# 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.)

2. Becker		Yeatman	FP	<b>Pre-meeting</b>	
1. Becker		Becker	AG	Fav/CS	
ANAL	YST	STAFF DIRECTOR	REFERENCE		ACTION
DATE:	April 19, 20	23 REVISED:			
SUBJECT:	Hemp				
INTRODUCER:	Agriculture Committee; and Senators Burton and Rodriguez				
BILL:	CS/SB 1676				
Prepared By: The Professional Staff of the Committee on Fiscal Policy					

# Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

# I. Summary:

CS/SB 1676 makes a number of changes to the regulation of hemp in this state. Specifically, the bill:

- Adds hemp extract to the definition of "food."
- Revises the definition of "hemp" to exempt hemp extract, which may not exceed 0.3 percent total delta-9-tetrahydrocannabinol on a wet-weight basis and specifies the term does not include synthetically derived cannabinoids.
- Adds snuff, chewing gum, and smokeless products derived from or containing hemp to the definition of "hemp extract."
- Defines "synthetically derived cannabinoid."
- Defines "total tetrahydrocannabinol."
- Modifies how hemp extract may be sold in this state, including:
  - o Requiring the batch to be processed in a facility that meets certain requirements;
  - o Requiring it to be sold in a container that meets certain requirements, one of which is that the container is not attractive to children; and
  - Requiring it to only be sold to businesses that meet certain requirements.
- Prohibits hemp extract products intended for human ingestion from being sold to a person who is under 21 years of age.
- Specifies that hemp extract products may not exceed .5 milligrams of total tetrahydrocannabinol per serving or 2 milligrams total tetrahydrocannabinol per package.
- Revises the Department of Agriculture and Consumer Services (department) rulemaking authority to reflect the approval of the state hemp plan and to require the department to adopt rules relating to the packaging of hemp extract products.

The bill shall take effect July 1, 2023.

#### 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.<sup>1</sup>

#### **Cannabis**

Cannabis is a Schedule I controlled substance.<sup>2</sup> It is a felony of the third degree<sup>3</sup> to sell, manufacture, deliver, or possess with intent to sell, manufacture, or deliver, cannabis in Florida.<sup>4</sup>

As a controlled substance in chapter 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].<sup>5</sup>

# 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.

<sup>&</sup>lt;sup>1</sup> See University of Florida, *UF/IFAS Industrial Hemp Pilot Project* at: <a href="https://programs.ifas.ufl.edu/hemp/">https://programs.ifas.ufl.edu/hemp/</a> (last visited March 17, 2023).

<sup>&</sup>lt;sup>2</sup> Section 893.03(1)(c)7., F.S.

<sup>&</sup>lt;sup>3</sup> Section 775.082, F.S., provides that a felony of the third degree is punishable by a term of imprisonment not to exceed 5 years. Section 775.083, F.S., provides that a felony of the third degree is punishable by a fine not to exceed \$5,000.

<sup>&</sup>lt;sup>4</sup> Section 893.13(1)(a)2., F.S.

<sup>&</sup>lt;sup>5</sup> Section 893.02(3), F.S.

Subsequently, the Legislature passed SB 8-A in Special Session A of 2017.<sup>6</sup> The bill revised the Compassionate Medical Cannabis Act of 2014<sup>7</sup> 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.<sup>11</sup>

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.<sup>13</sup>

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 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.<sup>14</sup>

<sup>&</sup>lt;sup>6</sup> Chapter 2017-232, Laws of Fla.

<sup>&</sup>lt;sup>7</sup> Chapter 2014-157, Laws of Fla.

<sup>&</sup>lt;sup>8</sup> THC, or tetrahydrocannabinol, is the main active ingredient in cannabis and is responsible for most of the psychological effects of cannabis.

<sup>&</sup>lt;sup>9</sup> 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: <a href="https://www.psychologytoday.com/us/blog/sleep-newzzz/201809/despite-what-you-may-think-cbd-is-not-weed">https://www.psychologytoday.com/us/blog/sleep-newzzz/201809/despite-what-you-may-think-cbd-is-not-weed</a> (last visited March 16, 2023).

<sup>&</sup>lt;sup>10</sup> See s. 381.986(1)(e) and (f), F.S.

<sup>&</sup>lt;sup>11</sup> Section 1004.4351, F.S.

<sup>&</sup>lt;sup>12</sup> See s. 381.986(14), F.S.

<sup>&</sup>lt;sup>13</sup> Agricultural Improvement Act of 2014, Pub. L. No. 113-79, s. 7606, 128 Stat. 912 (2014) (codified at 7 U.S.C. s. 5940). <sup>14</sup> *Id*.

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. 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. The department has adopted a rule addressing safety, compliance, and accountability and other concerns.

#### 2018 Federal Farm Bill

In the Agricultural Improvement Act of 2018 (2018 Farm Bill), the U.S. Congress legalized industrial hemp as an agricultural product by removing hemp's classification as a controlled substance.<sup>17</sup> 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.<sup>18</sup>

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

#### **State Hemp Program**

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

<sup>&</sup>lt;sup>15</sup> Section 1004.4473(2)(a), F.S.

<sup>&</sup>lt;sup>16</sup> Fla. Admin. Code R. 5B-57.013 (2018).

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

<sup>&</sup>lt;sup>18</sup> Agricultural Improvement Act of 2018, Pub. L. No. 115-334, s. 10113, 132 Stat. 409 (2018) (codified at 7 U.S.C. s. 16390)

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

<sup>&</sup>lt;sup>20</sup> See s. 581.217, F.S.

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, containing more than trace amounts of cannabinoid, or for inhalation which is derived from or contains hemp and which does not contain other controlled substances." The term does not include synthetic CBD or seeds or seed-derived ingredients that are generally recognized as safe by the United States Food and Drug Administration. Products that are intended for inhalation and contain hemp extract may not be sold in this state to a person who is under 21 years of age. <sup>22</sup>

The department was required to seek federal approval of the state plan for the regulation of the cultivation of hemp with the United States Secretary of Agriculture (USDA) in accordance with the 2018 Farm Bill within 30 days of adopting rules.<sup>23</sup> A license is required to cultivate hemp<sup>24</sup> and to obtain a license, a person must apply to the department and submit a full set of fingerprints.<sup>25</sup> 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.<sup>26</sup> The department must deny an application under certain circumstances.<sup>27</sup>

# **CDC Health Advisory**

In September 2021, the Center for Disease Control (CDC) sent out a Health Alert Network (HAN) Health Advisory alerting public health departments and the public about the increased availability of cannabis products containing delta-8-THC and the potential for adverse events due to insufficient labeling of products containing THC and cannabidiol (CBD).<sup>28</sup> The advisory reports that there is an increase in delta-8 THC products appearing in both marijuana and hemp marketplaces and are also available online.<sup>29</sup> The advisory suggests that some products containing delta-8 THC are only labeled as containing delta-9 THC, which leads consumers to underestimate the psychoactive potential. Consumers may get confused at businesses that sell delta-8 THC in the same place that sell hemp or CBD, products that are not intoxicating, and may experience unexpected or increased THC intoxication.<sup>30</sup>

<sup>21</sup> Section 581.219(3)(e), F.S.

<sup>&</sup>lt;sup>22</sup> Section 581.217(7)(c), F.S.

<sup>&</sup>lt;sup>23</sup> Section 581.217(4), F.S.

<sup>&</sup>lt;sup>24</sup> Section 581.217(5)(a), F.S.

<sup>&</sup>lt;sup>25</sup> Section 581.217(5)(b), F.S.

<sup>&</sup>lt;sup>26</sup> Section 581.217(5)(d), F.S.

<sup>&</sup>lt;sup>27</sup> Section 581.217(5)(e), F.S.

<sup>&</sup>lt;sup>28</sup> See https://emergency.cdc.gov/han/2021/pdf/CDC HAN 451.pdf (last visited March 17, 2023).

<sup>&</sup>lt;sup>29</sup> Id.

<sup>&</sup>lt;sup>30</sup> Id.

#### Delta-8 THC-involved adverse events

In 2021, the American Association of Poison Control Centers (AAPCC) introduced a delta-8 THC product code into its National Poison Data System (NPDS), to monitor adverse events. From January 1 to July 31, 2021, 660 delta-8 THC exposures were recorded with the new product code, and one additional case was recoded as a delta-8 THC exposure from October 2020. Eighteen percent of exposures (119 of 661 cases) required hospitalization, and 39% (258 of 661 cases) involved pediatric patients less than 18 years of age.<sup>31</sup>

The advisory warned that delta-8 intoxication can cause adverse effects similar to those observed during delta-9 THC intoxication, which may include:

- Lethargy,
- Uncoordinated movements and decreased psychomotor activity,
- Slurred speech,
- Increased heart rate progressing to slowed heart rate,
- Low blood pressure,
- Difficulty breathing,
- Sedation, and
- Coma.<sup>32</sup>

#### CDC Recommendations

The CDC also provided recommendations for consumers, public health departments/poison control centers, retailers and healthcare providers. The recommendations included, but are not limited to:

- Consumers should be aware of possible limitations in the labeling of products containing THC and CBD even from approved marijuana and hemp retailers. Products reporting only delta-9 THC concentration, but not total THC, may underestimate the psychoactive potential for consumers.
- Consumers should be aware that products labeled as hemp or CBD may contain delta-8 THC, and that products containing delta-8 THC can result in psychoactive effects. Delta-8 THC products are currently being sold in many states, territories, and tribal nations where non-medical adult cannabis use is not permitted by law. In addition, retailers may sell products outside of regulated dispensaries in states, territories, and tribal nations where cannabis use is permitted by law. This may provide consumers with a false sense of safety, as delta-8 THC products may be labeled as hemp or CBD, which consumers may not associate with psychoactive ingredients.
- States, territories, and tribal nations that have passed laws allowing non-medical use of adult cannabis or that may allow such use in the future may consider requiring the reporting of total THC content, including ingredients like delta-8 THC and other compounds that may be synthetically produced, on product labeling.

<sup>&</sup>lt;sup>31</sup> Id.

<sup>&</sup>lt;sup>32</sup> Id.

 Retailers selling cannabis products should report total THC content on product labeling, including ingredients like delta-8 THC that may be synthetically produced to create a psychoactive effect.

 Healthcare providers should be vigilant in observing patients presenting with THC-like intoxication symptoms who do not report an exposure to marijuana or history of use.
 Symptomatic patients should be questioned about their use of CBD or delta-8 THC products.<sup>33</sup>

### FDA Consumer Update: Delta-8 THC

In 2022, the Food and Drug Administration (FDA) released a consumer report to inform the public about Delta-8 THC.<sup>34</sup> The consumer report outlined five points on delta-8 THC:

- Products containing delta-8 THC have not been approved by the FDA and may be marketed as "hemp products," which consumers associate with being "non-psychoactive."
- The FDA has received 104 reports of adverse events in patients who consumed delta-8 THC products between December 1, 2020, and February 28, 2022. Additionally, national poison control centers received 2,362 exposure cases of delta-8 THC products between January 2021 and February 2022.
- Delta-8 THC contains psychoactive and intoxicating effects, similar to delta-9 THC (i.e., the component responsible for the "high" people may experience from using cannabis).
- The natural amount of delta-8 THC in hemp is very low, and additional chemicals are needed to convert other cannabinoids in hemp, like CBD, into delta-8 THC (i.e., synthetic conversion). The FDA reports that some manufacturers may use potentially unsafe household chemicals to make delta-8 THC through a chemical synthesis process.
- Some Delta-8 THC marketing may appeal to children and may be purchased online. As such the FDA is recommending keeping delta-8 THC products out of the reach of children and due to pets to decrease the potential occurrence of adverse events.<sup>35</sup>

# III. Effect of Proposed Changes:

CS/SB 1676 makes a number of changes to the regulation of hemp in the state. The bill adds hemp extract as defined in s. 581.217, F.S., to the definition of "food" and specifies that hemp extract is considered a food that requires time and temperature control for safety and integrity of the product.

Current law provides that hemp-derived cannabinoids, including, but not limited, to cannabidiol, are not controlled substances.<sup>36</sup> The bill changes cannabidiol to cannabinol and specifies these are not controlled substances if they are in compliance with s. 581.217, F.S. The bill revises the definition of "hemp" to exempt hemp extract, which may not exceed 0.3 percent total delta-9-tetrahydrocannabinol on a wet-weight basis and specifies the term does not include synthetically derived cannabinoids.

<sup>&</sup>lt;sup>33</sup> Id

<sup>&</sup>lt;sup>34</sup> See <a href="https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc">https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc</a> (last visited March 17, 2023).

<sup>&</sup>lt;sup>35</sup> Id.

<sup>&</sup>lt;sup>36</sup> Section 581.217(2)(b), F.S.

It adds snuff, chewing gum, and smokeless products derived from or containing hemp, excluding cannabinoids that are synthetically derived, to the definition of "hemp extract." It defines "synthetically derived cannabinoid" as any cannabinoid created by any process other than direct extraction from hemp and without further reacting with other chemicals to increase the concentration of a present cannabinoid. It defines "total tetrahydrocannabinol" as the sum of all cannabinoids as defined by the department in milligrams.

Current law provides regulation of how hemp extract may be sold in this state. <sup>37</sup> The bill specifies that hemp extract may only be sold in this state if the product has a certificate of analysis prepared by an independent testing laboratory that states the batch contained .05 milligrams total cannabinoids per serving. It adds a requirement that the batch be processed in a facility that holds a current and valid permit issued by a human health or food safety regulatory entity with authority over the facility, and that facility meets the human health or food sanitization requirements of the regulatory entity. Such compliance must be documented by a report from the regulatory entity confirming that the facility meets such requirements.

The bill adds a requirement that hemp extract be distributed or sold in a container that:

- Is suitable to contain products for human consumption;
- Is composed of materials designed to minimize exposure to light;
- Mitigates exposure to high temperatures;
- Is not attractive to children; and
- Is compliant with the United States Poison Prevention Packaging Act of 1970.

The bill requires that hemp extract only be sold to a business in this state if that business is properly permitted by s. 581.217(7), F.S. It clarifies that hemp extract distributed or sold in this state is subject to the applicable requirements of ch. 500, ch. 502, or ch. 508, removing the specification that a violation of this shall be considered adulterated or misbranded.

Current law provides that hemp extract products that are intended for inhalation may not be sold to a person who is under 21 years of age.<sup>38</sup> The bill adds a requirement that such products intended for human ingestion may not be sold to a person who is under 21 years of age. It also specifies that such products may not exceed .5 milligrams of total tetrahydrocannabinol per serving or 2 milligrams total tetrahydrocannabinol per package.

The bill revises the department's rulemaking authority, granting it the authority to adopt rules to administer the state hemp program. It also requires the department to adopt rules to provide for packaging and labeling requirements that ensure that hemp extract intended for human ingestion or inhalation is not attractive to children and for advertising regulations that ensure hemp extract intended for human ingestion or inhalation is not marketed or advertised in a manner that specifically targets or is attractive to children.

The bill requires the department to adopt rules pursuant to s. 120.536(1), F.S., and s. 120.54, F.S., to establish the cannabinoids to include in calculating total cannabinoids, which must include, at a minimum, delta-8 tetrahydrocannabinol, delta-9 tetrahydrocannabinol, delta-9

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<sup>&</sup>lt;sup>37</sup> Section 581.217(7), F.S.

<sup>&</sup>lt;sup>38</sup> Section 581.217(7)(c), F.S.

tetrahydrocannalibonic acid, delta-10 tetrahydrocannabinol, delta-9,11 tetrahydrocannabinol, exotetrahydrocannabinol, and hexahydrocannabinol.

The bill reenact s. 893.02(3), F.S., the definition of "cannabis," to reflect changes made by the bill.

The bill takes effect July 1, 2023.

#### IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

# V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Businesses may be impacted by the additional regulations, specifically packaging requirements and THC limits.

C. Government Sector Impact:

The department will be able to inspect and regulate hemp extract as a food product. It is unclear whether or not this will have a fiscal impact to the department.

#### VI. Technical Deficiencies:

There are conflicting limits for how many milligrams of total cannabinoids that each container/package may include.

#### VII. Related Issues:

None.

#### VIII. Statutes Affected:

This bill substantially amends sections 500.03 and 581.217 of the Florida Statutes. This bill reenacts section 893.02 of the Florida Statutes.

#### 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 March 20, 2023:

The CS reverts what the term hemp-derived cannabinoids includes back to current law, revises the definition of "hemp" to add that hemp extract may not exceed 0.5 total cannabinoids per container, revises the definition of "synthetically derived cannabinoid," revises the definition of "total tetrahydrocannabinol," requires that hemp extract may only be sold in the state if the batch contains less than 0.5 milligrams total cannabinoids per serving, requires that products that are intended for human consumption or ingestion may not exceed .5 total tetrahydrocannabinol per serving or 2 milligrams total tetrahydrocannabinol per package, and revises the department's rulemaking authority.

#### B. Amendments:

None.

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