

Consumable Hemp 101

Basics Fact Sheet



The Association of Food and Drug Officials does not endorse the use of cannabis, including marijuana, CBD or hemp. This document is intended to familiarize regulators with information which may assist when dealing with potential regulations in a state.

GENERAL

- Hemp and marijuana are the plant *Cannabis Sativa* which comes from the plant family *Cannabaceae*.
- The distinction between hemp and marijuana is determined by the plant's THC concentration.
- Hemp must have a THC level of 0.3 percent or less and marijuana can have a THC level over 0.3 percent.
- Why 0.3 percent for CBD and hemp? The 2018 Farm Bill definition of "hemp" including "no more than 0.3 percent THC on a dry weight basis removed this level from the definition of marijuana in the Controlled Substances Act.
- Cannabinoids are naturally occurring compound found in the *Cannabis Sativa* plant. There are over 400 different naturally occurring compounds in the plant.
- The two most talked about cannabinoids are CBD and THC.
- Cannabidiol (CBD) does not produce a psychoactive effect known as a "high".
- Delta-9-tetrahydrocannabinol (THC) is the well-known compound which has the psychoactive effect known as a "high".



BACKGROUND

- The production of hemp was approved in The Agriculture Improvement Act of 2018 (2018 Farm Bill).
- The 2018 Farm Bill removed hemp, hemp seeds, derivatives including extracts from the Drug Enforcement Agency (DEA) list of scheduled Controlled Substances.
- The United States Department of Agriculture (USDA) was directed to issue regulations and guidance for the nation.
- States are required to submit plans and receive approval from the USDA for the domestic production of hemp.
- States having approved plans from USDA: <https://www.ams.usda.gov/rules-regulations/hemp/state-and-tribal-plan-review>
- USDA authority and regulations are for the growing and harvesting of hemp and do not address any approvals for hemp derivatives or CBD to be used as food additives.

- The Food and Drug Administration (FDA) has oversight for food, dietary supplements, and medicine in the United States.
- There is currently no federal law which approves the use of hemp extracts or CBD oil in any food, beverage, or dietary supplement.
- CBD is currently not generally recognized as safe (GRAS) and is considered an “adulterant” in the FD&C Act.
- There are no federal laws for producing food containing CBD oil, labeling requirements, levels of toxicity, laboratory testing methods, approved pesticides, etc.
- Hemp seed-derived ingredients have been approved by FDA as GRAS to be used in food: <https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notice-hemp-seed-derived-ingredients-use-human-food>.
- FDA warning letters are being issued to companies who violate the FD&C Act for selling CBD products in interstate commerce who make marketing claims to prevent, diagnose, mitigate, treat or cure diseases in human and animal foods.
- As of March, 2020, FDA has approved one CBD product, Epidiolex, as a prescription drug to treat severe forms of epilepsy.

CURRENT SITUATION

- States are independently enacting legislation to recognize products containing CBD intended for ingestion are considered “food” (either conventional foods, or dietary supplements), and CBD as an ingredient in food or animal feed is not considered an adulterant.
- States are adopting laws and regulations for the licensing, processing, inspection, labeling, testing, test methods and more, which will allow their state to produce and sell foods which contain CBD oil.



PUBLIC HEALTH CONCERNS

- Lack of consistent laws and regulations across the nation makes it difficult for consumers to know if the CBD products they are consuming are regulated.
- Consumers may have a false sense of security that companies producing CBD products are regulated and inspected for accuracy of labels, concentrations of CBD, and verification of independent analysis on the products for contaminants (biological, chemical).
- Currently there is no federally recognized information regarding the effects of CBD on the developing fetus, pregnant mother, or a breastfed baby.
- Unknown health effects may exist from risks associated with pesticides, heavy metals, bacteria, fungus, and other contaminants.
- There may be effects related to liver toxicity(damage) and harmful interactions with other drugs.
- For more information on health impacts of cannabis derived products see <http://www.afdo.org/resources/Documents/Cannabis-Page/AFDO%20Cannabis%20Usage%20Fact%20Sheet.pdf>.

CONSIDERATIONS

- THC is sensitive to hot and cold temperature and can alter the concentration of THC. Practices where temperature control is critical include distillation, processing, storage, and transportation.
- Sourcing of hemp oil from other states where regulations may be different.
- Labeling of CBD products from other states where regulations may be different.



ADDITIONAL RESEOURCES:

- <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#relatedinfo>
- <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/about/cannabidiol.html>

AFDO is an international leader and trusted resource for building consensus and promoting uniformity on public health and consumer protection issues related to the regulation of foods, drugs, devices, cosmetics and consumer products.

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