

5K-4.030. Kratom Products.

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West's Florida Administrative Code
Title 5. Department of Agriculture and Consumer Services
Subtitle 5k. Division of Food Safety
Chapter 5K-4. Food

Effective: January 10, 2024

Rule 5K-4.030, F.A.C.
Fla. Admin. Code r. 5K-4.030

5K-4.030. Kratom Products.

Currentness

(1) Definitions. The definitions provided in Section 500.03, F.S., and the following shall apply to this rule:

- (a) “Approved Source” means an establishment manufacturing Kratom Products for human consumption that meets local, state, or federal regulatory food safety or health standards from the jurisdiction of origin.
- (b) “Human Consumption” means human ingestion and/or human inhalation. Products intended for Human Consumption include, snuff, chewing gum, and other smokeless products. This term does not include topical applications.
- (c) “Ingestion” means the process of consuming Kratom Products through the mouth, whether by swallowing into the gastrointestinal system or through tissue absorption.
- (d) “Inhalation” means the process of consuming Kratom Products through the mouth or nasal passages into the respiratory system.
- (e) “Kratom Product” means a food product, food ingredient, dietary ingredient, dietary supplement, or beverage intended for human consumption which contains any part of the leaf of the plant *Mitragyna speciosa* or an extract, synthetic alkaloid, or synthetically derived compound of such plant and is manufactured as a powder, capsule, pill, beverage, or other edible form.
- (f) “Self-Service Merchandising” means an open display of Kratom Products to which the public has access without the intervention of the vendor or a store employee.

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(g) "Vending machines" for the purposes of this rule are defined as any self-service device, which upon completion of payment, dispense Kratom Products without the necessity of replenishing the device between each operation.

(2) Permits.

(a) Each establishment distributing products consisting of or containing Kratom Products must be permitted as a Food Establishment pursuant to Section 500.12, F.S., and Rule 5K-4.020, F.A.C.

(b) The annual permit fee for a Food Establishment distributing Kratom Products is \$650.00.

(3) Packaging and Labeling.

(a) Kratom Products must be packaged and labeled as required by Chapter 500, F.S.

(b) The label and advertisement shall not contain claims indicating the product is intended for diagnosis, cure, mitigation, treatment, or prevention of disease, rendering it a drug as defined in 21 U.S.C. § 321(g)(1), revised as of January 3, 2022, incorporated by reference and available online at <http://www.flrules.org/Gateway/reference.asp?No=Ref-16176>, or by requesting a copy by emailing FoodSafety@FDACS.gov. Pursuant to Section 500.03(1)(m) 4., F.S., such articles shall be considered misbranded.

(c) Manufacturers of Kratom Products are subject to the applicable requirements of Chapter 500, F.S. and 21 C.F.R 111, which is incorporated by reference in Rule 5K-4.002, F.A.C.

(d) Kratom Products marketed or labeled as a dietary supplement are subject to the applicable requirements of Chapter 500, F.S. and 21 C.F.R 111, which is incorporated by reference in Rule 5K-4.002, F.A.C.

(4) Age Limit for Kratom.

(a) Any retailer that sells Kratom shall post a clear and conspicuous sign directly adjacent to the display of the product which states the following: THE SALE OF KRATOM TO PERSONS UNDER THE AGE OF 21 IS PROHIBITED. PROOF OF AGE IS REQUIRED FOR PURCHASE.

(b) Kratom may not be mailed, shipped, or otherwise delivered to a purchaser unless, before the delivery to the purchaser, the Food Establishment obtains confirmation that the purchaser is 21 years of age or older.

(c) Food Establishments shall require proof of age from a purchaser of any Kratom product before selling the product to that person. Food Establishments shall exercise diligence in the management and supervision of their premises and in the supervision and training of their employees to prevent the underage sale of these products.

(d) Kratom shall not be offered for sale by means of self-service merchandising unless proof of age has been verified before allowing access to the self-service merchandising.

(e) The giving or sampling of Kratom products by a Food Establishment to any person under the age of 21 is prohibited.

(f) Kratom products shall not be offered for sale by means of vending machines.

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(5) Penalties.

(a) Violations of this rule will be evaluated and penalties imposed in accordance with Rule 5K-4.035, F.A.C.

(b) Kratom Products distributed or sold in violation of this rule shall be considered adulterated or misbranded pursuant to Chapter 500, F.S.

(c) Kratom Products must meet the requirements of this rule. Such products not meeting the requirements of this rule may not be sold in this state.

(d) Violations of this rule shall result in the imposition of stop-sale/stop-use orders, an administrative fine of up to \$5,000 per violation, permit suspension, permit revocation, or any combination thereof.

(e) The sale of Kratom Products to persons under the age of 21 is punishable as provided in chapter 500, F.S.

(f) Kratom Products distributed or sold in violation of this subsection is subject to Section 500.172, F.S. and penalties as provided in Section 500.121, F.S.

Credits

Adopted Jan. 10, 2024.

Authority: 500.09, 500.12, **500.92**, 570.07(23), FS. Law Implemented 500.03, 500.04, 500.09, 500.10, 500.11, 500.12, 500.121, 500.13, **500.92**, 500.172, FS.

Adopted rules current with amendments effective on or before August 13, 2026. Some rules may be more current, see credits for details. For Emergency rules, see credit for details.

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