-9 and delta-8 THC, respectively, but based no differing numbering systems.

[19] See, for example, E.A. Carlini, "The Good and the Bad Effects of (-) Trans-Delta-9-Tetrahydrocannabinol (Δ9-THC) on Humans," *Toxicon* 44:461-467, July 2004.

[20] See, for example: HIA, https://www.thehia.org/HIAhemppressreleases/4196924. See also: J. Beckerman, Hemp Ace International, "The Curious Legal Status of CBD & Industrial Hemp-Derived Cannabinoids" webinar, September 13, 2016.

[21] Beckerman cites: DEA, *The Dangers and Consequences of Marijuana Abuse*, 2014: specifically, "non-tetrahydrocannabinol marijuana derivatives that exists [sic] in the plant, such as cannabidiol and cannabinol."

[22] Canada's Minister of Justice, "Industrial Hemp Regulations," SOR/98-156, August 29, 2016, http://laws-lois.justice.gc.ca/PDF/SOR-98-156.pdf. Canada also has set a maximum level of 10 parts per million (ppm) for THC residues in products derived from hemp grain, such as flour and oil (See: Agriculture and Agri-Food Canada, "Industrial Hemp," http://www.agr.gc.ca/eng/industry-markets-and-trade/statistics-and-market-information/by-product-sector/crops/pulses-and-special-crops-canadian-industry/industrial-hemp/?id=1174595656066.)

In the European Union (EU), the regulatory threshold for hemp is the "weight of THC (tetrahydrocannabinol) in the weight of a sample maintained at constant weight is no more than... "0,2 % for the purposes of the grant of aid for subsequent marketing."[23] In New South Wales, Australia, there is a THC limit of 1%.[24] Regulatory thresholds for hemp grown in other countries, such as in China, Russia, and elsewhere, are more difficult to pin down. In most cases, hemp seeds are certified as having no more than 0.3% THC prior to cultivation.[25]

In Canada, marijuana plants are regarded as often having a THC level of 5% or more.[26] Some researchers suggest that marijuana plants have a THC level of more than 1%.[27]

### Cannabinoids

More than 480 natural components are found within the *Cannabis sativa* plant, of which 66 are classified as cannabinoids, or chemicals unique to the plant. Cannabinoids are separated into the following subclasses:

- Delta-9 tetrahydrocannabinol (delta-9 THC) — Number of known variants: 9
- Delta-8 tetrahydrocannabinol (delta-8 THC) — Number of known variants: 2
- Cannabigerol (CBG) — Number of known variants: 6
- Cannabichromene (CBC) — Number of known variants: 5
- Cannabidiol (CBD) — Number of known variants: 7
- Cannabinol (CBN) — Number of known variants: 7
- Cannabinodiol (CBND or CBDL) — Number of known variants: 2
- Cannabicyclol (CBL) — Number of known variants: 3
- Cannabielsoin (CBE) — Number of known variants: 5
- Cannabitriol (CBT) — Number of known variants: 9
- Other miscellaneous types — Number of known variants: 11

The most well-known and researched is delta-9-tetrahydrocannabinol (delta-9-THC), which is the primary psychoactive ingredient in cannabis. THC and CBD are generally considered to be among the most abundant cannabinoids in cannabis, and are both considered to be medically valuable.

**Source:** Institute of Medicine, Marijuana and Medicine: Assessing the Science Base, J.E. Joy, S.J. Watson, Jr., and J.A. Benson, Jr. (editors), 1999; and Australia's National Cannabis Prevention and Information Centre factsheet, "Cannabinoids," posted by the University of Washington's Alcohol & Drug Abuse Institute, http://learnaboutmarijuanawa.org/factsheets/cannabinoids.htm.

[23] Council Regulation (EC) No 1420/98 of 26 June 1998 amending Regulation (EEC) No 619/71 laying down general rules for granting aid for flax and hemp, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998R1420&from=EN. For other detailed country information, see nova-Institute, "Scientifically Sound Guidelines for THC in Food in Europe," July 2015, http://eiha.org/media/2015/08/15-07-24-Report-Scientifically-Safe-Guidelines-THC-Food-nova-EIHA.pdf.

[24] New South Wales government, "Growing Low THC Hemp under Licence in NSW, Frequently Asked Questions," PUB12/66, http://www.dpi.nsw.gov.au/__data/assets/pdf_file/0004/431095/Growing-low-THC-hemp-in-NSW-faq.pdf.

[25] See, for example, provisions in Colorado Industrial Hemp Act C.R.S. 35-61-101 (1), http://tornado.state.co.us/gov_dir/leg_dir/olls/sl2014a/sl_315.htm. The Association of Official Seed Certifying Agencies (AOSCA) has developed standards for certifying hemp seed.

[26] Agriculture and Agri-Food Canada, "Industrial Hemp," http://www.agr.gc.ca/eng/industry-markets-and-trade/statistics-and-market-information/by-product-sector/crops/pulses-and-special-crops-canadian-industry/industrial-hemp/?id=1174595656066.

[27] F. Grotenhermen and M. Karus, "Industrial Hemp is Not Marijuana: Comments on the Drug Potential of Fiber Cannabis," nova-Institute, http://www.internationalhempassociation.org/jiha/jiha5210.html.

## Confusion Regarding Possible Restrictions on Commerce

Some in the hemp industry remain concerned about the inclusion of language in the joint statement indicating that "industrial hemp products... may not be sold in States where such sale is prohibited," since broadly speaking "industrial hemp products" are already widely marketed, sold and distributed. Some claim this restriction on sales is contrary to provisions in both the CSA and the 2014 farm bill.[28]

The joint statement also emphasizes that "industrial hemp plants and seeds may not be transported across State lines," and restates DEA's position that the importation of viable cannabis seeds be carried out by DEA-registered persons, in accordance with the Controlled Substances Import and Export Act (CSIEA).[29] This remains a contentious issue, following DEA's blocking of viable hemp seed[30] from Italy, imported by the State of Kentucky's Department of Agriculture in May 2014. To facilitate release of the hemp seeds, the state filed a lawsuit in U.S. District Court against the DEA, the Justice Department, U.S. Customs and Border Protection (CBP), and the U.S. Attorney General.[31] Although Kentucky's seeds were eventually released and planted,[32] these events have created uncertainty for U.S. hemp growers.

The farm bill defines the term ''agricultural pilot program'' to mean "a pilot program to study the growth, cultivation, or *marketing* of industrial hemp" (italics added). Furthermore, the FY2016 appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (P.L. 114-113, §763) included a provision stating that "none of the funds made available" by the agricultural appropriation may be used" to prohibit the *transportation, processing, sale, or use* of industrial hemp that is grown or cultivated" (italics added), in accordance with the 2014 farm bill provision.

Additional background information is provided in CRS Report RL32725, *Hemp as an Agricultural Commodity*. See section titled "DEA's Blocking of Imported Viable Hemp Seeds."

[28] See, for example: HIA, https://www.thehia.org/HIAhemppressreleases/4196924.

[29] 21 U.S.C. §§951-971. See, for example, Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA Office of Diversion Control, to Luke Morgan, counsel for Kentucky Department of Agriculture, May 13, 2014.

[30] Viable seeds refer to seeds that are alive and have the potential to germinate and develop into normal reproductively mature plants, under appropriate growing conditions.

[31] Kentucky Department of Agriculture v. U.S. Drug Enforcement Agency, U.S. Customs and Border Protection, U.S. Justice Department, and Eric Holder (Western District of Kentucky, Louisville Division), May 2014, http://media.kentucky.com/smedia/2014/05/14/16/44/X9Fs3.So.79.pdf.

[32] J. Patton, "Hemp Seeds Planted in Central Kentucky for First Time in Decades," *Lexington Herald-Ledger*, May 27, 2014.

# Appendix. Joint DEA/USDA/FDA "Statement of Principles on Industrial Hemp"

As noted in the joint DEA/USDA/FDA "Statement of Principles on Industrial Hemp," published August 12, 2016, which is excerpted below:[33]

> USDA, having consulted with and received concurrence from the U.S. Drug Enforcement Administration (DEA) and the U.S. Food and Drug Administration (FDA), therefore, is issuing this statement of principles to inform the public regarding how Federal law applies to activities involving industrial hemp so that individuals, institutions, and States that wish to participate in industrial hemp agricultural pilot programs can do so in accordance with Federal law.

- The growth and cultivation of industrial hemp may only take place in accordance with an agricultural pilot program to study the growth, cultivation, or marketing of industrial hemp established by a State department of agriculture or State agency responsible for agriculture in a State where the production of industrial hemp is otherwise legal under State law.
- The State agricultural pilot program must provide for State registration and certification of sites used for growing or cultivating industrial hemp. Although registration and certification is not further defined, it is recommended that such registration should include the name of the authorized manufacturer, the period of licensure or other time period during which such person is authorized by the State to manufacture industrial hemp, and the location, including Global Positioning System coordinates, where such person is authorized to manufacture industrial hemp.
- Only State departments of agriculture, and persons licensed, registered, or otherwise authorized by them to conduct research under an agricultural pilot program in accordance with section 7606, and institutions of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)), or persons employed by or under a production contract or lease with them to conduct such research, may grow or cultivate industrial hemp as part of the agricultural pilot program.
- 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 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.
- For purposes of marketing research by institutions of higher education or State departments of agriculture (including distribution of marketing 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.
- Section 7606 specifically authorized certain entities to "grow or cultivate" industrial hemp but did not eliminate the requirement under the Controlled Substances Import

[33] 81 *Federal Register* 156: 53395-53396, August 12, 2016. See also DEA's website: http://www.deadiversion.usdoj.gov/fed_regs/rules/2016/fr0812_4.htm.

and Export Act that the importation of viable cannabis seeds must be carried out by persons registered with the DEA to do so. In addition, any USDA phytosanitary requirements that normally would apply to the importation of plant material will apply to the importation of industrial hemp seed.

- Section 7606 did not amend the Federal Food, Drug, and Cosmetic Act. For example, section 7606 did not alter the approval process for new drug applications, the requirements for the conduct of clinical or nonclinical research, the oversight of marketing claims, or any other authorities of the FDA as they are set forth in that Act.
- The Federal Government does not construe section 7606 to alter the requirements of the Controlled Substances Act (CSA) that apply to the manufacture, distribution, and dispensing of drug products containing controlled substances. Manufacturers, distributors, dispensers of drug products derived from cannabis plants, as well as those conducting research with such drug products, must continue to adhere to the CSA requirements.
- Institutions of higher education and other participants authorized to carry out agricultural pilot programs under section 7606 may be able to participate in USDA research or other programs to the extent otherwise eligible for participation in those programs.