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:	SB 1734
INTRODUCER:	Senator Collins
SUBJECT:	Florida Kratom Consumer Protection Act
DATE:	March 24, 2025
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Dike	McKay	CM	**Pre-meeting**
2.			AEG	
3.			FP	

I. Summary:

SB 1734 amends the Florida Kratom Consumer Protection Act to create requirements for kratom products manufactured, delivered, offered for sale, distributed, or sold by processors in this state. The bill sets out requirements for processors for state and federal registration, proof of testing and analysis for kratom products, and reporting of adverse health events. The bill also creates penalties for violations of s. 500.92, F.S.

The bill takes effect July 1, 2025.

II. Present Situation:

Florida Kratom Consumer Protection Act of 2023

In 2023, the Legislature enacted the Florida Kratom Consumer Protection Act,[1] which made it unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, any kratom product to a person under 21 years of age. The Florida Department of Agriculture and Consumer Services (FDACS) adopted rules to implement the act.[2]

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.[3] The leaves are

[1] Section 500.92, F.S.
[2] Fla. Admin. Code R. 5K-4.030.
[3] Drug Enforcement Administration, *Kratom* (April 2020), available at https://www.dea.gov/sites/default/files/2020-06/Kratom-2020_0.pdf (last visited Mar. 24, 2025).

crushed and then smoked, brewed with tea, or placed into gel capsules.[4] Consumption of kratom leaves can produce stimulant and sedative effects, and may also lead to psychotic symptoms.[5]

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.[6] Low doses of kratom are said to produce a stimulant effect, while higher doses may produce an opioid-like effect.[7] Additionally, research points to the potential for further development of mitragynine and the use of kratom as a harm reduction agent.[8] 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.[9] While research on kratom is in early stages, kratom itself has the potential to be addictive and has not been shown to be safe or effective for any medical use.[10]

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.[11] 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 Alabama,[12] Arkansas,[13] Indiana,[14] Rhode Island,[15] Vermont,[16] and Wisconsin.[17] In 12 other states the possession, sale, manufacture, and distribution of kratom products is regulated.[18]

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,[19] in May of 2021, the FDA

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[4] *Id.*
[5] *Id.*
[6] *See* Dimy Fluyau and Neelambika Revedigar, *Biochemical Benefits, Diagnosis, and Clinical Risks Evaluation of Kratom*, FRONTIERS IN PSYCH. J. VOL. 8 (April 24, 2017) available at https://www.frontiersin.org/articles/10.3389/fpsyt.2017.00062/full (last visited Mar. 24, 2025).
[7] Fluyau and Neelambika, *supra* note 6.
[8] *See* Charles Veltri and Oliver Grundmann, *Current Perspectives on the Impact of Kratom Use*, SUBSTANCE ABUSE AND REHAB. J. VOL. 10, 23-31 (July 1, 2019) available at https://pubmed.ncbi.nlm.nih.gov/31308789/ (last visited Mar. 24, 2025).
[9] *Id.*; *see also* FLORIDA DEPT. LAW ENF'T, Drugs Identified in Deceased Persons by Florida Medical Examiners (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 Mar. 24, 2025). 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.
[10] NAT'L CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH, *Kratom*, available at https://www.nccih.nih.gov/health/kratom (last visited Mar. 24, 2025).
[11] *See* SARASOTA, FL, Code of Ordinances, Sec. 62-351 (2014).
[12] *See* ALABAMA PUBLIC HEALTH, *Controlled Substance List* (Jan. 20, 2021), available at https://www.alabamapublichealth.gov/blog/assets/controlledsubstanceslist.pdf (last visited Mar. 24, 2025).
[13] *See* ARKANSAS DEPT. 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 Mar. 4, 2025).
[14] *See* IC 35-31.5-2-321.
[15] *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 Mar. 24, 2025).
[16] *See* Vt. Admin. Code 12-5-23:4.0.
[17] *See* W.S.A. 961.14.
[18] *See* LEGIS. ANALYSIS AND PUB. POL'Y ASS'N, *Regulation of Kratom in America: Update* (September 2022), available at https://legislativeanalysis.org/wp-content/uploads/2022/10/Kratom-Fact-Sheet-FINAL.pdf (last visited Mar. 24, 2025).
[19] The import alert labels kratom as an adulterating ingredient. *See* U.S. FDA, *Import Alert 54-15*, available at https://www.accessdata.fda.gov/CMS_IA/importalert_1137.html (last visited Mar. 24, 2025) The FDA labeled kratom as

announced the seizure of around 37,500 tons of adulterated kratom in Florida, worth an estimated $1.3 million.[20] 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.[21]

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.[22] 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.[23] 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.[24]

III. Effect of Proposed Changes:

Kratom Consumer Protection

Section 1 amends s. 500.92, F.S., to establish product, reporting, and registration requirements, in addition to punishments for violations of the bill for kratom products sold in this state.

Definitions

The bill provides the following definitions:

- "Attractive to children" means a product manufactured: (1) In a shape that resembles a human, a cartoon character, or an animal; (2) In a form that resembles an existing candy product that is a widely distributed, branded food item; or (3) Using any color additives.
- "Finished kratom product" means a kratom product that is ready for sale to the end user. For purposes of registration, a finished kratom product is differentiated by its ingredients, not by its weight, volume, or size.
- "Kratom" means the plant or any part of the plant Mitragyna speciosa.
- "Kratom beverage" means a prepackaged liquid kratom product in the form of a tea, seltzer or tonic water, or tincture.
- "Kratom food service establishment" means any public food service establishment licensed as provided in ch. 509, F.S. which sells finished kratom products.

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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.

[20] U.S. FDA, *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 Mar. 24, 2025).

[21] *Id*.

[22] *Id*.

[23] *Id*.; *see also* FDA, *FDA Roundup: April 28, 2023*, available at https://www.fda.gov/news-events/press-announcements/fda-roundup-april-28-2023 (last visited Mar. 24, 2025) (describing a 2023 seizure of kratom-adulterated products).

[24] *Id*.

- "Processor" means a person who manufactures, delivers, or offers for sale, distributes, or sells kratom products.

Product Requirements

Under the bill, a processor may not manufacture, deliver, offer for sale, distribute, or sell a finished kratom product that:

- Is not in the delivery form of dried leaves, kratom beverages, powders, pills, or capsules.
- Contains a level of synthetic 7-hydroxymitragynine in the alkaloid fraction which is greater than 2% of the alkaloid composition of the kratom product.
- Is not registered with FDACS pursuant to s. 500.92, F.S.
- Does not have a certificate of analysis submitted to FDACS as required by this section.
- Does not comply with the packaging and labeling requirements set forth in ch. 500, F.S., and the rules adopted pursuant thereto. Such kratom products are considered misbranded.
- Is extracted using solvents other than water or Class 3 solvents set forth in USP-NF chapter 467.
- Contains levels of Class 3 solvents greater than the limits set forth in USP-NF chapter 467.
- Is attractive to children.
- Is in a container that:
  - Is not suitable to contain products for human consumption;
  - Is not compliant with the U.S. Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.; or
  - Does not contain graduated measuring devices, if applicable.
- Is adulterated, including containing metals, pesticides, or pathogens in excess of the limits set by this section or FDACS's rules.

Additionally, a processor may not manufacture, deliver, offer for sale, distribute, or sell a finished kratom product that does not include directions for consumption of the kratom product on the product's label, including, but not limited to:

- Maximum dosage of 40 milligrams of mitragynine per serving.
- Number of servings per package.
- Milligrams of 7-hydroxmitragynine and mitragynine per serving.
- A warning which advises consumers of the number of servings that may be safely consumed in a 24-hour period.
- A warning prohibiting use by individuals who are under 21 years of age.
- A warning which advises against use by individuals who are pregnant or breastfeeding.
- A warning which advises the consumer to consult a health care professional before use, that the product may be habit-forming, and that it may cause adverse health effects.
- A warning stating the following: "These statements have not been evaluated by the United States Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
- The expiration date.
- The name and place of business of the registrant.

Permit and Federal Registration Requirements

The bill provides that kratom products may only be manufactured by, delivered to, offered for sale by, distributed by, or sold by a processor who holds a permit to operate as a food establishment as defined in s. 500.03, F.S. A processor may not operate as a cottage food operation pursuant to s. 500.80, F.S. and is not exempt from food permit requirements pursuant to s. 500.12(1)(a)1, F.S. The bill also requires that a processor that manufactures, processes, packs, or offers for sale kratom, kratom products, or finished kratom products must be properly registered with the FDA, except for processors exclusively selling finished kratom products at retail.

State Registration Requirements

A processor must register its finished kratom product with FDACS annually. A processor must also certify by sworn statement that any finished kratom product that any finished kratom product the processor manufactures, delivers, offers for sale, distributes, or sells in this state:

- Is registered with the state; and
- Does not contain dangerous or harmful substances, including, but not limited to, red-OH, synthetic 7-OH, synthetic 7-hydroxymitragynine, synthetic mitragynine, pseudoindoxyl, super alkaloid, or any other synthetically derived compounds, synthetic alkaloids, or controlled substances.

For each batch of a registered finished kratom product, the processor must submit a certificate of analysis to FDACS from an independent, third-party, accredited laboratory. The laboratory must be accredited under the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025:2017 General Requirements for Competence of Testing and Calibration Laboratories standard by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement. The bill also requires that:

- The processor may not have any direct or indirect financial or economic interest in the laboratory or accrediting body.
- The processor must maintain the certificates of analysis for at least one year after the finished kratom product's expiration date.
- The certificate of analysis must demonstrate that the finished kratom product complies with the statutory and rule concentration limits for:
  - Alkaloid and alkaloid metabolites;
  - Residual solvents;
  - Heavy metals, including cadmium, arsenic, mercury, and lead; and
  - Pesticides and any other substance limited by FDACS regulations.

Further, kratom food service establishments:

- Must comply with s. 500.92, F.S., for finished kratom products that they serve.
- Are not required to have a separate registration for kratom beverages combined with another food or beverage by the kratom food service establishment for consumption on the premises.
- Shall not serve kratom beverages combined with alcohol, drugs, or other kratom products.

The bill also sets out that a processor assumes all responsibility and liability for its kratom and kratom products.

Reporting and Testing

If a processor or FDACS receives notice of any adverse health event suspected of being related to the processor's kratom product, the processor or FDACS must submit an adverse event report to the FDA per 21 U.S.C. s. 379aa-1(b)(1).

If probable cause exists that a kratom product may be adulterated, FDACS may require an independent third-party test of the kratom product, and the processor must pay the cost of the test. If the processor does not make such payment to FDACS within 30 days after receiving the invoice for the testing fee, FDACS must revoke the registration for that product.

Violations

The bill mandates that a processor that manufactures, delivers, offers for sale, distributes, or sells a finished kratom product that (1) contains a level of synthetic 7-hydroxymitragynine in the alkaloid fraction which is greater than 2% of the alkaloid composition of the kratom product or (2) is not registered with FDACs, commits a felony of the third degree, punishable as provided in s. 775.082, F.S., or s. 232 775.083, F.S.

Kratom products possessed, manufactured, delivered, offered for sale, distributed, or sold in violation of this bill by an entity regulated under ch. 500, F.S., are subject to s. 500.172, F.S., and an immediate stop-sale order, and the entity is subject to penalties as provided in s. 500.121, F.S. FDACS may not grant permission to remove or use, except for disposal, finished kratom products subject to a stop-sale order which are attractive to children until the finished kratom products comply with s. 500.92, F.S.

If a processor fails to provide a certificate of analysis within two days of receiving a request from FDACS, or fails to immediately report an adverse health event, FDACS may revoke the processor's finished kratom product registration.

Under the bill, a processor that manufactures, delivers, offers for sale, distributes, or sells a kratom product that contains:

- any controlled substance listed in s. 893.03, F.S.;
- an alkaloid not naturally present in kratom;
- a synthetic alkaloid or a synthetic alkaloid metabolite, including, but not limited to, red-OH, synthetic 7-OH, synthetic 7-hydroxymitragynine, synthetic mitragynine, pseudoindoxyl, super alkaloid; or
- any other synthetically derived compounds of the plant Mitragyna speciosa, or a level of 7-hydroxymitragynine in the alkaloid fraction which is greater than 2%

is in violation s. 500.92, F.S.

Further, if a laboratory fails to ensure the accuracy of its certificates of analysis, the laboratory is subject to administrative fines as provided by FDACS rule pursuant to this bill.

Funding for Implementation

Section 2 appropriates $1,920,141.22 in recurring funds, $1,791,608 in nonrecurring funds, and $1,508,152.18 for salary for 24 full-time employees from the General Inspection Trust Fund to FDACS for the 2025-2026 fiscal year to implement this bill.

Effective Date

Section 3 provides an effective date of July 1, 2025.

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 identified.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Indeterminate. There will be an increased cost to processors to manufacture, produce, and sell kratom products in the state due to the registration, reporting, and testing requirements in the bill.

C. Government Sector Impact:

There is an increased workload on FDACS to govern registration and reporting requirements for kratom products. The bill appropriates $1,920,141.22 in recurring funds,

$1,791,608 in nonrecurring funds, and $1,508,152.18 for salary for 24 full-time employees from the General Inspection Trust Fund to FDACS for implementation.

VI. Technical Deficiencies:

None.

VII. Related Issues:

In their agency bill analysis, the Florida Department of Law Enforcement (FDLE) noted that:

- A laboratory cannot determine whether an alkaloid is synthetic or natural.
- Red-OH and super alkaloid appear to be names of tablets containing 7-hydroxymitragynine.
- Synthetic 7-OH is synthetic 7-hydroxymitragynine.
- If FDACS requests that FDLE be the third-party laboratory for testing, FDLE does not have the instrumentation or training needed to perform full quantification to determine whether the level of active ingredient is greater than 2% of the product's alkaloid composition.

As such, the processor may not be able to guarantee that their kratom product does not contain synthetic alkaloids in the sworn statement required by subsection (6)(a). Moreover, some of the listed substances may be duplicative of other listed substances in subsection (8)(e).

VIII. Statutes Affected:

This bill substantially amends section 500.92 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.