

By Senator Gruters

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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"; requiring that finished kratom products sold to consumers at certain establishments meet certain requirements; requiring that kratom products be manufactured only by a processor who holds a certain permit issued by the Department of Agriculture and Consumer Services; prohibiting specified operations; prohibiting exemptions from certain requirements; requiring certain processors to be properly registered with the United States Food and Drug Administration; requiring processors to comply with certain regulations; requiring processors to maintain product liability insurance with a specified occurrence limit; requiring processors of a finished kratom product to retain and submit a certificate of analysis from an accredited laboratory to the Department of Agriculture and Consumer Services for each batch of finished kratom product; specifying requirements for such laboratory; prohibiting processors from having any financial or economic interest in such laboratory or the body accrediting such laboratory; requiring processors to maintain their certificates of analysis for a specified amount of time after the finished kratom product's expiration date; requiring that the certificate of analysis demonstrate that the finished kratom product is in compliance with statutory and

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rule concentration limits for specified substances;
requiring that certain finished kratom products comply
with product registration and testing requirements;
providing an exception; providing nonapplicability;
providing requirements for finished kratom products
produced in this state and subsequently shipped or
transported out of this state for sale outside of this
state; 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 prohibitions; 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 the act; authorizing the
levying of administrative fines for laboratories that
fail to comply with certain requirements; providing an
appropriation; providing an effective date.

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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; or

2. In a form that resembles an existing candy product that is widely distributed or branded.

(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, a seltzer or tonic water, or a 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~~

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

(g) "Processor" means an entity that:

1. Refines kratom into input ingredients for the purpose of manufacturing a finished kratom product;

2. Manufactures finished kratom products; or

3. Packages finished kratom products for resale.

(3) KRATOM PRODUCT RETAIL SALE REQUIREMENTS.—Finished kratom products sold to consumers at retail establishments, including a food establishment as defined in s. 500.03(1), a convenience store, or a kava or kratom bar:

(a) Must be in one of the following delivery forms:

1. Dried leaf;

2. Kratom beverage;

3. Powder;

4. Pill;

5. Liquid dietary supplement;

6. Gummy or food; or

7. Capsule.

(b) Must possess a certificate of analysis, which must be submitted to the department pursuant to paragraph (4) (e).

(c) Must be registered with the department pursuant to this section.

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

1. Maximum dosage of 100 milligrams of kratom alkaloids per serving;

2. Number of servings per package;

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

119 4. A warning advising consumers of the number of servings
120 that may be safely consumed in a 24-hour period;

121 5. A warning prohibiting use by individuals who are under
122 21 years of age;

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

125 7. A warning advising the consumer to consult a health care
126 professional before use, that the product may be habit-forming,
127 and that it may cause adverse health effects;

128 8. A warning stating the following: "These statements have
129 not been evaluated by the United States Food and Drug
130 Administration. This product is not intended to diagnose, treat,
131 cure, or prevent any disease.";

132 9. The expiration date; and

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

134 (e) Must comply with the packaging and labeling
135 requirements set forth in this chapter and with the rules
136 adopted pursuant thereto.

137 (f) May not be attractive to children.

138 (g) Must be packaged in a container that:

139 1. Is suitable to contain products for human consumption.

140 2. Is compliant with the United States Poison Prevention
141 Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.

142 3. Contains a graduated measuring device, if applicable.

143 (h) May not be adulterated, including containing metals,
144 pesticides, or pathogens in excess of the limits set by this
145 section or department rule.

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146 (i) May be sold only in establishments that restrict entry
147 to persons who are 21 years of age or older and require age
148 verification.

149 (j) May not be served in a form that combines or mixes
150 finished kratom products with psychoactive substances that
151 impact the central nervous system, including, but not limited
152 to, alcohol, caffeine, kava, cannabinoids, and nicotine.

153 (4) PERMIT FOR PROCESSING FINISHED KRATOM PRODUCTS AND
154 FEDERAL AND STATE REGISTRATION REQUIREMENTS FOR PROCESSORS.—

155 (a) Kratom products may be manufactured or distributed in
156 this state only by a processor who holds a permit issued by the
157 department to operate as a food establishment as defined in s.
158 500.03(1). A processor may not operate as a cottage food
159 operation pursuant to s. 500.80 and is not exempt from food
160 permit requirements pursuant to s. 500.12(1)(a)1.

161 (b) A processor that manufactures, processes, packs, or
162 offers for sale kratom, kratom products, or finished kratom
163 products must be properly registered with the United States Food
164 and Drug Administration.

165 (c) A processor shall comply with 21 C.F.R. part 210.

166 (d) A processor shall maintain product liability insurance
167 with an occurrence limit of \$3 million.

168 (e) For each batch of a registered, finished kratom
169 product, the processor shall retain and, upon request, submit a
170 certificate of analysis to the department from an accredited
171 laboratory. The laboratory must be accredited under the
172 International Organization for Standardization
173 (ISO)/International Electrotechnical Commission (IEC) 17025:2017
174 general requirements for competence of testing and calibration

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laboratories standard by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement or a subsequent arrangement. The processor may not have any direct or indirect financial or economic interest in the laboratory or accrediting body. The processor shall maintain the certificates of analysis for a minimum of 1 year after the finished kratom product's expiration date. The certificate of analysis must demonstrate that the finished kratom product is in compliance with the statutory and rule concentration limits for:

1. Alkaloid and alkaloid metabolites;
2. Residual solvents;
3. Heavy metals, including cadmium, arsenic, mercury, and lead; and
4. Pesticides and any substance limited by department rule.

(f) A finished kratom product served by a kratom food service establishment must comply with the requirements of this 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.

(g) Subsection (3) does not apply to finished kratom products processed or manufactured in this state and subsequently shipped or transported out of this state for sale or use outside of this state.

(h) Finished kratom products produced in this state and subsequently shipped or transported out of this state for sale outside of this state:

1. May not be sold, shipped, or transported to a consumer

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in this state, a retail establishment in this state, or to a person who intends to sell such products to a consumer in this state;

2. Must be in a package marked "NOT FOR USE OR RETAIL SALE IN FLORIDA" in a bold font size of at least 36 points; and

3. Must be physically separated from finished kratom products that are, or are intended to be, sold or used in this state.

(5) 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 9 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.

(6) PROHIBITIONS.—

(a) It is unlawful to serve kratom beverages combined with alcohol, drugs, or other kratom products.

(b) 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.

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(7)~~(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, offers for sale, distributes, or sells a finished kratom product that violates paragraph (3)(b) or paragraph (3)(c) commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

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

(d) If a processor fails to provide the department with a certificate of analysis within 7 days after receiving a request from the department or fails to immediately report an adverse health event to the department as required by this section, the department may revoke the processor's finished kratom product registration.

(e) A processor that manufactures, delivers, offers for sale, distributes, or sells a kratom product that contains any controlled substance or adulterants is in violation of this section.

(f) A laboratory that fails to ensure the accuracy of its

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certificates of analysis issued pursuant to this section is
subject to an administrative fine as provided by department
rule.

~~(8)(5)~~ RULES.—The department shall adopt rules to
administer this section.

Section 2. For the 2026-2027 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 October 1, 2026.