

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 842

INTRODUCER: Senator Perry

SUBJECT: Florida Kratom Consumer Protection Act

DATE: January 12, 2024

REVISED: _____

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

I. Summary:

SB 842 amends the Florida Kratom Consumer Protection Act to provide definitions, certain prohibitions, and administrative fines for violations of kratom product standards.

The bill defines “kratom extract” and “processor” and provides that a processor 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.

A processor who violates requirements related to product standards is subject to an administrative fine, unless the processor relied in good faith upon the representation of a manufacturer, processor, packer, or distributor of the kratom product.

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 Department of Agriculture and Consumer Services (DACs) was required and did adopt rules to administer the act.²

Kratom

Kratom is a tropical tree native to Southeast Asia that contains mitragynine and 7-hydroxymitragynine in its leaves, which are two major psychoactive ingredients.³ The leaves are 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

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.¹⁰ 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

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 January 12, 2024).

⁴ *Id.*

⁵ *Id.*

⁶ 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/fpsy.2017.00062/full> (last visited January 12, 2024).

⁷ *Id.*

⁸ 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 January 12, 2024).

⁹ *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.

¹⁰ See Sarasota, FL., Code of Ordinances, Sec. 62-351 (2014).

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

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,¹⁸ 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.¹⁹ 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.²⁰

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.²¹ 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.²² 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.²³

III. Effect of Proposed Changes:

The bill amends the Florida Kratom Consumer Protection Act by specifying and using the following definitions:

¹¹ See Alabama Public Health, *Controlled Substance List* (Jan. 20, 2021), available at <https://www.alabamapublichealth.gov/blog/assets/controlledsubstanceslist.pdf> (last visited January 12, 2024).

¹² 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 January 12, 2024).

¹³ See IC 35-31.5-2-321.

¹⁴ 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 January 12, 2024).

¹⁵ See Vt. Admin. Code 12-5-23:4.0.

¹⁶ See W.S.A. 961.14.

¹⁷ See Regulation of Kratom in America: Update (September 2022), available at [Kratom Fact Sheet \(legislativeanalysis.org\)](https://www.legislativeanalysis.org/kratom-fact-sheet) (last visited January 12, 2024).

¹⁸ The import alert labels kratom as an adulterating 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.

¹⁹ 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 January 12, 2024).

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *Id.*

- “Kratom extract” means a food product or dietary ingredient that contains any part of the leaf of the plant *Mitragyna speciosa* which has been extracted and concentrated to provide more standardized dosing;
- “Processor” means a person who sells, prepares, manufactures, distributes, or maintains kratom products.

The bill also 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 controlled 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 speciosa*;
- 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-NF²⁴ chapter 467.²⁵

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 bill takes effect July 1, 2024.

²⁴ 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.

²⁵ 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. 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 January 12, 2024).

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:

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:

None.

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.

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