



330544

LEGISLATIVE ACTION

Senate

.

House

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Floor: 1/RS/2R

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04/27/2023 05:34 PM

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Senator Gruters moved the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

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

501.9745 Kratom products; processor prohibitions;
registration; fines.-

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



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11 (2) DEFINITIONS.—As used in this section, the term:
12 (a) "Kratom extract" means a food product or dietary
13 ingredient that contains any part of the leaf of the plant
14 Mitragyna speciosa which has been extracted and concentrated to
15 provide more standardized dosing.
16 (b) "Kratom product" means a food product, food ingredient,
17 dietary ingredient, dietary supplement, or beverage intended for
18 human consumption which contains any part of the leaf of the
19 plant Mitragyna speciosa or an extract of such plant and is
20 manufactured as a powder, capsule, pill, or beverage or any
21 other edible form.
22 (c) "Processor" means a person who sells, prepares,
23 manufactures, distributes, or maintains kratom products.
24 (3) PROHIBITIONS.—
25 (a) A processor may not sell, prepare, distribute, or
26 expose for sale:
27 1. A kratom product that:
28 a. Is adulterated with a dangerous non-kratom substance
29 that affects the quality or strength of the kratom product to
30 such a degree that it may injure a consumer.
31 b. Contains a poisonous or otherwise harmful non-kratom
32 ingredient, including, but not limited to, any substance listed
33 in s. 893.03.
34 c. Contains a level of 7-hydroxymitragynine in the alkaloid
35 fraction which is greater than 1 percent of the alkaloid
36 composition of the product.
37 d. Contains a synthetic alkaloid, including, but not
38 limited to, synthetic mitragynine, synthetic 7-
39 hydroxymitragynine, or any other synthetically derived compound



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40 of the plant *Mitragyna speciosa*.

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

44 f. Has a label that contains any claim that the product is
45 intended to diagnose, treat, cure, or prevent any medical
46 condition or disease.

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

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

51 (4) REGISTRATION.—A processor shall annually register with
52 the department any kratom product it intendeds to offer for sale
53 to an end consumer in this state which is in an approved kratom
54 delivery form. The registration must include a certificate of
55 analysis from an independent certified third-party laboratory
56 which shows that the kratom product is in compliance with the
57 requirements of this section for safe kratom products. The
58 Department of Agriculture and Consumer Services is not required
59 to test or inspect kratom products pursuant to chapter 500;
60 however, nothing prohibits the department from performing tests
61 and conducting inspections based on consumer complaints, based
62 on agency referrals, or as the department deems necessary.

63 (5) REPORTING REQUIREMENTS.—

64 (a) If the department receives a report that any kratom
65 product offered for sale in this state is not in compliance with
66 the requirements of this section for safe kratom products, the
67 department must require the processor to produce an updated
68 certificate of analysis in a reasonable timeframe from an



69 independent certified third-party laboratory which shows that
70 the kratom product is in compliance with the requirements of
71 this section for safe kratom products.

72 (b) If a processor receives notice of an adverse event
73 related to its kratom product, the processor must submit via
74 certified mail to the department a copy of the adverse event
75 report required to be submitted to the United States Food and
76 Drug Administration under the Federal Food, Drug, and Cosmetic
77 Act, 21 U.S.C. s. 379aa-1(b)(1).

78 (c) If a processor fails to provide the department with an
79 updated certificate of analysis within the specified timeframe
80 or fails to report an adverse event to the department as
81 required by this subsection, the department may revoke the
82 processor's kratom product registration.

83 (6) VIOLATIONS.—

84 (a) A person who violates this section commits a
85 misdemeanor of the second degree, punishable as provided in s.
86 775.082 or s. 775.083.

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

92 (7) RULES.—The department shall adopt rules to administer
93 this section.

94 Section 2. This act shall take effect July 1, 2024.

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96 ===== T I T L E A M E N D M E N T =====

97 And the title is amended as follows:



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98 Delete everything before the enacting clause
99 and insert:

100 A bill to be entitled
101 An act relating to the Florida Kratom Consumer
102 Protection Act; creating s. 501.9745, F.S.; providing
103 a short title; defining terms; prohibiting processors
104 from selling, preparing, distributing, or exposing for
105 sale certain kratom products; prohibiting processors
106 from distributing, selling, or exposing for sale a
107 kratom product to an individual under 21 years of age;
108 requiring processors to annually register kratom
109 products with the Department of Agriculture and
110 Consumer Services; providing requirements for such
111 registration; providing construction; requiring
112 processors to report certain violations and adverse
113 events to the department; providing for the revocation
114 of a processor's kratom product registration under
115 certain circumstances; providing criminal penalties;
116 providing an exception; requiring the department to
117 adopt rules; providing an effective date.