

By the Committee on Commerce and Tourism; and Senators Collins and Calatayud

577-02803-25

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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 retain and 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

577-02803-25

20251734c1

product's expiration 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.

577-02803-25

20251734c1

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

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* in any form.

(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

577-02803-25

20251734c1

88 plant *Mitragyna speciosa* ~~or an extract, synthetic alkaloid, or~~
89 ~~synthetically derived compound of such plant~~ and is manufactured
90 as a powder, capsule, pill, beverage, or other consumable ~~edible~~
91 form.

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

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

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

98 1. Dried leaf;

99 2. Kratom beverage;

100 3. Powder;

101 4. Pill;

102 5. Liquid dietary supplement;

103 6. Gummy or food that are not attractive to children; or

104 7. Capsule.

105 (b) Contains or is adulterated with synthesized or semi-
106 synthesized kratom alkaloids or kratom constituents.

107 (c) Contains a level of 7-hydroxymitragynine in the
108 alkaloid fraction which is greater than 2 percent of the
109 alkaloid composition of the kratom product.

110 (d) Is not registered with the department pursuant to this
111 section.

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

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

577-02803-25

20251734c1

- 117 1. Maximum dosage of 40 milligrams of mitragynine per
118 serving;
- 119 2. Number of servings per package;
- 120 3. Milligrams of 7-hydroxymitragynine and mitragynine per
121 serving;
- 122 4. A warning advising consumers of the number of servings
123 that may be safely consumed in a 24-hour period;
- 124 5. A warning prohibiting use by individuals who are under
125 21 years of age;
- 126 6. A warning advising against use by individuals who are
127 pregnant or breastfeeding;
- 128 7. A warning advising the consumer to consult a health care
129 professional before use, that the product may be habit-forming,
130 and that it may cause adverse health effects;
- 131 8. A warning stating the following: "These statements have
132 not been evaluated by the United States Food and Drug
133 Administration. This product is not intended to diagnose, treat,
134 cure, or prevent any disease.";
- 135 9. The expiration date; and
- 136 10. The name and place of business of the registrant.
- 137 (g) Does not comply with the packaging and labeling
138 requirements set forth in this chapter and the rules adopted
139 pursuant thereto. Such kratom products are considered
140 misbranded.
- 141 (h) Is attractive to children.
- 142 (i) Is in a container that:
- 143 1. Is not suitable to contain products for human
144 consumption;
- 145 2. Is not compliant with the United States Poison

577-02803-25

20251734c1

Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.; or

3. Does not contain a graduated measuring device, if applicable.

(j) 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 or as a convenience store or kava or kratom bar that does not prepare, serve, or sell other food products besides kratom products and is not considered a cottage food operation. 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

577-02803-25

20251734c1

175 sale, distributes, or sells in this state is registered with the
176 department and does not contain dangerous or harmful substances,
177 including, but not limited to, red-OH, synthetic 7-OH, synthetic
178 7-hydroxymitragynine, synthetic mitragynine, pseudoindoxyl,
179 super alkaloid, or any other synthetically derived compounds,
180 synthetic alkaloids, or controlled substances. Such registration
181 must be renewed annually.

182 (b) A processor shall assume all responsibility and
183 liability for its kratom, kratom product, or finished kratom
184 product.

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

203 1. Alkaloid and alkaloid metabolites;

577-02803-25

20251734c1

204 2. Residual solvents;

205 3. Heavy metals, including cadmium, arsenic, mercury, and
206 lead; and

207 4. Pesticides and any substance limited by department rule.

208 (d) A finished kratom product served by a kratom food
209 service establishment must comply with the requirements of this
210 section; however, a separate registration under this subsection
211 is not required when a kratom beverage is combined with another
212 food or beverage by the kratom food service establishment for
213 consumption on premises. Serving kratom beverages combined with
214 alcohol, drugs, or other kratom products is prohibited.

215 (7) REPORTING AND TESTING.—

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

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

230 ~~(8)~~(4) VIOLATIONS.—

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

577-02803-25

20251734c1

233 775.083.

234 (b) A processor that manufactures, delivers, or offers for
235 sale, distributes, or sells a finished kratom product that
236 violates paragraph (3)(b) or paragraph (3)(c) commits a felony
237 of the third degree, punishable as provided in s. 775.082 or s.
238 775.083.

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

248 (d) If a processor fails to provide the department with a
249 certificate of analysis within 2 days after receiving a request
250 from the department or fails to immediately report an adverse
251 health event to the department as required by this section, the
252 department may revoke the processor's finished kratom product
253 registration.

254 (e) A processor that manufactures, delivers, offers for
255 sale, distributes, or sells a kratom product that contains any
256 controlled substance listed in s. 893.03 or an alkaloid not
257 naturally present in kratom, contains a synthetic alkaloid or a
258 synthetic alkaloid metabolite, including, but not limited to,
259 red-OH, synthetic 7-OH, synthetic 7-hydroxymitragynine,
260 synthetic mitragynine, pseudoindoxyl, super alkaloid, or any
261 other synthetically derived compounds of the plant *Mitragyna*

577-02803-25

20251734c1

speciosa, or contains a level of 7-hydroxymitragynine in the
alkaloid fraction which is greater than 2 percent, is in
violation of this section.

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