

By the Committee on Commerce and Tourism; and Senators Gruters and Stewart

577-02319-23

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1 A bill to be entitled
2 An act relating to the Florida Kratom Consumer
3 Protection Act; creating s. 501.9745, F.S.; providing
4 a short title; defining terms; prohibiting processors
5 from selling, preparing, distributing, or exposing for
6 sale certain kratom products; prohibiting processors
7 from distributing, selling, or exposing for sale a
8 kratom product to an individual under 21 years of age;
9 requiring processors to annually register kratom
10 products with the Department of Agriculture and
11 Consumer Services; providing requirements for such
12 registration; requiring processors to report certain
13 violations and adverse events to the department;
14 providing for the revocation of a processor's kratom
15 product registration under certain circumstances;
16 providing civil penalties; providing an exception;
17 requiring the department to adopt rules; providing an
18 effective date.

19
20 Be It Enacted by the Legislature of the State of Florida:

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

24 501.9745 Kratom products; processor prohibitions;
25 registration; fines.—

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

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

29 (a) "Kratom extract" means a food product or dietary

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30 ingredient that contains any part of the leaf of the plant
31 *Mitragyna speciosa* which has been extracted and concentrated to
32 provide more standardized dosing.

33 (b) "Kratom product" means a food product, food ingredient,
34 dietary ingredient, dietary supplement, or beverage intended for
35 human consumption which contains any part of the leaf of the
36 plant *Mitragyna speciosa* or an extract of such plant and is
37 manufactured as a powder, capsule, pill, or beverage or any
38 other edible form.

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

41 (3) PROHIBITIONS.—

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

44 1. A kratom product that:

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

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

51 c. Contains a level of 7-hydroxymitragynine in the alkaloid
52 fraction which is greater than 1 percent of the alkaloid
53 composition of the product.

54 d. Contains a synthetic alkaloid, including, but not
55 limited to, synthetic mitragynine, synthetic 7-
56 hydroxymitragynine, or any other synthetically derived compound
57 of the plant *Mitragyna speciosa*.

58 e. Does not include directions for the safe and effective

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59 use of the product, including, but not limited to, a suggested
60 serving size, on the product's packaging or label.

61 f. Has a label that contains any claim that the product is
62 intended to diagnose, treat, cure, or prevent any medical
63 condition or disease.

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

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

68 (4) REGISTRATION.—A processor shall annually register with
69 the department any kratom product it intendeds to offer for sale
70 to an end consumer in this state which is in an approved kratom
71 delivery form. The registration must include a certificate of
72 analysis from an independent certified third-party laboratory
73 which shows that the kratom product is in compliance with the
74 requirements of this section for safe kratom products.

75 (5) REPORTING REQUIREMENTS.—

76 (a) If the department receives a report that any kratom
77 product offered for sale in this state is not in compliance with
78 the requirements of this section for safe kratom products, the
79 department must require the processor to produce an updated
80 certificate of analysis in a reasonable timeframe from an
81 independent certified third-party laboratory which shows that
82 the kratom product is in compliance with the requirements of
83 this section for safe kratom products.

84 (b) If a processor receives notice of an adverse event
85 related to its kratom product, the processor must submit via
86 certified mail to the department a copy of the adverse event
87 report required to be submitted to the United States Food and

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88 Drug Administration under the Federal Food, Drug, and Cosmetic
89 Act, 21 U.S.C. s. 379aa-1(b)(1).

90 (c) If a processor fails to provide the department with an
91 updated certificate of analysis within the specified timeframe
92 or fails to report an adverse event to the department as
93 required by this subsection, the department may revoke the
94 processor's kratom product registration.

95 (6) VIOLATIONS.—

96 (a) A processor who violates paragraph (3)(a), subsection
97 (4), or subsection (5) is subject to an administrative fine of
98 not more than \$500 for the first offense and not more than
99 \$1,000 for the second or subsequent offense.

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

105 (7) RULES.—The department shall adopt rules to administer
106 this section.

107 Section 2. This act shall take effect July 1, 2023.