Congressional Research Service
Informing the legislative debate since 1914

IN FOCUS

August 18, 2023

FDA's Oversight of Hemp-Derived Compounds

In January 2023, the Food and Drug Administration (FDA) issued a statement that the agency would "work with Congress" to develop "a new regulatory pathway" for cannabidiol (CBD), a hemp-based cannabinoid. This action followed years of FDA review by a high-level internal working group related to the regulation of CBD products. In July 2023, several Members of Congress issued a Request for Information (RFI) soliciting stakeholders on how to "provide a legal pathway" for marketing CBD products. Some in Congress have continued to introduce legislation that would allow for the use of hemp-derived CBD and related substances in dietary supplements and as a food additive. This issue, or aspects of it, could be debated as Congress considers reauthorization of the next farm bill.

Background

The Agriculture Improvement Act of 2018 (P.L. 115-334; 2018 farm bill) removed long-standing federal restrictions on the cultivation of hemp. Following the 2018 farm bill, hemp is now an agricultural crop regulated by the U.S. Department of Agriculture (USDA) under the Domestic Hemp Production Program (7 U.S.C. §1639(o)-(r); 7 C.F.R. §990). The 2018 farm bill, however, explicitly preserved the authority of the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§301 et seq.) related to hemp-based products such as CBD and other hemp-derived cannabinoids that may be used as an ingredient in food and some consumer products. Immediately after enactment of the 2018 farm bill, FDA stated that it is "unlawful" under FFDCA to introduce food containing added cannabinoids into interstate commerce, or to market such products as (or in) dietary supplements, "regardless of whether the substances are hemp-derived." Although FDA has continued to maintain that it is unlawful to add hemp-derived cannabinoids to food or to market cannabinoids including CBD as an ingredient in food and beverages or as a dietary supplement, consumer products containing these compounds continue to be marketed in violation of FDA's determination. *Hemp Business Daily* reports there were more than 3,000 known hemp-derived CBD brands in 2020.

Some claim that the lack of a federal regulatory framework for hemp-derived compounds has contributed, in part, to disruption of the U.S. hemp market, leading to both lower prices received by growers and subsequent production declines. USDA reports that the farm-level value of hemp sales and planted acres declined sharply between 2021 and 2022. This decline spans all production types (i.e., grown in the open field or under protection, such as in a greenhouse) and all market segments (i.e., hemp flower, grain, seed, and fiber). Losses were pronounced in the hemp flower market, which is the source of most hemp-based derivatives and compounds such as hemp-derived CBD and other cannabinoids. USDA reports that the farm-level value of all hemp flower production totaled $204 million in 2022, down from $687 million in 2021 (**Table 1**). Estimates of the retail value of hemp-derived cannabinoids vary but likely exceed $2 billion annually in the United States.

Table 1. U.S. Hemp Production by Market, 2021-2022

Production Type and Market Segment	2021	2022	Change
	($million)		(percentage)
Hemp Production in Outdoor Open Field			
Floral hemp	623.0	179.0	(71%)
Hemp grains	6.0	3.6	(40%)
Hemp fiber	41.4	28.3	(32%)
Hemp seed	41.5	1.5	(96%)
Subtotal	**711.9**	**212.4**	**(70%)**
Hemp Production Under Protection			
Floral hemp	64.4	24.7	(62%)
Hemp seed	23.7	0.6	(98%)
Clones/Transplants	23.8	0.7	(97%)
Subtotal	**111.9**	**26.1**	**(77%)**
Total Farm-Level Value	**823.8**	**238.4**	**(71%)**
Planted Acres (all uses)	**54,152**	**28,314**	**(48%)**

Source: CRS from USDA's 2021 and 2022 National Hemp Report, https://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Hemp/.

Hemp-Derived *Cannabinoids*

Botanically, hemp is from the plant species *Cannabis sativa*—the same plant as marijuana—but from different varieties or cultivars and grown for non-psychoactive purposes. *Cannabinoids* refer to the unique chemical compounds produced in the cannabis plant (both hemp and marijuana). There are more than 100 cannabinoids in the cannabis plant. These compounds exist in varying amounts in the cannabis plant and are known to exhibit a range of psychological and physiological effects. The two most well-researched and abundant cannabinoids in the cannabis plant are tetrahydrocannabinol (THC) and CBD. THC is the primary psychoactive compound; some THC variants and isomers (such as delta-8 THC) are known intoxicants. Certain other cannabinoids, notably CBD, are not considered to be psychoactive. Still other cannabinoids, as well as their interactions with THC, have not been extensively researched. More background is available in CRS Report R44742, *Defining Hemp: A Fact Sheet*.

FDA's Review of Cannabis Compounds

In May 2019, FDA conducted a public hearing and initiated its formal review "to obtain scientific data and information about the safety, manufacturing, product quality, marketing,

labeling, and sale of products containing cannabis or cannabis-derived compounds" (84 *Federal Register* 12969; Docket No: FDA-2019-N-1482). FDA's docket contains roughly 4,300 public comments and submitted materials. Currently, the only FDA-approved use of CBD as a pharmaceutical drug that contains an active ingredient derived from cannabis is Epidiolex, which is medically prescribed to treat seizures associated with rare and severe forms of epilepsy. More background on FDA requirements related to the use of hemp-derived compounds as an ingredient in food, dietary supplements, and other consumer products is available in CRS Report R46189, *FDA Regulation of Cannabidiol (CBD) Consumer Products: Overview and Considerations for Congress*.

FDA has conducted a series of cannabinoid-related activities since initiating its review in 2019, as documented on the agency's websites related to cannabis. FDA has continued to issue warning letters to companies for illegally selling CBD products or food and beverage products that contain CBD; for selling such products for advertised uses such as pain relief, to treat medical conditions, or opioid addiction; or for use in food-producing animals. FDA has also issued warning letters to companies illegally selling delta-8 THC products. Both FDA and the Federal Trade Commission (FTC) have issued warnings to companies for illegally selling certain copycat food products containing delta-8 THC that are misleading to consumers, since they are packaged to mimic popular brands like Doritos and Jolly Rancher. FDA also has issued warnings to consumers about the accidental ingestion by children of food products containing THC and other cannabinoid-containing products.

FDA has continued to conduct its scientific data and information review of products containing cannabis or cannabis-derived compounds, including hemp-based compounds. FDA and its science advisory committee have compiled documentation and conducted literature reviews on the safety of ingesting cannabinoid-containing products, including gender differences in use and response. FDA also has issued industry guidance for clinical research. FDA has responded to Generally Recognized as Safe (GRAS) notices for hemp seed-derived ingredients for use in human food and beverages, covering hulled hemp seed (GRN765), hemp seed protein powder (GRN771), and hemp seed oil (GRN778). FDA has rejected citizen petitions that would allow CBD products to be marketed as dietary supplements. FDA continues to review petitions for hemp seedcake and meal for use as an animal feed ingredient. FDA claims data is needed to help ensure ingredients derived from hemp are safe for use in feed for food-producing animals.

In January 2023, FDA concluded that "existing regulatory frameworks for foods and supplements are not appropriate" for CBD, referring the issue to the U.S. Congress. FDA stated that the agency's "existing foods and dietary supplement authorities provide only limited tools for managing many of the risks associated with CBD products" and that "under the law, any substance, including CBD, must meet specific safety standards to be lawfully marketed as a dietary supplement or food additive." FDA stated "a new regulatory pathway would benefit consumers by providing safeguards and oversight to manage and minimize risks related to CBD products" such as through clear product labeling, prevention of contaminants, content limits, and control measures (e.g., minimum purchase age to "mitigate the risk of ingestion by children"). A new regulatory pathway could also provide access and oversight of certain CBD-containing products for animals such as domesticated pets and food-producing animals. Current FDA safety standards for dietary supplements require that products are "reasonably expected to be safe" while the safety standards for food ingredients require products to have "reasonable certainty of no harm."

Selected FDA Statements on the Safety of Hemp-Derived CBD and Other Cannabinoids

Following are selected excerpts from FDA's statements, various agency warning letters, and consumer safety announcements.

- "The use of CBD raises various safety concerns, especially with long-term use. Studies have shown the potential for harm to the liver, interactions with certain medications and possible harm to the male reproductive system. CBD exposure is also concerning when it comes to certain vulnerable populations such as children and those who are pregnant" and "poses risks to animals, and people could be unknowingly exposed to CBD through meat, milk and eggs from animals fed CBD."
- "… CBD products that are especially concerning from a public health perspective due to the route of administration, including nasal, ophthalmic and inhalation."
- "… there have been numerous poison control center alerts involving pediatric patients who were exposed to delta-8 THC-containing products" and "animal poison control centers have indicated a sharp overall increase in accidental exposure of pets to these products."

Source: CRS from various FDA press releases. For more on the potential safety risks, see CRS Report R46189, *FDA Regulation of Cannabidiol (CBD) Consumer Products: Overview and Considerations for Congress*.

Recent Congressional Actions

The 118th Congress has continued to consider legislation that would allow hemp-derived CBD and hemp-derived CBD-containing substances to be marketed as dietary supplements or food additives (e.g., H.R. 4849/S. 2451, H.R. 1628, H.R. 1629). In addition, the Subcommittee on Health Care and Financial Services of the House Committee on Oversight and Accountability held a hearing in July 2023 titled "Hemp in the Modern World: The Yearslong Wait for FDA Action," which examined FDA's oversight of hemp and hemp CBD products.

In July 2023, several Members of Congress and leadership of the House Energy and Commerce and Senate Health, Education, Labor, and Pensions (HELP) Committees issued a bicameral RFI on FDA's regulation of CBD. The RFI solicits stakeholders on how to provide a "legal pathway to market for CBD products," including other cannabinoid-containing hemp products. The RFI's questions for stakeholders span market dynamics; regulatory pathways and scope; federal-state regulatory and enforcement interactions; public safety and risk; consumer protections and quality controls; and questions related to product form, packaging, accessibility, and labeling.

Renée Johnson, Specialist in Agricultural Policy

Disclaimer