Florida Department of Agriculture and Consumer Services
Division of Food Safety

HEMP FOOD
ESTABLISHMENT GUIDANCE
Florida Senate Bill 1020 passed in May 2019 and was signed by the governor into law effective July 1st, 2019. This bill created section 581.217, Florida Statutes, and gives the Florida Department of Agriculture and Consumer Services (FDACS) regulatory authority over Hemp and Hemp Extract. As part of the State Hemp Program, FDACS Division of Food Safety has adopted Rule 5K-4.034, Florida Administrative Code. This rule regulates the sale of Hemp Extract.

1. Definitions

“Hemp” means the plant *Cannabis sativa L.* and any part of that plant, including the seeds, that has a total delta-9-tetrahydrocannabinol (THC) concentration which does not exceed 0.3%.

“Hemp Extract” means a substance or compound intended for *ingestion*, containing more than trace amounts of cannabinoid that is derived from or contains hemp and that does not contain other controlled substances. The term does not include seeds or seed-derived ingredients that are generally recognized as safe by the United States Food and Drug Administration.

A “Hemp Food Establishment” is an establishment engaged in manufacturing, processing, packing, holding, preparing, or selling food consisting of or containing Hemp Extract at wholesale or retail.

“Ingestion” is the process of taking food into the body through the mouth and into the gastrointestinal tract through eating or drinking.

2. Is CBD the same as Hemp?

Cannabinoids such as Cannabidiol (CBD) are derived from the Hemp plant. Products containing CBD, other cannabinoids, or any part of the Hemp plant as defined above are considered “Hemp Extract” and will be subject to Rule 5K-4.034, FAC.

3. What is the difference between Hemp and marijuana?

They are both varieties of the plant *Cannabis sativa L.*, however, Hemp has a total THC level that does not exceed 0.3%. Marijuana has THC levels that exceed this amount.

4. What is a “Hemp Food Establishment?”

Any establishment that manufactures, processes, packs, holds, prepares, or sells food consisting of or containing Hemp Extract is considered a Hemp Food Establishment and is required to have a food permit to operate in Florida.
5. What kind of Hemp products does FDACS Division of Food Safety regulate?
Any Hemp Extract or product containing Hemp Extract intended for ingestion will be regulated by the Division of Food Safety.

6. If I already have a food permit with FDACS, what do I need to do to sell Hemp products?
When you apply for your annual food permit, you will be asked if you sell or plan to sell Hemp products intended for human ingestion. You must report “yes” on your food permit renewal application and you will be designated as a “Hemp Food Establishment.” If you offer Hemp products after your permit has been issued, you must call the business center at 850-245-5520 or go online to FDACS.gov to update your records.

7. Will my food permit fee change if I begin to sell Hemp extract products?
The annual permit fee for Hemp Food Establishments is $650. If your current food permit fees are less than this, they will increase to $650.

8. If I do not have a food permit through FDACS, what steps do I need to take?
A food permit application may be submitted online, faxed or mailed to the business center. Please note that faxing or mailing your permit application will likely result in a delay in the processing of your permit application. Your facility must also meet the appropriate Minimum Construction Standards (MCS) based on the processing and operations planned for your business. MCS guidance and the permit application information can be found at www.fdacs.gov/Divisions-Offices/Food-Safety. An optional FDACS plan review service is available upon request to review and approve the establishment’s proposed facility layout prior to the permitting process.
9. Can businesses that operate under the Cottage Food Laws offer Hemp products?

No, the Cottage Food Laws do not cover Hemp Extract and a food permit will be required to carry Hemp Extract products.

10. Will I need a food permit if I only sell Hemp Extract products for ingestion online and do not store any Hemp products at my physical location?

Yes, a food permit is still required. There are specific labeling requirements in Florida Law and the products are subject to testing by the state’s laboratories. Additionally, online sellers of Hemp Extract are required to make sure their products meet the "approved source" requirements in Rule 5K-4.034, FAC. This means any products sold online must be manufactured in a facility that is subject to a food safety inspection program and meets their inspection requirements.

11. Will I need a special food permit if I want to sell Hemp Extract products intended for human ingestion from a mobile sales unit?

Mobile food establishments may sell Hemp Extract as long as they meet all of the requirements for both mobile food establishments and Hemp food establishments; both of which include being properly permitted.

12. What kind of health claims am I allowed to make for the Hemp Extract that I carry?

Any statement or claim, either on the container itself or on any advertisement for the product, that the Hemp Extract is intended to diagnose, cure, mitigate, treat, or prevent a disease is not allowed.
13. What is considered an “approved source” for my Hemp Extract?

All Hemp Extract must be processed and distributed by facilities that are permitted and inspected by their local and/or state food safety jurisdictions. Hemp Food Establishments selling food products containing hemp extract can be asked to provide a copy of the processor/distributor’s food permit and most recent inspection report to FDACS upon request showing that they meet their local jurisdiction’s food inspection requirements.

14. What are the labeling requirements for items such as a bottle that is sold in a sealed box? Are both the bottle and box required to meet the hemp labeling requirements?

Both the bottle and box must meet the general labeling requirements for all food products as shown in Section 1 of the Labeling Guidelines on page 6 of this guidance. The hemp labeling requirements shown in Section 2 only apply to the external container that the consumer will take with them.

15. How can I verify that the Hemp products that I carry have acceptable levels of THC?

This is accomplished through laboratory testing. All Hemp food products must be accompanied by a lab report called a “Certificate of Analysis.” Hemp extract may only be distributed and sold in the state if the product has a certificate of analysis prepared by an independent laboratory that states that the batch contained a total delta-9 tetrahydrocannabinol concentration that did not exceed 0.3 percent, pursuant to the testing of a random sample of the batch.

16. Where can I get the Certificate of Analysis (COA) for the Hemp products that I carry?

Hemp manufacturers are required to test each batch of Hemp Extract that they produce. If the manufacturer is unable to provide a COA, the Hemp Extract is not in conformance with Florida Law.
17. Are there any additional storage requirements for Hemp Extract food products?

Hemp Extract must be packaged in containers that minimize exposure to light. To prevent the degradation of cannabinoids, storage at or below room temperature is recommended.

18. What if I find out that a Hemp Extract product that I carry has unacceptable levels of THC?

FDACS has published a Hemp Waste Disposal Manual that is available on FDACS.gov. This manual must be followed for disposing any Hemp Extract with THC that exceeds acceptable levels. In addition, a completed “Notice of Disposal” form also available on FDACS.gov must be submitted to FDACS upon disposal.

19. Where can I go to find additional information about Hemp?

You may call the FDACS business center at (850) 245-5520 or go online to www.fdacs.gov/Cannabis/Hemp-CBD-in-Florida for additional information about Hemp in Florida. Also, please refer to section 581.217, Florida Statutes and Rule 5K-4.034, Florida Administrative Code for specific Hemp Extract regulations.
HEMP EXTRACT LABELING GUIDELINES

1. Existing labeling requirements pursuant to 21 CFR Part 101 for all packaged food products include the following:
   - The common name of the product.
   - A list of ingredients (including sub-ingredients) in order of abundance.
   - The business name and address of the manufacturer, packer, or distributor.
   - An accurate declaration of the quantity of the contents in both SI and U.S. Customary units, such as ml. and oz.
   - A Nutrition Facts panel, unless exempt.
   - Servings per container and the serving size.
   - The label, and advertisement, shall not contain claims indicating the product is intended for diagnosis, cure, mitigation, treatment, or prevention of disease rendering it a drug as defined in 21 U.S.C. 321(g)(1).

2. In addition to the above requirements, food products containing hemp extract must be distributed and sold in a container that includes:
   1. A scannable barcode or quick response code linked to the certificate of analysis of the hemp extract by an independent testing laboratory,
   2. The batch number,
   3. The internet address of a website where batch information may be obtained,
   4. The expiration date,
   5. The number of milligrams of each marketed cannabinoid per serving.

Nutrition Facts

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<th>Amount/serving</th>
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30 servings per container

Serving size 1 dropperful (1mL)

Calories per serving 10

15 mg of CBD per serving.

Sample CBD Co., Orlando, FL 32810. Find more info at: www._______com
Questions about Hemp?

For additional information, visit our website:
FDACS.gov/Cannabis/Hemp-CBD-in-Florida