

Florida Department of Agriculture and Consumer Services Division of Food Safety

HEMP FOOD ESTABLISHMENT GUIDANCE



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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 is in rulemaking to adopt Rule 5K-4.034. This rule will regulate 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% on a dry-weight basis.

"Hemp Extract" means a substance or compound intended for ingestion that is derived from or contains Hemp and that does not contain other controlled substances.

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 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% on a dry weight basis. 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 human ingestion will be regulated by the Division of Food Safety. Hemp Extract products intended for animal ingestion will be regulated by the FDACS Division of Agricultural Environmental Services. Find out more at https://www.fdacs.gov/Divisions-Offices/Agricultural-Environmental-Services

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 FDACS 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, or faxed or mailed to the FDACS 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 package 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. Retailers selling the end product must be able 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. Are Hemp products that are "Generally Recognized as Safe" (GRAS) by the FDA excluded from the requirements of s. 581.217, FS?

No, GRAS Hemp products are not excluded from s. 581.217, F.S., or Rule 5K-4.034, FAC. If any part of the Hemp plant, including the seeds, is used in a product intended for human ingestion, it must follow all of the requirements of s. 581.217, F.S., and Rule 5K-4.034, FAC.

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." This report must represent the product and verify through laboratory testing that the levels of THC are less than 0.3% on a dry weight basis.

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

Hemp processors are required to test each batch of Hemp Extract that they produce. If the processor 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.



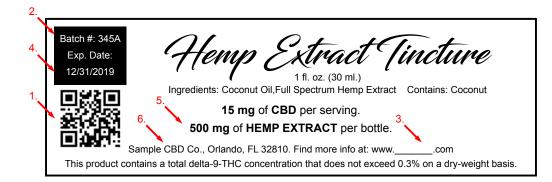
HEMP EXTRACT LABELING GUIDELINES

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 quantity.
- The business name and address of the manufacturer, packer, or distributor.
- · An accurate declaration of the quantity of the contents in proper dual units.
- A Nutrition Facts panel, unless exempt.
- 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 packaging 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 Hemp Extract. The specific cannabinoids marketed must be listed. The serving size shall be displayed on the nutrition facts label of the product,
- 6. A statement that the product contains a total delta-9 tetrahydrocannabinol concentration that does not exceed 0.3% on a dry-weight basis.



Nutrition Facts	Amount/serving		% Daily Value*	Amount/serving	% Daily Value*	*The % Daily Valu
	Total Fat 1g		1%	Total Carbohydrate 0g	0%	(DV) tells you he much a nutrient
	Saturated Fat 1g		5%	Dietary Fiber 0g	0%	
30 servings per container Serving size 1 dropperful (1mL)	Trans Fat 0g			Total Sugars 0g		
	Polyunsaturated Fat 1g			Includes 0g Added Sugars	0%	
	Monounsaturated Fat 0g			Sugar Alcohol 0g		
	Cholesterol 0mg		0%	Protein Og	0%	
Calories 10	Sodium Omg		0%			
	Vitamin D 0mcg	0% •	 Calcium 0mg 	0% • Iron Omg	0%	
	Potassium 0mg	0%				



Questions about Hemp?

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



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