	406	5210		
L	EGISLATIVE AC	TION		
Senate			House	
Comm: RS				
03/25/2025				
The Committee on Commerce	e and Tourism	(Collins)	recommended	the
following:				
Senate Amendment (w Delete lines 77 - 18		ndment)		
and insert:				
Mitragyna speciosa in any	y form.			
(d) "Kratom beverag	ge" means a pr	epackaged	liquid krato	m
product in the form of a	tea, seltzer	or tonic	water, or	

8 <u>tincture</u>.

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(e) "Kratom food service establishment" means any public food service establishment licensed as provided in chapter 509



11	which sells finished kratom products.
12	(f) "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 <i>Mitragyna speciosa</i> or an extract, synthetic alkaloid, or
16	synthetically derived compound of such plant and is manufactured
17	as a powder, capsule, pill, beverage, or other <u>consumable edible</u>
18	form.
19	(g) "Processor" means a person who manufactures, delivers,
20	offers for sale, distributes, or sells kratom products.
21	(3) PRODUCT REQUIREMENTSA processor may not manufacture,
22	deliver, offer for sale, distribute, or sell a finished kratom
23	product that:
24	(a) Is not one of the following approved delivery forms:
25	1. Dried leaf;
26	2. Kratom beverage;
27	3. Powder;
28	<u>4. Pill;</u>
29	5. Liquid dietary supplement;
30	6. Gummy or food that are not attractive to children; or
31	7. Capsule.
32	(b) Contains or is adulterated with synthesized or semi-
33	synthesized kratom alkaloids or kratom constituents.
34	(c) Contains a level of 7-hydroxymitragynine in the
35	alkaloid fraction which is greater than 2 percent of the
36	alkaloid composition of the kratom product.
37	(d) Is not registered with the department pursuant to this
38	section.
39	(e) Does not have a certificate of analysis submitted to

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40	the department as required by this section.
41	(f) Does not include directions for consumption of the
42	kratom product on the product's label, including, but not
43	limited to:
44	1. Maximum dosage of 40 milligrams of mitragynine per
45	serving;
46	2. Number of servings per package;
47	3. Milligrams of 7-hydroxymitragynine and mitragynine per
48	serving;
49	4. A warning advising consumers of the number of servings
50	that may be safely consumed in a 24-hour period;
51	5. A warning prohibiting use by individuals who are under
52	21 years of age;
53	6. A warning advising against use by individuals who are
54	pregnant or breastfeeding;
55	7. A warning advising the consumer to consult a health care
56	professional before use, that the product may be habit-forming,
57	and that it may cause adverse health effects;
58	8. A warning stating the following: "These statements have
59	not been evaluated by the United States Food and Drug
60	Administration. This product is not intended to diagnose, treat,
61	cure, or prevent any disease.";
62	9. The expiration date; and
63	10. The name and place of business of the registrant.
64	(g) Does not comply with the packaging and labeling
65	requirements set forth in this chapter and the rules adopted
66	pursuant thereto. Such kratom products are considered
67	misbranded.
68	(h) Is extracted using solvents other than water or Class 3

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69	solvents set forth in USP-NF chapter 467.
70	(i) Contains levels of Class 3 solvents greater than the
71	limits set forth in USP-NF chapter 467.
72	(j) Is attractive to children.
73	(k) Is in a container that:
74	1. Is not suitable to contain products for human
75	consumption; or
76	2. Is not compliant with the United States Poison
77	Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.
78	3. Does not contain a graduated measuring device, if
79	applicable.
80	(1) Is adulterated, including containing metals,
81	pesticides, or pathogens in excess of the limits set by this
82	section or department rule.
83	(4) (3) AGE RESTRICTIONIt is unlawful to sell, deliver,
84	barter, furnish, or give, directly or indirectly, any kratom
85	product to a person who is under 21 years of age.
86	(5) PERMIT AND FEDERAL REGISTRATION REQUIREMENTS FOR
87	PROCESSORS
88	(a) Kratom products may only be manufactured by, delivered
89	to, offered for sale by, distributed by, or sold by a processor
90	who holds a permit to operate as a food establishment as defined
91	in s. 500.03 or a convenience store or kava or kratom bar that
92	does not prepare, serve, or sell other food products besides
93	kratom products is not considered cottage food operations. A
94	processor may not operate as a cottage food operation pursuant
95	to s. 500.80 and is not exempt from food permit requirements
96	pursuant to s. 500.12(1)(a)1.
97	(b) A processor that manufactures, processes, packs, or

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98	offers for sale kratom, kratom products, or finished kratom
99	products must be properly registered with the United States Food
100	and Drug Administration. Processors exclusively selling finished
101	kratom products at retail are not required to register with the
102	United States Food and Drug Administration.
103	(6) REGISTRATION
104	(a) A processor shall certify by sworn statement that any
105	finished kratom product it manufactures, delivers, offers for
106	sale, distributes, or sells in this state is registered with the
107	department and does not contain dangerous or harmful substances,
108	including, but not limited to, red-OH, synthetic 7-OH, synthetic
109	7-hydroxymitragynine, synthetic mitragynine, pseudoindoxyl,
110	super alkaloid, or any other synthetically derived compounds,
111	synthetic alkaloids, or controlled substances. Such registration
112	must be renewed annually.
113	(b) A processor shall assume all responsibility and
114	liability for its kratom, kratom product, or finished kratom
115	product.
116	(c) For each batch of a registered finished kratom product,
117	the processor shall retain and submit, upon request, a
118	certificate of analysis to the department from an accredited
119	laboratory affiliated with a university based in Florida. The
120	laboratory must be accredited under the International
121	Organization for Standardization (ISO)/International
122	Electrotechnical Commission (IEC) 17025:2017 General
123	Requirements for Competence of Testing and Calibration
124	Laboratories standard by an accreditation body that is a
125	signatory to the International Laboratory Accreditation
126	Cooperation Mutual Recognition Arrangement or a subsequent

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127	arrangement. The processor may
128	
129	=========== T I T L E A M E N D M E N T =================================
130	And the title is amended as follows:
131	Delete line 20
132	and insert:
133	processor of a finished kratom product to retain and
134	submit a

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