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.)

Prepared By: The Professional Staff of the Committee on Commerce and Tourism

BILL:	CS/SB 136
INTRODUCER:	Commerce and Tourism Committee and Senator Gruters
SUBJECT:	Florida Kratom Consumer Protection Act
DATE:	March 7, 2023
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	McMillan	McKay	CM	**Fav/CS**
2.			AEG	
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 136 creates the Florida Kratom Consumer Protection Act, and provides that a processor, which is a person who sells, prepares, manufactures, distributes, or maintains kratom products, may not sell, prepare, or distribute a kratom product that:

- Is adulterated to such a degree that it may injure a consumer;
- Contains a poisonous or otherwise harmful non-kratom ingredient;
- Contains a level of 7-hydroxymitragynine in the alkaloid fraction which is greater than 1 percent of the alkaloid composition of the product;
- Contains a synthetic alkaloid;
- Does not include directions for the safe and effective use of the product; or
- Has a label that contains any claim that the product is intended to diagnose, treat, cure, or prevent any medical condition or disease.

The bill establishes that a processor may not sell, prepare, or distribute kratom extract that contains levels of residual solvents higher than the standards set forth in United States Pharmacopeia and the National Formulary (USP-NF) chapter 467. Additionally, a processor may not distribute, sell, or expose for sale a kratom product to an individual under 21 years of age.

The bill requires a processor to annually register any kratom product it intends to sell with the Department of Agriculture and Consumer Services (DACS), and keep its registration up to date. Additionally, a processor who receives notice of an adverse event related to its kratom product,

must submit a copy of the adverse event to the DACS. A processor who violates requirements related to product standards, registration, or reporting is subject to an administrative fine.

The DACS may revoke the product registration of a processor who fails to timely provide an updated product registration, or fails to report an adverse event, and the DACS is required to adopt rules to administer the provisions of the Act.

The bill takes effect July 1, 2023.

II. Present Situation:

Kratom

Kratom is a tropical tree native to Southeast Asia that contains mitragynine and 7-hydroxymytragynine in its leaves, which are two major psychoactive ingredients.[1] The leaves are crushed and then smoked, brewed with tea, or placed into gel capsules.[2] Consumption of kratom leaves can produce stimulant and sedative effects, and may also lead to psychotic symptoms.[3]

Some research finds that kratom can be used as a substitute for opiate users to combat withdrawal symptoms, as well as to treat muscle ache, fatigue, and other conditions.[4] Low doses of kratom are said to produce a stimulant effect, while higher doses may produce an opioid-like effect.[5] Additionally, research points to the potential for further development of mitragynine and the use of kratom as a harm reduction agent.[6] Even so, the toxicity of kratom remains a topic of discussion, as well as its potential to cause herb-drug interactions and even be involved in fatalities.[7]

Currently, kratom is not listed as a controlled substance under federal law or Florida law. However, in 2014, Sarasota County banned kratom, labeling it as a designer drug.[8] With the exception of Sarasota County, in Florida, all parts of the plant and its extracts are legal to cultivate, buy, possess, and distribute without a license or prescription. Kratom is illegal in

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[1] Drug Enforcement Administration, *Kratom* (April 2020), available at https://www.dea.gov/sites/default/files/2020-06/Kratom-2020_0.pdf (last visited March 7, 2023).
[2] *Id*.
[3] *Id*.
[4] *See* Dimy Fluyau and Neelambika Revedigar, *Biochemical Benefits, Diagnosis, and Clinical Risks Evaluation of Kratom*, Frontiers in Psychiatry Journal Volume 8 (April 24, 2017) available at https://www.frontiersin.org/articles/10.3389/fpsyt.2017.00062/full (last visited March 7, 2023).
[5] *Id*.
[6] *See* Charles Veltri and Oliver Grundmann, *Current Perspectives on the Impact of Kratom Use*. Substance Abuse and Rehabilitation Journal Volume 10 23-31 (July 1, 2019) available at https://pubmed.ncbi.nlm.nih.gov/31308789/ (last visited March 7, 2023).
[7] *Id*. *See also* Drugs Identified in Deceased Persons by Florida Medical Examiners, FDLE (May 2022), available at https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2021-Interim-Drug-Report-FINAL.aspx (last visited March 7, 2023). In May of 2022 the Florida Department of Law Enforcement published its 2021 Interim Report, which found a 36% rise in kratom-involved deaths over the first half of 2021.
[8] *See* Sarasota, FL., Code of Ordinances, Sec. 62-351 (2014).

Alabama,[9] Arkansas,[10] Indiana,[11] Rhode Island,[12] Vermont,[13] and Wisconsin.[14] In 12 other states the possession, sale, manufacture, and distribution of kratom products is regulated.[15]

Following an updated import alert that provides information to U.S. Food and Drug Administration (FDA) field staff about detaining without physical examination imported dietary supplements and bulk dietary ingredients that are or contain kratom,[16] in May of 2021, the FDA announced the seizure of around 37,500 tons of adulterated kratom in Florida, worth an estimated $1.3 million.[17] The FDA's Associate Commissioner for Regulatory Affairs stated that there is substantial concern regarding the safety of kratom and the risk it may pose to public health, and indicated that there are currently no FDA-approved uses for kratom.[18]

The U.S. Department of Justice, on behalf of the FDA, filed a complaint in the U.S. District Court for the Middle District of Florida alleging that kratom is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that it does not present a significant or unreasonable risk of illness or injury.[19] Additionally, the FDA stated that dietary supplements and bulk dietary ingredients that are or contain kratom are adulterated under the Federal Food, Drug, and Cosmetic Act.[20] On October 26, 2021, a consent decree of condemnation and destruction against the articles seized by the FDA in May of 2021 was entered, which requires the claimants to pay a penal bond and destroy all seized articles.[21]

The Department of Agriculture and Consumer Services

The Department of Agriculture and Consumer Services (department) safeguards the public and supports Florida's agricultural economy by ensuring the safety and wholesomeness of food and

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[9] *See* Alabama Public Health, *Controlled Substance List* (Jan. 20, 2021), available at https://www.alabamapublichealth.gov/blog/assets/controlledsubstanceslist.pdf (last visited March 7, 2023).
[10] *See* Arkansas Department of Health, *List of Controlled Substances*, available at http://secureservercdn.net/166.62.109.105/e17.085.myftpupload.com/wp-content/uploads/2016/02/arkansas-controlled_substances_list.pdf (last visited March 7, 2023).
[11] *See* IC 35-31.5-2-321.
[12] *See* Rhode Island Dept. of Health, Notice of Designation of Controlled Substance (May 31, 2017), available at https://docs.wixstatic.com/ugd/9ba5da_9836aee2b9f04a30b55fe480fe3c6ff4.pdf. (last visited March 7, 2023).
[13] *See* Vt. Admin. Code 12-5-23:4.0.
[14] *See* W.S.A. 961.14.
[15] *See* Regulation of Kratom in America: Update (September 2022), available at Kratom Fact Sheet (legislativeanalysis.org) (last visited March 7, 2023).
[16] The import alert labels kratom as an adultering ingredient. *See* Food and Drug Administration, Import Alert 54-15, Import Alert 54-15 (fda.gov) (last visited March 3, 2023) The FDA labeled kratom as adulterating based on the absence of a history of use or other evidence of safety establishing that kratom will reasonably be expected to be safe as a dietary ingredient, kratom and kratom-containing dietary supplements and bulk dietary ingredients are adulterated because they contain a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.
[17] U.S. Food and Drug Administration, *FDA Announces Seizure of Adulterated Dietary Supplements Containing Kratom* (May 21, 2021), available at https://www.fda.gov/news-events/press-announcements/fda-announces-seizure-adulterated-dietary-supplements-containing-kratom (last visited March 7, 2023).
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*

other consumer products through inspection and testing programs.[22] In particular, the Division of Food Safety (division) is responsible for assuring Floridians have a safe and properly represented food supply.[23]

Florida Food Safety Act

The division regulates food products under the Florida Food Safety Act (FFSA), which includes articles used for food or drink for human consumption, as well as dietary supplements.[24] Under the FFSA, individuals may not sell food that is adulterated, adulterate food, or receive food in commerce that is adulterated or misbranded.[25]

The following are examples of when food is deemed adulterated:

- Food that bears or contains any poisonous or deleterious substance which may render it injurious to health;
- Food that bears or contains any added poisonous or added deleterious substance; a food additive; or a color additive, which is unsafe;
- Food that is or bears or contains any food additive which is unsafe;
- Food whose container is composed, in whole or in part, of any poisonous or deleterious substance;
- Food where any substance has been substituted wholly or in part therefor;
- Food where damage or inferiority has been concealed in any manner; and
- A dietary supplement or its ingredients that present a significant risk of illness or injury due to certain labeling and ingredient requirements.[26]

If a food is offered for sale and its label or labeling does not comply with the requirements of 21 U.S.C. s. 343(r) pertaining to nutritional content claims and health claims, it is considered to be misbranded. Labels for supplements may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.[27]

The DACS may take the following actions:

- Inspect food that may be adulterated or misbranded;[28]
- Seize food that is adulterated or misbranded;[29]
- Suspend permits of those who sell food that is adulterated or misbranded, adulterate or misbrand food, or receive food in commerce that is adulterated or misbranded;[30] and

[22] *See* The Florida Department of Agriculture and Consumer Services, *About Us*, available at About Us / Home - Florida Department of Agriculture & Consumer Services (fdacs.gov) (last visited March 7, 2023).
[23] *See* The Florida Department of Agriculture and Consumer Services, *Division of Food Safety*, available at Food Safety / Divisions & Offices / Home - Florida Department of Agriculture & Consumer Services (fdacs.gov) (last visited March 7, 2023).
[24] *See* ch. 500, F.S.
[25] Section 500.04, F.S. These prohibitions are similar to Federal law. *See also* 21 U.S.C. 331.
[26] Section 500.10, F.S.
[27] Section 500.11(1)(n), F.S.; *See also* 21 U.S.C. s. 343 (r)(6)(C).
[28] Section 500.147(1), F.S.
[29] Section 500.173, F.S.
[30] Section 500.12(4), F.S.

- Impose a fine for adulterated or misbranded food, not to exceed $5,000[31] per violation.[32]

III. Effect of Proposed Changes:

The bill creates the Florida Kratom Consumer Protection Act in s. 501.9745, F.S., and establishes the following definitions:

- "Kratom extract" means a food product or dietary ingredient that contains any part of the leaf of the plant Mitragyna speciose which has been extracted and concentrated to provide more standardized dosing;
- "Kratom product" means a food product, food ingredient, dietary ingredient, dietary supplement, or beverage intended for human consumption which contains any part of the leaf of the plant Mitragyna speciose or an extract of such plant and is manufactured as a powder, capsule, pill, beverage, or other edible form; and
- "Processor" means a person who sells, prepares, manufactures, distributes, or maintains kratom products.

The bill provides that a processor may not sell, prepare, distribute, or expose for sale a kratom product that:

- Is adulterated with a dangerous non-kratom substance that affects the quality or strength of the kratom product to such a degree that it may injure a consumer;
- Contains a poisonous or otherwise harmful non-kratom ingredient, including, but not limited to, any substance listed in s. 893.03, F.S.;
- Contains a level of 7-hydroxymitragynine in the alkaloid fraction which is greater than 1 percent of the alkaloid composition of the product;
- Contains a synthetic alkaloid, including, but not limited to, synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compound of the plant Mitragyna speciose;
- Does not include directions for the safe and effective use of the product, including, but not limited to, a suggested serving size, on the product's packaging or label; or
- Has a label that contains any claim that the product is intended to diagnose, treat, cure, or prevent any medical condition or disease.

The bill establishes that a processor may not sell, prepare, distribute, or expose for sale kratom extract that contains levels of residual solvents higher than the standards set forth in USP-NF[33] chapter 467.[34] Additionally, a processor may not distribute, sell, or expose for sale a kratom product to an individual under 21 years of age.

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[31] Section 570.971(1)(b), F.S.
[32] Section 500.121, F.S.
[33] The United States Pharmacopeia (USP) and the National Formulary (NF) contains standards for medicines, dosage forms, drug substances, excipients, biologics, compounded preparations, medical devices, dietary supplements, and other therapeutics. The current version of USP-NF standards deemed official by USP are enforceable by the U.S. Food and Drug Administration for medicines manufactured and marketed in the United States.
[34] Residual solvents in pharmaceuticals are defined as organic volatile chemicals that are used or produced in the manufacture of drug substances or excipients, or in the preparation of drug products. The residual solvents are not completely removed by practical manufacturing techniques. Drug products should contain no higher levels of residual solvents than can be supported by safety data. Solvents that are known to cause unacceptable toxicities, "Class 1," should be avoided in the production of drug substances, excipients, or drug products unless their use can be strongly justified in a risk-benefit assessment. Solvents associated with less severe toxicity, "Class 2," should be limited in order to protect patients from potential adverse effects.

The bill requires a processor to annually register with the Department of Agriculture and Consumer Services (DACS) any kratom product it intends to sell, which must include a certificate of analysis from an independent certified third-party laboratory.

The bill requires the DACS to have a processor produce an updated certificate of analysis if the DACS receives a report that any kratom product offered for sale in Florida is not in compliance with the requirements in the Florida Kratom Consumer Protection Act. Additionally, if a processor receives notice of an adverse event related to its kratom product, the processor must submit a copy of the adverse event to the DACS.[35]

The bill authorizes the DACS to revoke a processor's kratom product registration if the processor fails to keep their registration up to date within the specified timeframe or fails to report an adverse event.

The bill provides that a processor who violates the kratom product standards provisions is subject to an administrative fine of not more than $500 for the first offense and not more than $1000 for the second or subsequent offense. However, a processor selling kratom products at retail does not violate the kratom product standards provisions if it is shown by a preponderance of the evidence that the processor relied in good faith upon the representations of a manufacturer, processor, packer, or distributor of the kratom product.

The DACS is required to adopt rules to administer s. 501.9745, F.S.

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.

Less toxic solvents, "Class 3," should be used where practical. *See* The United States Pharmacopeia and the National Formulary, *Residual Solvents,* available at https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalChapter467Current.pdf (last visited March 7, 2023).

[35] The bill provides that the copy of the adverse event must be sent via certified mail and follow the reporting requirements under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 379aa-1 (b)(1).

E. Other Constitutional Issues:

None Identified.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Processors of kratom products will be required to adhere to the regulations set forth in the Florida Kratom Consumer Protection Act, which may benefit consumers.

C. Government Sector Impact:

There will potentially be an increase in administrative fines collected by the DACS. Additionally, the DACS will likely see an increase in regulatory costs.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill does not provide enforcement authority relating to the age restriction.

VIII. Statutes Affected:

This bill creates section 501.9745 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 Commerce and Tourism on March 6, 2023:
The committee substitute makes the following changes:

- Provides that a processor may not sell, prepare, or distribute, a kratom product that contains a level 7-hydroxymitragynine in the alkaloid fraction which is greater than 1 percent of the alkaloid composition of the product;
- Requires a processor to annually register any kratom product it intends to offer for sale with the Department of Agriculture and Consumer Services (DACS), which must include a certificate of analysis from an independent certified third-party laboratory;
- Provides that a processor must update its registration if the DACS receives a report that any kratom product is not in compliance with the registration requirement;
- Establishes that a processor who receives notice of an adverse event related to its kratom product, must submit a copy of the adverse event to the DACS;

- Provides that the DACS may revoke a processor's kratom product registration under certain circumstances; and
- Requires the DACS to adopt rules.

B. Amendments:

None.