

Amendment No.

CHAMBER ACTION

Senate

House

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1 Representative Andrade offered the following:

2
3 **Amendment (with title amendment)**

4 Remove everything after the enacting clause and insert:

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

7 501.9745 Kratom products; processor prohibitions;
8 registration; fines.-

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:

12 (a) "Kratom extract" means a food product or dietary
13 ingredient that contains any part of the leaf of the plant

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14 Mitragyna speciosa which has been extracted and concentrated to
15 provide more standardized dosing.

16 (b) "Kratom product" means a food product, food
17 ingredient, dietary ingredient, dietary supplement, or beverage
18 intended for human consumption which contains any part of the
19 leaf of the plant *Mitragyna speciosa* or an extract of such plant
20 and is manufactured as a powder, capsule, pill, or beverage or
21 any 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
35 alkaloid fraction which is greater than 1 percent of the
36 alkaloid composition of the product.

37 d. Contains a synthetic alkaloid, including, but not
38 limited to, synthetic mitragynine, synthetic 7-

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39 hydroxymitragynine, or any other synthetically derived compound
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
48 solvents higher than the standards set forth in USP-NF chapter
49 467.

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

52 (4) REGISTRATION.—A processor shall annually register with
53 the department any kratom product it intends to offer for sale
54 to an end consumer in this state which is in an approved kratom
55 delivery form. The registration must include a certificate of
56 analysis from an independent certified third-party laboratory
57 which shows that the kratom product is in compliance with the
58 requirements of this section for safe kratom products.

59 (5) REPORTING REQUIREMENTS.—

60 (a) If the department receives a report that any kratom
61 product offered for sale in this state is not in compliance with
62 the requirements of this section for safe kratom products, the
63 department must require the processor to produce an updated

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64 certificate of analysis in a reasonable timeframe from an
65 independent certified third-party laboratory which shows that
66 the kratom product is in compliance with the requirements of
67 this section for safe kratom products.

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

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

79 (6) VIOLATIONS.—

80 (a) A person who violates this section commits a
81 misdemeanor of the second degree, punishable as provided in s.
82 775.082 or s. 775.083.

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

88 (7) RULES.—The department shall adopt rules to administer

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89 | this section.

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

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93 | **T I T L E A M E N D M E N T**

94 | Remove everything before the enacting clause and insert:

95 | A bill to be entitled

96 | An act relating to the Florida Kratom Consumer

97 | Protection Act; creating s. 501.9745, F.S.; providing

98 | a short title; defining terms; prohibiting processors

99 | from selling, preparing, distributing, or exposing for

100 | sale certain kratom products; prohibiting processors

101 | from distributing, selling, or exposing for sale a

102 | kratom product to an individual under 21 years of age;

103 | requiring processors to annually register kratom

104 | products with the Department of Agriculture and

105 | Consumer Services; providing requirements for such

106 | registration; requiring processors to report certain

107 | violations and adverse events to the department;

108 | providing for the revocation of a processor's kratom

109 | product registration under certain circumstances;

110 | providing criminal penalties; providing an exception;

111 | requiring the department to adopt rules; providing an

112 | effective date.

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