



730292

LEGISLATIVE ACTION

Senate	.	House
	.	
	.	
Floor: 1/R/2R	.	Floor: RC
05/04/2023 05:03 PM	.	05/03/2023 05:23 PM
	.	

---

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:



730292

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



730292

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.



730292

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,



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 effect 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,



730292

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.