

By Senator Collins

14-00600B-25

20251734__

A bill to be entitled

An act relating to the Florida Kratom Consumer Protection Act; amending s. 500.92, F.S.; defining terms; revising the definition of the term "kratom product"; prohibiting processors from manufacturing, delivering, offering for sale, distributing, or selling finished kratom products that do not meet specified requirements; requiring that kratom products be manufactured by, delivered to, offered for sale by, distributed by, or sold by a processor who holds a certain permit; prohibiting specified operations; prohibiting exemption from certain requirements; requiring such processors to be registered with the United States Food and Drug Administration; providing an exception; requiring processors to make a certain certification regarding their finished kratom products; requiring a processor to assume responsibility and liability for its kratom, kratom product, and finished kratom product; requiring a processor of a finished kratom product to submit a certificate of analysis from a certain laboratory to the Department of Agriculture and Consumer Services for each batch of finished kratom product; specifying requirements for such laboratory; prohibiting the processor from having any financial or economic interest in such laboratory or the body accrediting such laboratory; requiring the processor to maintain its certificates of analysis for a specified amount of time after the finished kratom product's expiration

14-00600B-25

20251734__

date; requiring that the certificate of analysis demonstrate that the finished kratom product is in compliance with statutory and rule concentration limits for specified substances; requiring that certain finished kratom products comply with product registration and testing requirements; providing an exception; prohibiting the serving of kratom beverages combined with alcohol, drugs, or other kratom products; requiring a processor or the department to submit a certain report to the United States Food and Drug Administration if a processor or the department receives a certain notice; authorizing the department to conduct an independent third-party test of a kratom product if probable cause exists that the product is adulterated; requiring the processor to pay the testing cost; authorizing the department to revoke the processor's product registration if the processor fails to pay for such test within a specified timeframe; providing criminal penalties; providing that certain kratom products are subject to a stop-sale order; authorizing the department to revoke a processor's finished kratom product registration under certain circumstances; providing that a processor whose kratom product contains a controlled substance or other prohibited substances is in violation of this act; providing an administrative fine; providing an appropriation; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

14-00600B-25

20251734__

Section 1. Section 500.92, Florida Statutes, is amended to read:

500.92 Florida Kratom Consumer Protection Act.—

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

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

(a) “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.

(b) “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.

(c) “Kratom” means the plant or any part of the plant *Mitragyna speciosa*.

(d) “Kratom beverage” means a prepackaged liquid kratom product in the form of a tea, seltzer or tonic water, or tincture.

(e) “Kratom food service establishment” means any public food service establishment licensed as provided in chapter 509 which sells finished kratom products.

(f) “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, synthetic alkaloid, or~~

14-00600B-25

20251734__

~~synthetically derived compound of such plant~~ and is manufactured as a powder, capsule, pill, beverage, or other edible form.

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

(3) PRODUCT REQUIREMENTS.—A processor may not manufacture, deliver, offer for sale, distribute, or sell a finished kratom product that:

(a) Is not one of the following approved delivery forms:

1. Dried leaf;

2. Kratom beverage;

3. Powder;

4. Pill; or

5. Capsule.

(b) Contains a level of synthetic 7-hydroxymitragynine in the alkaloid fraction which is greater than 2 percent of the alkaloid composition of the kratom product.

(c) Is not registered with the department pursuant to this section.

(d) Does not have a certificate of analysis submitted to the department as required by this section.

(e) Does not include directions for consumption of the kratom product on the product's label, including, but not limited to:

1. Maximum dosage of 40 milligrams of mitragynine per serving;

2. Number of servings per package;

3. Milligrams of 7-hydroxymitragynine and mitragynine per serving;

4. A warning advising consumers of the number of servings

14-00600B-25

20251734__

that may be safely consumed in a 24-hour period;

5. A warning prohibiting use by individuals who are under 21 years of age;

6. A warning advising against use by individuals who are pregnant or breastfeeding;

7. A warning advising 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;

8. 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.";

9. The expiration date; and

10. The name and place of business of the registrant.

(f) Does not comply with the packaging and labeling requirements set forth in this chapter and the rules adopted pursuant thereto. Such kratom products are considered misbranded.

(g) Is extracted using solvents other than water or Class 3 solvents set forth in USP-NF chapter 467.

(h) Contains levels of Class 3 solvents greater than the limits set forth in USP-NF chapter 467.

(i) Is attractive to children.

(j) Is in a container that:

1. Is not suitable to contain products for human consumption; or

2. Is not compliant with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.

3. Does not contain a graduated measuring device, if

14-00600B-25

20251734__

applicable.

(k) Is adulterated, including containing metals, pesticides, or pathogens in excess of the limits set by this section or department rule.

(4)~~(3)~~ AGE RESTRICTION.—It is unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, any kratom product to a person who is under 21 years of age.

(5) PERMIT AND FEDERAL REGISTRATION REQUIREMENTS FOR PROCESSORS.—

(a) 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. A processor may not operate as a cottage food operation pursuant to s. 500.80 and is not exempt from food permit requirements pursuant to s. 500.12(1)(a)1.

(b) A processor that manufactures, processes, packs, or offers for sale kratom, kratom products, or finished kratom products must be properly registered with the United States Food and Drug Administration. Processors exclusively selling finished kratom products at retail are not required to register with the United States Food and Drug Administration.

(6) REGISTRATION.—

(a) A processor shall certify by sworn statement that any finished kratom product it manufactures, delivers, offers for sale, distributes, or sells in this state is registered with the department 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,

14-00600B-25

20251734__

175 synthetic alkaloids, or controlled substances. Such registration
176 must be renewed annually.

177 (b) A processor shall assume all responsibility and
178 liability for its kratom, kratom product, or finished kratom
179 product.

180 (c) For each batch of a registered finished kratom product,
181 the processor shall submit a certificate of analysis to the
182 department from an independent, third-party, accredited
183 laboratory. The laboratory must be accredited under the
184 International Organization for Standardization
185 (ISO)/International Electrotechnical Commission (IEC) 17025:2017
186 General Requirements for Competence of Testing and Calibration
187 Laboratories standard by an accreditation body that is a
188 signatory to the International Laboratory Accreditation
189 Cooperation Mutual Recognition Arrangement. The processor may
190 not have any direct or indirect financial or economic interest
191 in the laboratory or accrediting body. The processor shall
192 maintain the certificates of analysis for a minimum of 1 year
193 after the finished kratom product's expiration date. The
194 certificate of analysis must demonstrate that the finished
195 kratom product is in compliance with the statutory and rule
196 concentration limits for:

- 197 1. Alkaloid and alkaloid metabolites;
198 2. Residual solvents;
199 3. Heavy metals, including cadmium, arsenic, mercury, and
200 lead; and
201 4. Pesticides and any substance limited by department rule.
202 (d) A finished kratom product served by a kratom food
203 service establishment must comply with the requirements of this

14-00600B-25

20251734__

section; however, a separate registration under this subsection is not required when a kratom beverage is combined with another food or beverage by the kratom food service establishment for consumption on premises. Serving kratom beverages combined with alcohol, drugs, or other kratom products is prohibited.

(7) REPORTING AND TESTING.—

(a) If a processor or the department receives notice of any adverse health event suspected to be related to the processor's kratom product, the processor or the department must submit an adverse event report as set out in chapter IX of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 379aa-1(b)(1) to the United States Food and Drug Administration.

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

(8)~~(4)~~ VIOLATIONS.—

(a) A violation of subsection (4) ~~(3)~~ is a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

(b) A processor that manufactures, delivers, or offers for sale, distributes, or sells a finished kratom product that violates paragraph (3)(b) or paragraph (3)(c) commits a felony of the third degree, punishable as provided in s. 775.082 or s. 775.083.

14-00600B-25

20251734__

233 (c) Kratom products possessed, manufactured, delivered,
234 offered for sale, distributed, or sold in violation of this
235 section by an entity regulated under this chapter are subject to
236 s. 500.172 and an immediate stop-sale order, and the entity is
237 subject to penalties as provided in s. 500.121. The department
238 may not grant permission to remove or use, except for disposal,
239 finished kratom products subject to a stop-sale order which are
240 attractive to children until the finished kratom products comply
241 with this section.

242 (d) If a processor fails to provide the department with a
243 certificate of analysis within 2 days after receiving a request
244 from the department or fails to immediately report an adverse
245 health event to the department as required by this section, the
246 department may revoke the processor's finished kratom product
247 registration.

248 (e) A processor that manufactures, delivers, offers for
249 sale, distributes, or sells a kratom product that contains any
250 controlled substance listed in s. 893.03 or an alkaloid not
251 naturally present in kratom, contains a synthetic alkaloid or a
252 synthetic alkaloid metabolite, including, but not limited to,
253 red-OH, synthetic 7-OH, synthetic 7-hydroxymitragynine,
254 synthetic mitragynine, pseudoindoxyl, super alkaloid, or any
255 other synthetically derived compounds of the plant *Mitragyna*
256 *speciosa*, or contains a level of 7-hydroxymitragynine in the
257 alkaloid fraction which is greater than 2 percent, is in
258 violation of this section.

259 (f) A laboratory that fails to ensure the accuracy of its
260 certificates of analysis issued pursuant to this section is
261 subject to an administrative fine as provided by department

14-00600B-25

20251734__

rule.

~~(9)(5)~~ RULES.—The department shall adopt rules to administer this section.

Section 2. For the 2025-2026 fiscal year, the sums of \$1,920,141.22 in recurring funds and \$1,791,608 in nonrecurring funds from the General Inspection Trust Fund are appropriated to the Department of Agriculture and Consumer Services, and 24 full-time equivalent positions with associated salary rate of 1,508,152.18 are authorized, for the purpose of implementing this act.

Section 3. This act shall take effect July 1, 2025.