

1 A bill to be entitled
2 An act relating to the Florida Kratom Consumer
3 Protection Act; amending s. 500.92, F.S.; defining
4 terms; revising the definition of "kratom product";
5 prohibiting processors from manufacturing, delivering,
6 holding, offering for sale, distributing, or selling
7 finished kratom products that do not meet specified
8 requirements; requiring that kratom products be
9 manufactured by, delivered to, offered for sale,
10 distributed by, or sold by a processor who holds a
11 certain permit; prohibiting specified operations;
12 prohibiting exemption from certain requirements;
13 requiring certain processors to be registered with the
14 United States Food and Drug Administration; providing
15 an exception; requiring processors to make a certain
16 certification regarding their finished kratom
17 products; requiring a processor to assume
18 responsibility and liability for its kratom, kratom
19 product, and finished kratom product; requiring a
20 processor of a finished kratom product to submit a
21 certificate of analysis from a certain laboratory to
22 the Department of Agriculture and Consumer Services
23 for each batch of finished kratom product; specifying
24 requirements for such laboratory; prohibiting the
25 processor from having any financial or economic

26 | interest in such laboratory or the body accrediting
27 | such laboratory; requiring the processor to maintain
28 | its certificates of analysis for a specified amount of
29 | time after the finished kratom product's expiration
30 | date; requiring that the certificate of analysis
31 | demonstrate that the finished kratom product is in
32 | compliance with statutory and rule concentration
33 | limits for specified substances; requiring that
34 | certain finished kratom products comply with product
35 | registration and testing requirements; providing an
36 | exception; prohibiting the serving of kratom beverages
37 | combined with alcohol, drugs, or other kratom
38 | products; requiring a processor or the department to
39 | submit a certain report to the United States Food and
40 | Drug Administration if a processor or the department
41 | receives a certain notice; authorizing the department
42 | to conduct an independent third-party test of a kratom
43 | product if probable cause exists that the product is
44 | adulterated; requiring the processor to pay the
45 | testing cost; authorizing the department to revoke the
46 | processor's product registration if the processor
47 | fails to pay for such test within a specified
48 | timeframe; providing a penalty; providing that certain
49 | kratom products are subject to a stop-sale order;
50 | authorizing the department to revoke a processor's

51 finished kratom product registration under certain
 52 circumstances; providing that a processor whose kratom
 53 product contains a controlled substance or other
 54 prohibited substances is in violation of this section;
 55 providing an administrative fine; providing an
 56 appropriation; providing an effective date.

57

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

59

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

62 500.92 Florida Kratom Consumer Protection Act.—

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

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

66 (a) "Attractive to children" means a product manufactured:

67 1. In a shape that resembles a human, a cartoon character,
 68 or an animal;

69 2. In a form that resembles an existing candy product that
 70 is a widely distributed, branded food item; or

71 3. Using any color additives.

72 (b) "Finished kratom product" means a kratom product that
 73 is ready for sale to the end user. For purposes of registration,
 74 a finished kratom product is differentiated by its ingredients,
 75 not by its weight, volume, or size.

76 (c) "Kratom" means the plant or any part of the plant
 77 Mitragyna speciosa.

78 (d) "Kratom beverage" means a prepackaged liquid kratom
 79 product in the form of a tea, seltzer or tonic water, or
 80 tincture.

81 (e) "Kratom food service establishment" means any public
 82 food service establishment licensed as provided in chapter 509
 83 which sells finished kratom products.

84 (f) "Kratom product" means a food product, food
 85 ingredient, dietary ingredient, dietary supplement, or beverage
 86 intended for human consumption which contains any part of the
 87 leaf of the plant Mitragyna speciosa ~~or an extract, synthetic~~
 88 alkaloid, ~~or synthetically derived compound of such plant~~ and is
 89 manufactured as a powder, capsule, pill, beverage, or other
 90 edible form.

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

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

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

- 97 1. Dried leaf;
- 98 2. Kratom beverage;
- 99 3. Powder;
- 100 4. Pill; or

101 5. Capsule.

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

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

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

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

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

114 2. Number of servings per package;

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

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

119 5. A warning prohibiting use by individuals who are under
120 21 years of age;

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

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

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

130 9. The expiration date; and

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

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

136 (g) Is extracted using solvents other than water or Class
137 3 solvents set forth in USP-NF chapter 467.

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

140 (i) Is attractive to children.

141 (j) Is in a container that:

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

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

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

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

151 (4)-(3) AGE RESTRICTION.—It is unlawful to sell, deliver,
 152 barter, furnish, or give, directly or indirectly, any kratom
 153 product to a person who is under 21 years of age.

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

156 (a) Kratom products may only be manufactured by, delivered
 157 to, offered for sale, distributed by, or sold by a processor who
 158 holds a permit to operate as a food establishment as defined in
 159 s. 500.03. A processor may not operate as a cottage food
 160 operation pursuant to s. 500.80 and is not exempt from food
 161 permit requirements pursuant to s. 500.12(1)(a)1.

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

168 (6) REGISTRATION.—

169 (a) A processor shall certify by sworn statement that any
 170 finished kratom product it manufactures, delivers, offers for
 171 sale, distributes, or sells in this state is registered with the
 172 department and does not contain dangerous or harmful substances,
 173 including, but not limited to, red-OH, synthetic 7-OH, synthetic
 174 7-hydroxymitragynine, synthetic mitragynine, pseudoindoxyl,
 175 super alkaloid, or any other synthetically derived compound,

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

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

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

- 198 1. Alkaloid and alkaloid metabolites;
199 2. Residual solvents;
200 3. Heavy metals, including cadmium, arsenic, mercury, and

201 lead;

202 4. Pesticides; and

203 5. Any substance limited by department rule.

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

211 (7) REPORTING AND TESTING.—

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

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

226 (8)-(4) VIOLATIONS.-

227 (a) A violation of subsection (4) ~~(3)~~ is a misdemeanor of
 228 the second degree, punishable as provided in s. 775.082 or s.
 229 775.083.

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

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

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

250 (e) A processor that manufactures, delivers, offers for

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

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

265 (9)(5) RULES.—The department shall adopt rules to
266 administer this section.

267 **Section 2.** For the 2025-2026 fiscal year, the sums of
268 \$1,920,141.22 in recurring funds and \$1,791,608 in nonrecurring
269 funds from the General Inspection Trust Fund are appropriated to
270 the Department of Agriculture and Consumer Services, and 24
271 full-time equivalent positions with associated salary rate of
272 1,508,152.18 are authorized, for the purpose of implementing
273 this act.

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