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LEGISLATIVE ACTION

Senate . House

. . . . .

Senator Gruters moved the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 501.9745, Florida Statutes, is created to read:

501.9745 Kratom products; processor prohibitions; registration; fines.—

(1) SHORT TITLE.—This section may be cited as the "Florida Kratom Consumer Protection Act."

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(2) DEFINITIONS.—As used in this section, the term:

(a) "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.

(b) "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 speciosa* or an extract of such plant and is manufactured as a powder, capsule, pill, or beverage or any other edible form.

(c) "Processor" means a person who sells, prepares, manufactures, distributes, or maintains kratom products.

(3) PROHIBITIONS.—

(a) A processor may not sell, prepare, distribute, or expose for sale:

1. A kratom product that:

a. 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.

b. Contains a poisonous or otherwise harmful non-kratom ingredient, including, but not limited to, any substance listed in s. 893.03.

c. Contains a level of 7-hydroxymitragynine in the alkaloid fraction which is greater than 1 percent of the alkaloid composition of the product.

d. Contains a synthetic alkaloid, including, but not limited to, synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compound

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of the plant *Mitragyna speciosa*.

e. 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.

f. Has a label that contains any claim that the product is intended to diagnose, treat, cure, or prevent any medical condition or disease.

2. Kratom extract that contains levels of residual solvents higher than the standards set forth in USP-NF chapter 467.

(b) A processor may not sell, distribute, or expose for sale a kratom product to an individual under 21 years of age.

(4) REGISTRATION.—A processor shall annually register with the department any kratom product it intendeds to offer for sale to an end consumer in this state which is in an approved kratom delivery form. The registration must include a certificate of analysis from an independent certified third-party laboratory which shows that the kratom product is in compliance with the requirements of this section for safe kratom products. The Department of Agriculture and Consumer Services is not required to test or inspect kratom products pursuant to chapter 500; however, nothing prohibits the department from performing tests and conducting inspections based on consumer complaints, based on agency referrals, or as the department deems necessary.

(5) REPORTING REQUIREMENTS.—

(a) If the department receives a report that any kratom product offered for sale in this state is not in compliance with the requirements of this section for safe kratom products, the department must require the processor to produce an updated certificate of analysis in a reasonable timeframe from an

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independent certified third-party laboratory which shows that the kratom product is in compliance with the requirements of this section for safe kratom products.

(b) If a processor receives notice of an adverse event related to its kratom product, the processor must submit via certified mail to the department a copy of the adverse event report required to be submitted to the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 379aa-1(b)(1).

(c) If a processor fails to provide the department with an updated certificate of analysis within the specified timeframe or fails to report an adverse event to the department as required by this subsection, the department may revoke the processor's kratom product registration.

(6) VIOLATIONS.—

(a) A person who violates this section commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

(b) A processor that sells kratom products at retail does not violate this section 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 food represented to be a kratom product.

(7) RULES.—The department shall adopt rules to administer this section.

Section 2. This act shall take effect July 1, 2024.

================ T I T L E A M E N D M E N T ================

And the title is amended as follows:

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Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to the Florida Kratom Consumer Protection Act; creating s. 501.9745, F.S.; providing a short title; defining terms; prohibiting processors from selling, preparing, distributing, or exposing for sale certain kratom products; prohibiting processors from distributing, selling, or exposing for sale a kratom product to an individual under 21 years of age; requiring processors to annually register kratom products with the Department of Agriculture and Consumer Services; providing requirements for such registration; providing construction; requiring processors to report certain violations and adverse events to the department; providing for the revocation of a processor’s kratom product registration under certain circumstances; providing criminal penalties; providing an exception; requiring the department to adopt rules; providing an effective date.