The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

3.					RC			
. Ox	Oxamendi		Imhof		IT	Pre-meeting		
. <u>Be</u>	cker	Becker		AG	Fav/CS			
	ANALYST		STAFF DIRECTOR		REFERENCE		ACTION	
DATE:		February 14, 2020 REVISED:						
SUBJECT:		State Hemp Program						
INTRODUCER:		Agriculture Committee and Senator Montford						
BILL:		CS/SB 1876						
	Pre	pared by: The	Profession	al Starr of the Co	ommittee on Innova	ition, maustry, a	and rechnology	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1876 makes changes to the state hemp program. Specifically, the bill:

- Includes hemp extract in the definition of "food" in the Florida Food Safety Act;
- Requires persons who operate minor food outlets (which sell only commercially prepackaged food that is not potentially hazardous, or not time or temperature controlled for safety, if the shelf space for those items does not exceed 12 total linear feet) that sell hemp extract to obtain a food permit from the Department of Agriculture and Consumer Services (department);
- Removes a reference to the Department of Health's regulation of medical marijuana in the definition of the term "contaminants unsafe for human consumption;"
- Includes a substance or compound that is intended for inhalation in the definition of "hemp extract;"
- Exempts synthetic cannabidiol (CBD) oil and seeds and seed-derived ingredients that are generally recognized as safe by the United States Food and Drug Administration from the definition of "hemp extract;"
- Modifies how delta-9-tetrahydrocannibinol (THC) is measured in hemp extract;
- Clarifies that a hemp extract container must contain the number of milligrams of each cannabinoid per serving;
- Provides that hemp extract that does not meet certain requirements is considered adulterated or misbranded;

• Prohibits the sale of products that are intended for inhalation and made from hemp extract to a person who is under 21 years of age;

- Allows the department to contract with entities to provide sample collection, laboratory testing, and disposal services; and
- Provides a process for the department to notify a licensee when hemp is produced with a
 THC level that exceeds 0.3 percent as well as removal and destruction procedures. Damages
 may not be awarded for the destruction of the plants.

II. Present Situation:

Industrial Hemp

Industrial hemp is a *Cannabis sativa* plant (cannabis) that has been cultivated for approximately 10,000 years as a fiber and grain crop. It is used for fiber, building materials, forages (animal feed), and pain relief as a topical oil.¹

Cannabis

Cannabis is a Schedule I controlled substance.² It is a felony of the third degree³ to sell, manufacture, deliver, or possess with intent to sell, manufacture, or deliver, cannabis in Florida.⁴ As a controlled substance in ch. 893, F.S., "cannabis" is defined to mean: all parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. The term does not include "marijuana," as defined in s. 381.986, F.S., if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed, in conformance with s. 381.986, F.S., [the Compassionate Medical Cannabis Act of 2014], hemp as defined in s. 581.217, F.S., [the state hemp program], or industrial hemp as defined in s. 1004.4473, F.S., [industrial hemp pilot projects].⁵

Medical Marijuana

On November 4, 2016, Amendment 2 was approved by the electors and is codified in Article X, section 29, of the Florida Constitution. This section of the constitution became effective on January 3, 2017, and created several exemptions from criminal and civil liability for:

- Qualifying patients medically using marijuana in compliance with the amendment;
- Physicians, solely for issuing physician certifications with reasonable care and in compliance with the amendment; and
- Medical marijuana treatment centers (MMTCs), their agents, and employees for actions or conduct under the amendment and in compliance with rules promulgated by the Florida Department of Health.

¹ See University of Florida, UF/IFAS Industrial Hemp Pilot Project at: https://programs.ifas.ufl.edu/hemp/ (last visited February 10, 2020).

² Section 893.03(1)(c)7., F.S.

³ Section 775.082, F.S., provides that a felony of the third degree is punishable by a term of imprisonment not to exceed five years. Section 775.083, F.S., provides that a felony of the third degree is punishable by a fine not to exceed \$5,000.

⁴ Section 893.13(1)(a)2., F.S.

⁵ Section 893.02(3), F.S.

Subsequently, the Legislature passed SB 8-A in Special Session A of 2017.⁶ The bill revised the Compassionate Medical Cannabis Act of 2014⁷ in s. 381.986, F.S., to implement Article X, section 29 of the Florida Constitution.

The term medical marijuana includes two distinct forms of the plant genus Cannabis:

- Marijuana without any limitation or restriction on the percentage of THC;⁸ and
- "Low-THC cannabis" in which the percentage of THC is limited to 0.8 percent or less and has more than 10 percent of cannabidiol weight for weight. 10

The Coalition for Medical Marijuana Research and Education located at the H. Lee Moffitt Cancer Center and Research Institute, Inc., is authorized to conduct medical marijuana research and education.¹¹

A MMTC and a qualified patient or caregiver are specifically exempt from the criminal prohibition against the possession of cannabis. 12

2014 Federal Farm Bill and State Industrial Hemp Pilot Programs

The Agricultural Improvement Act of 2014 (2014 Farm Bill) defined industrial hemp and allowed state departments of agriculture or universities to grow and produce industrial hemp as part of research or pilot programs. Specifically, the law allowed universities and state departments of agriculture to grow or cultivate industrial hemp if:

- The industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and
- The growing or cultivating of industrial hemp is allowed under the laws of the state in which such institution of higher education or state department of agriculture is located and such research occurs.¹³

The 2014 Farm Bill defines "industrial hemp" to mean:

...the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9

⁶ Chapter 2017-232, Laws of Fla.

⁷ Chapter 2014-157, Laws of Fla.

⁸ THC, or tetrahydrocannabinol, is the main active ingredient in cannabis and is responsible for most of the psychological effects of cannabis.

⁹ Cannabidiol (CBD) is a chemical compound, known as a cannabinoid, found in cannabis. CBD does not have the same psychoactivity as THC. *See* Michael J Breus, *Despite What You May Think... CBD Is Not Weed* (Sept. 20, 2018), Psychology Today, available at: https://www.psychologytoday.com/us/blog/sleep-newzzz/201809/despite-what-you-may-think-cbd-is-not-weed (last visited February 10, 2020).

¹⁰ See ss. 381.986(1)(e) and (f), F.S.

¹¹ Section 1004.4351, F.S.

¹² See s. 381.986(14), F.S.

¹³ Agricultural Improvement Act of 2014, Pub. L. No. 113-79, s. 7606, 128 Stat. 912 (2014) (codified at 7 U.S.C. s. 5940).

tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. 14

Section 1004.4473, F.S., authorizes the Florida Department of Agriculture and Consumer Services (department) to oversee the development of industrial hemp pilot projects for the Institute of Food and Agricultural Sciences (IFAS) at the University of Florida, Florida Agricultural and Mechanical University, any land grant university in the state that has a college of agriculture, and any Florida College System institution or state university that has an established agriculture, engineering, or pharmacy program. ¹⁵ The purpose of the pilot projects is to cultivate, process, test, research, create, and market safe and effective commercial applications for industrial hemp in the agricultural sector in this state. The department has adopted a rule addressing safety, compliance, and accountability and other concerns. ¹⁶

2018 Federal Farm Bill

In the 2018 Farm Bill, the U.S. Congress legalized industrial hemp as an agricultural product by removing hemp's classification as a controlled substance.¹⁷ The 2018 Farm Bill defines "hemp" to mean:

...the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.¹⁸

The 2018 Farm Bill allows a state department of agriculture or an Indian tribe to submit a plan to the United States Secretary of Agriculture and apply for primary regulatory authority over the production of hemp in their state or tribal territory. A state or tribal plan must include:

- A procedure for tracking land upon which hemp will be produced;
- Testing methods for determining THC concentration levels of hemp;
- Methods for effective disposal of noncompliant products;
- Enforcement procedures;
- Inspection procedures; and
- Certification procedures for the persons authorized to produce hemp producers, test hemp products, inspect hemp producers, and enforce the provisions of the state or tribal plan. 19

¹⁴ *Id*.

¹⁵ Section 1004.4473(2)(a), F.S.

¹⁶ Fla. Admin. Code R. 5B-57.013 (2018).

¹⁷ Agricultural Improvement Act of 2018, Pub. L. No. 115-334, s. 12619, 132 Stat. 409 (2018) (codified at 21 U.S.C 802(16)).

¹⁸ Agricultural Improvement Act of 2018, Pub. L. No. 115-334, s. 10113, 132 Stat. 409 (2018) (codified at 7 U.S.C. s. 1639o).

¹⁹ Agricultural Improvement Act of 2018, Pub. L. No. 115-334, s. 10113, 132 Stat. 409 (2018) (codified at 7 U.S.C. s. 1639p).

State Hemp Program

The state hemp program was created within the department to regulate the cultivation of hemp in Florida.²⁰

Section 581.217(3)(d), F.S., defines the term "hemp" to mean:

...the plant Cannabis sativa L. and any part of that plant, including the seeds thereof, and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers thereof, whether growing or not, that has a total delta-9-tetrahydrocannabinol concentration that does not exceed 0.3 percent on a dry-weight basis.

Section 581.217(3)(e), F.S., defines the term "hemp extract" to mean "a substance or compound intended for ingestion that is derived from or contains hemp and that does not contain other controlled substances."

The department is required to seek federal approval of the state plan for the regulation of the cultivation of hemp with the United States Secretary of Agriculture in accordance with the Agricultural Improvement Act of 2018 within 30 days of adopting rules. ²¹ A license is required to cultivate hemp²² and to obtain a license a person must apply to the department and submit a full set of fingerprints. ²³ A person seeking to cultivate hemp must provide the department with a legal land description and GPS coordinates of where the hemp will be cultivated. ²⁴ The department must deny an application under certain circumstances. ²⁵

Florida Seed Law

The duty to administer the Florida Seed Law²⁶ and enforce its provisions and requirements is vested in the department.²⁷ The Florida Seed Lawis intended as a comprehensive and exclusive regulation of seed. The department must sample, inspect, analyze, and test agricultural, vegetable, flower, tree, or shrub seed transported, sold, offered or exposed for sale, or distributed in the state for sowing or planting purposes.²⁸

Generally Recognized as Safe

Under sections 201(s) and 409 of the Federal Food, Drug and Cosmetic Act, any substance that is intentionally added to food is a food additive that is subject to premarket review and approval by the U.S. Food and Drug Administration (FDA). A substance may not be offered for sale as food unless the substance is generally recognized, among qualified experts, as having been

²⁰ See s 581.217, F.S.

²¹ Section 581.217(4), F.S.

²² Section 581.217(5)(a), F.S.

²³ Section 581.217(5)(b), F.S.

²⁴ Section 581.217(5)(d), F.S.

²⁵ Section 581.217(5)(e), F.S.

²⁶ Chapter 578, F.S.

²⁷ Section 578.11(1), F.S.

²⁸ Section 578.11(1), F.S.

adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.²⁹ The FDA has evaluated three products by Fresh Hemp Foods, Ltd. and determined that hulled hemp seed, hemp seed protein powder, and hemp seed oil were generally recognized as safe.³⁰ This applies to products from other companies if they are manufactured in a way that is consistent with the evaluated products and the products meet the listed specifications.³¹

Hemp Extract

Hemp extract is a substance or compound intended for ingestion that is derived from or contains hemp and that does not contain controlled substances.³² Hemp extract may only be sold in in this state if the product has a certificate of analysis prepared by an independent testing laboratory and is distributed or sold in packaging that meets certain requirements.³³

III. Effect of Proposed Changes:

CS/SB 1876 makes a number of changes to the state hemp program.

The bill amends s. 500.03(1)(n), F.S., to include hemp extract in the definition of "food" in the Florida Food Safety Act.

The bill amends s. 500.12(1)1., F.S., to require persons who operate minor food outlets³⁴ that sell hemp extract to obtain a food permit from the department.

The bill amends s. 481.217(3)(b), F.S., to remove a reference to the Department of Health's medical marijuana regulations in the definition of the term "contaminants unsafe for human consumption."

The definition of the term "hemp extract" in s. 581.217(3)(e), F.S., is amended by the bill to include the substances or compounds intended for inhalation. Current law limits the definition of the term to products intended for consumption.

Section 581.217(3)(e), F.S., is also amended to exclude synthetic CBD and seeds and seed-derived ingredients that are generally recognized as safe by the FDA from the definition of "hemp extract."

²⁹ See U.S. Food & Drug Administration Generally Recognized as Safe at: https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras (last visited February 10, 2020).

³⁰ See FDA Responds to Three GRAS Notices for Hemp-Seed Derived Ingredients for Use in Human Food at: https://www.fda.gov/food/generally-recognized-safe-gras/about-gras-notification-program (last visited February 10, 2020). ³¹ Id.

³² Section 581.217(3)(e), F.S.

³³ Section 581.217(7), F.S.

³⁴ Section 500.12(1)(a), F.S., exempts the operator of a minor food outlet from the requirement to have food permit issued by the department. A minor food mart sells commercially prepackaged food that is not potentially hazardous and not time or temperature controlled for safety, if the shelf space for those items does not exceed 12 total linear feet and other food is sold by the minor food outlet.

The bill removes the requirement in s. 581.217(7), F.S., that hemp extract be tested on a dryweight basis. It also clarifies that the distribution and labeling requirements in s. 581.217(7), F.S., apply to containers of hemp extract instead of to packaging. The bill requires that a container of hemp extract must contain the number of milligrams of each cannabinoid per serving.

The bill provides that hemp extract sold in violation of s. 581.217, F.S. is considered misbranded or adulterated.

The bill prohibits the sale of products that are intended for inhalation and made from hemp extract to a person who is under 21 years of age. However, the bill does not provide a penalty for a violation of this prohibition.

Section 581.217(11), F.S., is amended by the bill to allow the department to contact with entities to provide sample collection, laboratory testing, and disposal services.

The bill requires the department to notify a licensee when hemp is produced with a THC level that exceeds the allowable limit of 0.3 percent. Under the bill, the licensee must remove and destroy the plants that are out of compliance within 10 days of receiving the notice from the department. If the licensee fails to comply, the department must destroy the plants at the expense of the licensee. Damages may not be awarded to the licensee for the destruction of the plants.

The bill takes effect July 1, 2020.

IV. Constitutional Issues:

A.

D.

	None.					
B.	Public Records/Open Meetings Issues:					
	None.					
C.	Trust Funds Restrictions:					
	None.					

Municipality/County Mandates Restrictions:

E. Other Constitutional Issues:

State Tax or Fee Increases:

None.

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Small food retailers will now need to obtain a food permit if they sell hemp extract.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 500.03, 500.12, and 581.217.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Agriculture on February 4, 2020:

- Reverts seed certification requirements back to current law;
- Adds hemp extract to the definition of "food" in the Florida Food Safety Act;
- Requires small food retailers who are normally exempt from a food permit to obtain one if they sell hemp extract.
- Adds products that are inhaled to the definition of "hemp extract" and prohibits those products from being sold to someone under the age of 21;
- Deletes the prohibition on selling products that contain hemp extract to someone under the age of 18;
- Removes synthetic CBD oil from the definition of "hemp extract;" and
- Allows the department to contract for sample collection, laboratory testing, and disposal services.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.