



196652

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/07/2023	.	
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The Committee on Commerce and Tourism (Gruters) recommended 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.

58 (5) REPORTING REQUIREMENTS.—

59 (a) If the department receives a report that any kratom  
60 product offered for sale in this state is not in compliance with  
61 the requirements of this section for safe kratom products, the  
62 department must require the processor to produce an updated  
63 certificate of analysis in a reasonable timeframe from an  
64 independent certified third-party laboratory which shows that  
65 the kratom product is in compliance with the requirements of  
66 this section for safe kratom products.

67 (b) If a processor receives notice of an adverse event  
68 related to its kratom product, the processor must submit via



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69 certified mail to the department a copy of the adverse event  
70 report required to be submitted to the United States Food and  
71 Drug Administration under the Federal Food, Drug, and Cosmetic  
72 Act, 21 U.S.C. s. 379aa-1(b)(1).

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

78 (6) VIOLATIONS.—

79 (a) A processor who violates paragraph (3)(a), subsection  
80 (4), or subsection (5) is subject to an administrative fine of  
81 not more than \$500 for the first offense and not more than  
82 \$1,000 for the second or subsequent offense.

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  
89 this section.

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

91  
92 ===== T I T L E A M E N D M E N T =====

93 And the title is amended as follows:

94 Delete everything before the enacting clause  
95 and insert:

96 A bill to be entitled  
97 An act relating to the Florida Kratom Consumer



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