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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/25/2025	.	
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The Committee on Commerce and Tourism (Collins) recommended the following:

Senate Substitute for Amendment (406210) (with title amendment)

Delete lines 77 - 189
and insert:

Mitragyna speciosa in any form.

(d) "Kratom beverage" means a prepackaged liquid kratom product in the form of a tea, seltzer or tonic water, or tincture.

(e) "Kratom food service establishment" means any public



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11 food service establishment licensed as provided in chapter 509
12 which sells finished kratom products.

13 (f) "Kratom product" means a food product, food ingredient,
14 dietary ingredient, dietary supplement, or beverage intended for
15 human consumption which contains any part of the leaf of the
16 plant *Mitragyna speciosa* ~~or an extract, synthetic alkaloid, or~~
17 ~~synthetically derived compound of such plant~~ and is manufactured
18 as a powder, capsule, pill, beverage, or other consumable ~~edible~~
19 form.

20 (g) "Processor" means a person who manufactures, delivers,
21 offers for sale, distributes, or sells kratom products.

22 (3) PRODUCT REQUIREMENTS.—A processor may not manufacture,
23 deliver, offer for sale, distribute, or sell a finished kratom
24 product that:

25 (a) Is not one of the following approved delivery forms:

26 1. Dried leaf;

27 2. Kratom beverage;

28 3. Powder;

29 4. Pill;

30 5. Liquid dietary supplement;

31 6. Gummy or food that are not attractive to children; or

32 7. Capsule.

33 (b) Contains or is adulterated with synthesized or semi-
34 synthesized kratom alkaloids or kratom constituents.

35 (c) Contains a level of 7-hydroxymitragynine in the
36 alkaloid fraction which is greater than 2 percent of the
37 alkaloid composition of the kratom product.

38 (d) Is not registered with the department pursuant to this
39 section.



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40 (e) Does not have a certificate of analysis submitted to
41 the department as required by this section.

42 (f) Does not include directions for consumption of the
43 kratom product on the product's label, including, but not
44 limited to:

45 1. Maximum dosage of 40 milligrams of mitragynine per
46 serving;

47 2. Number of servings per package;

48 3. Milligrams of 7-hydroxymitragynine and mitragynine per
49 serving;

50 4. A warning advising consumers of the number of servings
51 that may be safely consumed in a 24-hour period;

52 5. A warning prohibiting use by individuals who are under
53 21 years of age;

54 6. A warning advising against use by individuals who are
55 pregnant or breastfeeding;

56 7. A warning advising the consumer to consult a health care
57 professional before use, that the product may be habit-forming,
58 and that it may cause adverse health effects;

59 8. A warning stating the following: "These statements have
60 not been evaluated by the United States Food and Drug
61 Administration. This product is not intended to diagnose, treat,
62 cure, or prevent any disease.";

63 9. The expiration date; and

64 10. The name and place of business of the registrant.

65 (g) Does not comply with the packaging and labeling
66 requirements set forth in this chapter and the rules adopted
67 pursuant thereto. Such kratom products are considered
68 misbranded.



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(h) Is attractive to children.

(i) Is in a container that:

1. Is not suitable to contain products for human consumption;

2. Is not compliant with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.; or

3. Does not contain a graduated measuring device, if applicable.

(j) Is adulterated, including containing metals, pesticides, or pathogens in excess of the limits set by this section or department rule.

(4) ~~(3)~~ AGE RESTRICTION.—It is unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, any kratom product to a person who is under 21 years of age.

(5) PERMIT AND FEDERAL REGISTRATION REQUIREMENTS FOR PROCESSORS.—

(a) Kratom products may only be manufactured by, delivered to, offered for sale by, distributed by, or sold by a processor who holds a permit to operate as a food establishment as defined in s. 500.03 or as a convenience store or kava or kratom bar that does not prepare, serve, or sell other food products besides kratom products and is not considered a cottage food operation. A processor may not operate as a cottage food operation pursuant to s. 500.80 and is not exempt from food permit requirements pursuant to s. 500.12(1)(a)1.

(b) A processor that manufactures, processes, packs, or offers for sale kratom, kratom products, or finished kratom products must be properly registered with the United States Food and Drug Administration. Processors exclusively selling finished



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kratom products at retail are not required to register with the
United States Food and Drug Administration.

(6) REGISTRATION.—

(a) A processor shall certify by sworn statement that any
finished kratom product it manufactures, delivers, offers for
sale, distributes, or sells in this state is registered with the
department and does not contain dangerous or harmful substances,
including, but not limited to, red-OH, synthetic 7-OH, synthetic
7-hydroxymitragynine, synthetic mitragynine, pseudoindoxyl,
super alkaloid, or any other synthetically derived compounds,
synthetic alkaloids, or controlled substances. Such registration
must be renewed annually.

(b) A processor shall assume all responsibility and
liability for its kratom, kratom product, or finished kratom
product.

(c) For each batch of a registered finished kratom product,
the processor shall retain and submit, upon request, a
certificate of analysis to the department from an accredited
laboratory affiliated with a university based in Florida. The
laboratory must be accredited under the International
Organization for Standardization (ISO)/International
Electrotechnical Commission (IEC) 17025:2017 General
Requirements for Competence of Testing and Calibration
Laboratories standard by an accreditation body that is a
signatory to the International Laboratory Accreditation
Cooperation Mutual Recognition Arrangement or a subsequent
arrangement. The processor may

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



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127 And the title is amended as follows:
128 Delete line 20
129 and insert:
130 processor of a finished kratom product to retain and
131 submit a