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 1076
INTRODUCER:	Senator Gruters
SUBJECT:	Florida Kratom Consumer Protection Act
DATE:	January 14, 2022
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	McMillan	McKay	CM	**Favorable**
2.			AEG	
3.			AP	

I. Summary:

SB 1076 creates the Florida Kratom Consumer Protection Act, which 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;
- Contains a level of 7-hydroxymitragynine in the alkaloid fraction which is greater than 2 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, distribute, or expose for sale 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 provides that a processor who violates s. 501.9745(3), F.S., is subject to an administrative fine. However, a processor selling kratom products at retail does not violate s. 501.9745(3), F.S., 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, 2022.

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 Alabama,[9] Arkansas,[10] Indiana,[11] Vermont,[12] and Wisconsin.[13] Other states such as Arizona,[14] Georgia,[15] and Utah[16] regulate kratom under their state's version of the Kratom Consumer Protection Act.

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, in May of 2021, the FDA

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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 Jan. 14, 2022).
[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).
[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).
[7] *Id*.
[8] *See* Sarasota, FL., Code of Ordinances, Sec. 62-351 (2014).
[9] *See* Alabama Public Health, *Controlled Substance List* (Jan. 20, 2021), available at https://www.alabamapublichealth.gov/blog/assets/controlledsubstanceslist.pdf (last visited Jan. 14, 2022).
[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 Jan. 14, 2022).
[11] *See* IC 35-31.5-2-321.
[12] *See* Vt. Admin. Code 12-5-23:4.0.
[13] *See* W.S.A. 961.14.
[14] *See* AZ Rev Stat § 36-795.02.
[15] *See* GA Code § 16-13-121.
[16] *See* UT Code § 4-45-101.

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]

III. Effect of Proposed Changes:

The bill creates the Florida Kratom Consumer Protection Act, 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.;[22]
- Contains a level of 7-hydroxymitragynine in the alkaloid fraction which is greater than 2 percent of the alkaloid composition of the product;

[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 Jan. 14, 2022).
[18] *Id*.
[19] *Id*.
[20] *Id*.
[21] *Id*.
[22] Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act and classifies controlled substances into five categories, known as schedules.

- 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[23] chapter 467.[24] Additionally, a processor may not distribute, sell, or expose for sale a kratom product to an individual under 21 years of age.

The bill provides that a processor who violates s. 501.9745(3), F.S., 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 s. 501.9745(3), F.S., 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, 2022.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

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[23] 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.

[24] 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 Jan. 14, 2022).

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:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill does not designate an entity to enforce violations, and does not provide an administrative penalty for a processor who violates s. 501.9745(4), F.S.

The Florida Department of Law Enforcement has indicated that they do not have the testing capabilities to prove non-compliance with this proposed law.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 501.9745

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.