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LEGISLATIVE ACTION

Senate

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House

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Floor: 2/RE/2R

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04/27/2023 06:10 PM

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Senator Gruters moved the following:

1 **Senate Substitute for Amendment (330544) (with title**
2 **amendment)**

3
4 Delete everything after the enacting clause
5 and insert:

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

8 501.9745 Kratom products; prohibition; penalties.-

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

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



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12 (a) "Kratom product" means a food product, food ingredient,
13 dietary ingredient, dietary supplement, or beverage intended for
14 human consumption which contains any part of the leaf of the
15 plant *Mitragyna speciosa* or an extract of such plant and is
16 manufactured as a powder, capsule, pill, or beverage or any
17 other edible form.

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

20 (3) PROHIBITIONS.—A processor may not sell, distribute, or
21 expose for sale any kratom product to an individual under 21
22 years of age.

23 (4) VIOLATIONS.—A person who violates this section commits
24 a misdemeanor of the second degree, punishable as provided in s.
25 775.082 or s. 775.083.

26 (5) RULES.—The department shall adopt rules to administer
27 this section.

28 Section 2. Effective July 1, 2024, section 501.9745,
29 Florida Statutes, as created by this act, is amended to read:

30 (Substantial rewording of section. See
31 s. 501.9745, F.S., as created by this act,
32 for present text.)

33 501.9745 Kratom products; prohibitions; registration;
34 penalties.—

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

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

38 (a) "Kratom extract" means a food product or dietary
39 ingredient that contains any part of the leaf of the plant
40 *Mitragyna speciosa* which has been extracted and concentrated to



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41 provide more standardized dosing.

42 (b) "Kratom product" means a food product, food ingredient,
43 dietary ingredient, dietary supplement, or beverage intended for
44 human consumption which contains any part of the leaf of the
45 plant *Mitragyna speciosa* or an extract of such plant and is
46 manufactured as a powder, capsule, pill, or beverage or any
47 other edible form.

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

50 (3) PROHIBITIONS.—

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

53 1. A kratom product that:

54 a. Is adulterated with a dangerous non-kratom substance
55 that affects the quality or strength of the kratom product to
56 such a degree that it may injure a consumer.

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

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

63 d. Contains a synthetic alkaloid, including, but not
64 limited to, synthetic mitragynine, synthetic 7-
65 hydroxymitragynine, or any other synthetically derived compound
66 of the plant *Mitragyna speciosa*.

67 e. Does not include directions for the safe and effective
68 use of the product, including, but not limited to, a suggested
69 serving size, on the product's packaging or label.



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

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

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

77 (4) REGISTRATION.—A person who manufactures kratom products
78 shall annually register with the department any kratom product
79 intended for sale to an end consumer in this state which is in
80 an approved kratom delivery form. The registration must include
81 a certificate of analysis from an independent, certified third-
82 party laboratory which shows that the kratom product is in
83 compliance with the requirements of this section for safe kratom
84 products.

85 (5) REPORTING REQUIREMENTS.—

86 (a) If the department receives a report that any kratom
87 product offered for sale in this state is not in compliance with
88 the requirements of this section for safe kratom products, the
89 department must require the manufacturer to produce an updated
90 certificate of analysis in a reasonable timeframe from an
91 independent, certified third-party laboratory which shows that
92 the kratom product is in compliance with the requirements of
93 this section for safe kratom products.

94 (b) If a manufacturer receives notice of an adverse event
95 related to the manufacturer's kratom product, the manufacturer
96 must submit by certified mail to the department a copy of the
97 adverse event report required to be submitted to the United
98 States Food and Drug Administration under the Federal Food,



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99 Drug, and Cosmetic Act, 21 U.S.C. s. 379aa-1(b) (1).

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

105 (6) VIOLATIONS.—

106 (a) A person who violates this section commits a
107 misdemeanor of the second degree, punishable as provided in s.
108 775.082 or s. 775.083.

109 (b) A processor that sells kratom products at retail does
110 not violate this section if it is shown by a preponderance of
111 the evidence that the processor relied in good faith upon the
112 representations of a manufacturer, processor, packer, or
113 distributor of food represented to be a kratom product.

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

116 Section 3. Except as otherwise expressly provided in this
117 act, this act shall take upon becoming a law.

118
119 ===== T I T L E A M E N D M E N T =====

120 And the title is amended as follows:

121 Delete everything before the enacting clause
122 and insert:

123 A bill to be entitled
124 An act relating to the Florida Kratom Consumer
125 Protection Act; creating s. 501.9745, F.S.; providing
126 a short title; defining the terms "kratom product" and
127 "processor"; prohibiting processors from distributing,



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128 selling, or exposing for sale any kratom product to an
129 individual under 21 years of age; providing criminal
130 penalties; requiring the Department of Agriculture and
131 Consumer Services to adopt rules; defining the term
132 "kratom extract"; prohibiting processors, beginning on
133 a specified date, from selling, preparing,
134 distributing, or exposing for sale certain kratom
135 products; requiring manufacturers to annually register
136 kratom products with the department; providing
137 requirements for such registration; requiring
138 manufacturers to report certain violations and adverse
139 events to the department; providing for the revocation
140 of a manufacturer's kratom product registration under
141 certain circumstances; providing criminal penalties;
142 providing an exception; requiring the department to
143 adopt rules; providing effective dates.