FLORIDA HOUSE OF REPRESENTATIVES BILL ANALYSIS

| This bill analysis was prepared by nonpartisan committee staff and does not constitute an official statement of legislative intent. | | | | |
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| BILL #: <u>CS/HB 1489</u> | COMPANION BILL: <u>CS/SB 1734</u> (Collins) | | | |
| TITLE: Florida Kratom Consumer Protection Act | LINKED BILLS: None | | | |
| SPONSOR(S): Owen | RELATED BILLS: None | | | |
| Committee References | | | | |
| Industries & Professional Activities | | | | |
| 16 Y, 2 N, As CS | | | | |
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SUMMARY

Effect of the Bill:

The bill revises the Florida Kratom Consumer Protection Act to provide requirements for the distribution and sale of kratom products. The bill restricts the types of businesses and locations where kratom products may be sold, and creates requirements for remote sales. The bill provides penalties for violations, procedures for the seizure, confiscation, and destruction of such products, and authorizes the Department of Agriculture and Consumer Services to administer and enforce these provisions. The bill prohibits using kratom products near certain schools. The bill authorizes certain alcoholic beverage licensees to sell such products.

Fiscal or Economic Impact:

Indeterminate. The bill may have an indeterminate fiscal impact on state government and the private sector.

| JUMP TO | <u>SUMMARY</u> | <u>ANALYSIS</u> | RELEVANT INFORMATION | BILL HISTORY |
|---------|----------------|-----------------|-----------------------------|--------------|

ANALYSIS

EFFECT OF THE BILL:

The bill revises the <u>Florida Kratom Consumer Protection Act</u>, as follows:

- Provides requirements for the testing, certification, distribution, and sale of kratom products.
- Restricts the types of businesses and locations where such products may be sold.
- Creates requirements for remote sales.
- Provides penalties for violations, and procedures for the seizure, confiscation, and destruction of such products.
- Authorizes the Department of Agriculture and Consumer Services to administer and enforce these provisions.
- Prohibits using kratom products near certain schools.
- Authorizes certain alcoholic beverage licensees to sell such products.

Certification of Laboratories

The bill requires the <u>Department of Agriculture and Consumer Services (DACS</u>) to certify any laboratory located within the state or another state which meets the qualifications of an independent testing laboratory. However, a medical marijuana testing laboratory certified pursuant to <u>s. 381.988, F.S.</u>, is not required to receive certification. (Section <u>1</u>)

The bill requires DACS, with the assistance of the Department of Health, to adopt <u>rules</u> establishing the standards for certification of independent testing laboratories, and adopt rules for the testing of kratom products. (Section <u>1</u>)

The rules must include, but are not limited to:

- Security standards.
- Minimum standards for personnel.

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- Sample collection methods and process standards. •
- Proficiency testing for Mitragynine, 7-hydroxymitragynine, and contaminants unsafe for human • consumption, as determined by department rule.
- Reporting content, format, and frequency. ٠
- Audits and onsite inspections. •
- Quality assurance.
- Equipment and methodology.
- Chain of custody.
- Any other standard the department deems necessary. (Section 1)

DACS is required to:

- Renew the certification biennially if the laboratory meets certain requirements or rules. •
- Adopt rules establishing a procedure for initial certification and biennial renewal. •
- Publish on its website a list of all laboratories that have received certification. (Section 1) •

The bill authorizes DACS to refuse to issue, renew, suspend, or revoke, the certification of an independent testing laboratory that is found to be in violation of certain provisions or DACS rules. (Section 1)

The bill requires the laboratories that receive certification DACS to agree to random unannounced audits and onsite inspections by DACS. (Section 1)

Distribution and Retail Sales

The bill authorizes the distribution and sale of kratom products in the state under the following conditions:

- The kratom product must:
 - Not be adulterated with a dangerous non-kratom substance affecting the quality or strength of the product to a degree that renders the product injurious to a consumer.
 - Not be contaminated with contaminants unsafe for human consumption or an otherwise deleterious non-kratom substance, including a controlled substance;
 - Contain a level of 7-hydroxymitragynine in the alkaloid fraction that is no more than two percent of 0 the overall alkaloid composition of the product; and
 - Not contain any synthetic alkaloids, including synthetic 7-hydroxymitragynine and synthetically 0 derived compounds from a plant of the Mitragyna speciosa.
- The kratom product must be tested by the manufacturer, the wholesaler, and the retailer by an • independent testing laboratory.
- The independent testing laboratory's certificate of analysis must state the kratom product was tested for:
 - Synthetic alkaloids.
 - 7-hydroxymitragynine.
 - Heavy metals.
 - Mycotoxins.
 - Pesticides.
 - Potency.
 - Residual solvents.
 - Any other controlled substance.
 - Any other substance the department deems necessary.
 - The kratom product must be distributed or sold in a container that:
 - Includes scannable barcode or quick response code linked to the certificate of analysis of the kratom product;
 - Includes the kratom product testing number;
 - Includes the expiration date of the kratom product;
 - Is suitable to contain products for human consumption;
 - Is composed of materials designed to minimize exposure to light;
 - Mitigates exposure to high temperatures;
 - Is a single color and is not transparent. However, this does not apply to the universal symbol;
 - Does not contain any pictures or images other than a single logo, which may not be attractive to children and may be no more than 20 percent of the container;

- Contains a clear and conspicuous warning developed by the department that the product is a kratom product;
- Contains a universal symbol that indicates the presence of kratom, which must be developed by the department;
- Is not attractive to children; and
- Is compliant with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq., without regard to provided exemptions. For purposes of this subparagraph, a beverage in a sealed container is considered compliant with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq. (Section <u>1</u>)

The bill does not require a wholesaler or retailer to test their kratom products if:

- The product is packaged in a container in a manner that may be sold to the ultimate consumer when the wholesaler or retailer receives the product from the manufacturer or wholesaler;
- The product was tested by the manufacturer or wholesaler; and
- The wholesaler or retailer does not open the container. (Section <u>1</u>)

The bill restricts the retail sale and delivery of kratom products, to the following methods:

- At establishments that:
 - Have a food permit from DACS; and
 - Prohibit persons under 21 years of age on the establishment's premises.
- At establishments that have a food permit from DACS and an alcoholic beverage quota license.
 - Establishments with a quota license, that allow persons under 21 years of age on the establishment's premises, are required to place kratom products, not including beverages, in an area inaccessible to customers.
 - Such establishments may place kratom products, not including beverages, in an open display unit as long as the unit is located in an area that is inaccessible to customers; or
- In accordance with the mail order, internet, and remote sales of kratom products requirements in <u>s. 500.93</u>, <u>F.S.</u> (Section <u>1</u>)

The bill prohibits kratom products from being sold, given, bartered, furnished, or delivered to consumers at festivals, fairs, trade shows, farmers markets, expositions, or pop-up retail establishments. The bill creates a graduated schedule of penalties for violations and the prohibition on underage sales, as follows:

- First offense: Second degree misdemeanor, punishable as provided in s. 775.082 or s. 775.083, F.S., F.S.
- Second offense within 12 months of the first offense: First degree misdemeanor, punishable as provided in <u>s. 775.082</u> or <u>s. 775.083</u>, F.S.
- **Third or subsequent offense within 12 months of the second offense**: Felony of the third-degree, punishable as provided in <u>s. 775.082</u> or <u>s. 775.083</u>, F.S. (Section 1)

DACS is also authorized to take any of the following actions against any person licensed or permitted for a violation: place on probation or reprimand the licensee or permit, revoke, suspend, or deny the issuance or renewal of the license or permit, impose an administrative fine not to exceed \$5,000 per violation or assess costs associated with investigation and prosecution. (Section <u>1</u>)

The bill requires DACS to enforce these provisions, and requires every state attorney, sheriff, police officer, and other appropriate county or municipal officer to enforce, or assist DACS in enforcement. (Section $\underline{1}$)

Definitions

The bill defines the following terms:

• "Attractive to children" means manufactured in the shape of or packaged in containers displaying humans, cartoons, animals, toys, or other features that target children; manufactured in a form or packaged in a container that bears any reasonable resemblance to an existing candy or snack product that is familiar to the public; manufactured in a form or packaged in a container that bears any reasonable resemblance to a branded food product such that the product could be mistaken for the branded food product, especially by children; or containing any color additives.

- "Contaminants unsafe for human consumption" includes, but is not limited to, any microbe, fungus, yeast, mildew, herbicide, pesticide, fungicide, residual solvent, metal, or other contaminant found in any amount that exceeds any of the accepted limitations as determined by rules adopted by the Department of Health in accordance with s. 381.986, or other limitation pursuant to the laws of this state, whichever amount is less.
- "Independent testing laboratory" means a laboratory that:
 - Does not have a direct or indirect interest in the entity whose product is being tested;
 - Does not have a direct or indirect interest in a facility that processes, distributes, dispenses, or sells kratom products in the state or in another jurisdiction or cultivates, processes, distributes, dispenses, or sells marijuana, as defined in s. 381.986; and
 - Is certified by the Department of Health as a medical marijuana testing laboratory pursuant to s. 381.988, or is certified by the department as being substantially equivalent to a medical marijuana testing laboratory.
- "Manufacturer" means any person or entity that engages in the process of manufacturing, preparing, or packaging of Kratom products.
- "Retailer" means any person or entity who sells kratom products to consumers.
- "Wholesaler" means any person or entity located inside or outside this state that delivers or sells products containing Kratom to retailers or other persons for purposes of resale. (Section <u>1</u>)

Mail order, Internet, Remote Sales, and Age Verification

The bill provides that:

- The sale of kratom products constitutes a delivery sale, as defined, and is a delivery sale regardless of whether the person accepting the order for the delivery sale is located inside or outside the state.
- A retailer is required to obtain a food permit from DACS under the Florida Food Safety Act before accepting an order for a delivery sale.
- A person may not make a delivery sale of Kratom product to any individual who is not 21 years of age or older.
- Each person accepting an order for a delivery sale must comply with the:
 - Age verification requirements.
 - Disclosure requirements.
 - Shipping requirements. (Section <u>2</u>)

The bill prohibits mailing, shipping, or otherwise delivering kratom products in connection with an order for a delivery sale unless, before the first delivery to the consumer, the person accepting the order:

- Obtains from the person submitting the order a certification that includes:
 - Reliable confirmation that the person is 21 years of age or older; and
 - A statement signed by the person in writing and under penalty of perjury which:
 - Certifies the address and date of birth of the person; and
 - Confirms that the person wants to receive delivery sales from a Kratom product retailer and understands that, under the laws of the state, the following actions are illegal:
 - Signing another person's name to the certification;
 - Selling Kratom products to individuals who are not 21 years of age or older; and
 - Purchasing Kratom products, if the person making the purchase is not 21 years of age or older.
- Makes a good faith effort to verify the information contained in the certification provided by the individual against a commercially available database that may be reasonably relied upon for accurate age information or obtains a photocopy or other image of a valid government-issued identification card stating the date of birth or age of the individual.
- Provides to the individual, via electronic mail or other means, a notice.
- If an order for Kratom products is made pursuant to an advertisement on the Internet, receives payment for the delivery sale from the consumer by a credit or debit card issued in the name of the consumer, or by personal or company check of the consumer.
- Submits, to each credit card acquiring company with which the person has credit card sales, identification information in an appropriate form and format so that the words "Kratom product" may be printed in the purchaser's credit card statement when a purchase of Kratom products is made by credit card payment.

• Makes a telephone call after 5 p.m. to the purchaser confirming the order before shipping the Kratom product. The telephone call may be a person-to-person call or a recorded message. The person accepting the order for delivery sale is not required to speak directly with a person and may leave a message on an answering machine or through voice mail. (Section <u>2</u>)

In addition to these shipping requirements, a person accepting an order for a delivery sale is authorized to request that a consumer provide an electronic mail address. (Section $\underline{2}$)

The bill requires the pre delivery shipping notice to include prominent and clearly legible statements that sales of Kratom products are:

- Illegal if made to individuals who are not 21 years of age or older.
- Restricted to those individuals who provide verifiable proof of age. (Section <u>2</u>)

The bill requires each person who mails, ships, or otherwise delivers Kratom products in connection with an order for a delivery sale to:

- Ship the Kratom product in a container that complies with the container requirements in <u>s. 500.92, F.S.</u>
- Include as part of the shipping documents, in a clear and conspicuous manner, the following statement: "Kratom product: Florida law prohibits shipping to individuals under 21 years of age."
- Use a method of mailing, shipping, or delivery which obligates the delivery service to require proof that the individual accepting the order for the delivery sale is 21 years of age or older and resides at the address listed on the order label, by reviewing a valid, government-issued identification card bearing a photograph of the individual who signs to accept delivery of the shipping container. (Section <u>2</u>)

If the person accepting a purchase order for a delivery sale delivers the Kratom product without using a delivery service, the person must comply with all of the requirements which apply to a delivery service. Any failure to comply constitutes a violation. (Section $\underline{2}$)

The delivery sale provisions do not apply to delivery sales of kratom products to a retailer or wholesaler. (Section <u>2</u>)

The bill provides that an individual 21 years of age or older who knowingly violates any provision of the shipping requirements commits a second degree misdemeanor, punishable as provided in s. 775.082 or <u>s. 775.083, F.S.</u>, and the Attorney General, or a state attorney may bring an action to prevent or restrain violations. (Section <u>2</u>)

The bill provides the following definitions:

- "Consumer" means a person in the state who comes into possession of any kratom product who, at the time of possession, is not intending to sell or distribute the kratom product, or is not a retailer.
 - "Delivery sale" means any sale of a kratom product to a consumer in the state for which:
 - The consumer submits the order for the sale by telephonic or other voice transmission, mail, delivery service, or the Internet or other online service; or
 - The kratom product is delivered by use of mail or a delivery service.
- "Delivery service" means any person engaged in the commercial delivery of letters, packages, or other containers.
- "Legal minimum purchase age" means the minimum age at which an individual may legally purchase kratom products in the state.
- "Shipping container" means a container in which Kratom product is shipped in connection with a delivery sale.
- "Shipping document" means a bill of lading, airbill, United States Postal Service form, or any other document used to verify the undertaking by a delivery service to deliver letters, packages, or other containers.
- "Kratom Product" has the same meaning as provided in s. 500.92. (Section 2)

Seizure and Destruction of Contraband Kratom Products

The bill provides that kratom products sold, offered for sale, delivered, or distributed contrary to any provision of ss. 500.92-<u>500.93, F.S.</u>, of the Florida Kratom Consumer Protection Act:

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- Are declared to be contraband;
- Are subject to seizure and confiscation under the Florida Contraband Forfeiture Act by any person whose duty it is to enforce those sections; and
- Must be disposed of as follows:
 - A court having jurisdiction must order such kratom products forfeited upon a showing that, by a preponderance of the evidence, such devices were sold, offered for sale, delivered, or distributed contrary to any provision of ss. 500.92-<u>500.93, F.S.</u> Once any chapter 120, F.S. proceedings related to such products have been completed, the court must order any seized kratom products destroyed except as provided by applicable court orders. A record of the place where such products were seized, the kinds and quantities of such products destroyed, and the time, place, and manner of the destruction of such products must be kept, and a return under oath reporting the destruction must be made to the court by the officer who destroys such products.
 - DACS or seizing law enforcement agency must keep a full and complete record of all products seized under this section showing:
 - The exact kinds, quantities, and forms of such products;
 - The persons from whom such products were seized and to whom they were delivered;
 - By whose authority such products were seized, delivered, and destroyed; and
 The dates of the seizure, disposal, or destruction of such products.
 - Such record must be open to inspection by all persons charged with the enforcement of <u>ss. 581.217</u> through 581.218, F.S., the state hemp program.
 - The cost of seizure, confiscation, and destruction of contraband kratom products is borne by the person from whom such products are seized.
 - Except as otherwise provided, the procedures of the Florida Contraband Forfeiture Act apply to this Act.
 - Kratom products has the same meaning as provided in <u>s. 500.92, F.S.</u> (Section <u>3</u>)

Ingesting Kratom Products Near School Property

The bill prohibits ingesting kratom products in, on, or within 1,000 feet of the real property comprising a public or private elementary, middle, or secondary school between the hours of 6 a.m. and midnight. This section does not apply to any person occupying a moving vehicle or within a private residence. (Section $\underline{4}$)

The bill authorizes law enforcement officers to issue a citation as prescribed by a county or municipality for violations, that include:

- The date and time of issuance.
- The name and address of the person cited.
- The date and time the civil infraction was committed.
- The statute violated.
- The facts constituting the violation.
- The name and authority of the law enforcement officer.
- The procedure for the person to follow to pay the civil penalty, to contest the citation, or to appear in court.
- The applicable civil penalty if the person elects not to contest the citation.
- The applicable civil penalty if the person elects to contest the citation. (Section <u>4</u>)

The bill provides that such citations are deemed a civil infraction punishable by a maximum civil penalty of \$25, or 50 hours of community service or, where available, successful completion of a school-approved anti-drug "alternative to suspension" program. (Section <u>4</u>)

The bill provides that failure to comply with the citation is deemed as a waiver of the right to contest the citation and an order to show cause may be issued by the court. (Section $\underline{4}$)

Division of Alcoholic Beverages and Tobacco

The bill authorizes:

• An alcoholic beverage vendor licensed to operate a place of business where beverages are sold only in sealed containers for consumption off the premises (<u>package store licensee</u>) to sell kratom products in accordance with the Florida Kratom Consumer Protection Act. (Section <u>5</u>)

- An alcoholic beverage <u>quota licensee</u> to sell kratom products in accordance with the Florida Kratom Consumer Protection Act. (Section <u>6</u>)
- The Department of Business and Professional Regulation (DBPR) Division of Alcoholic Beverages and Tobacco (ABT) to discipline the permit of a retail <u>tobacco products dealer</u>, or a retail <u>nicotine products</u> <u>dealer</u>, for violations of the Florida Kratom Consumer Protection Act. (Section <u>7</u> and <u>8</u>)

Effective Date

The effective date of the bill is January 1, 2025. (Section 9)

RULEMAKING:

The bill requires DACS to adopt <u>rules</u>:

- Establishing standards for certification of independent testing laboratories.
- For the testing of kratom products.
- A procedure for initial certification and biennial renewal.

The bill requires the Department of Health to assist DACS in developing rules for the certification of independent testing laboratories.

Lawmaking is a legislative power; however, the Legislature may delegate a portion of such power to executive branch agencies to create rules that have the force of law. To exercise this delegated power, an agency must have a grant of rulemaking authority and a law to implement.

FISCAL OR ECONOMIC IMPACT:

STATE GOVERNMENT:

Indeterminate. The bill may increase expenditures and revenues for DACS and DBPR, related to additional administration and enforcement costs, and the collection of related fees and fines.

PRIVATE SECTOR:

Indeterminate. The bill may increase expenditures for manufacturers, retailers, and wholesalers to satisfy the new regulatory requirements in the bill. However, such requirements may result in a cost savings to the extent that improvements are made to the health and safety related to the consumption of kratom products.

RELEVANT INFORMATION

SUBJECT OVERVIEW:

<u>Kratom</u>

Kratom is a tropical tree native to Southeast Asia, which contains two major psychoactive ingredients, mitragynine and 7-hydroxymytragynine, in its leaves.¹ The leaves are crushed and then smoked, brewed with tea, or placed into gel capsules.² Consumption of kratom leaves can produce stimulant and sedative effects, and may also lead to psychotic symptoms.³

Some research has found that kratom can be used as a substitute for opiate users to combat withdrawal symptoms, as well as to treat muscle ache, fatigue, and other conditions.⁴ Low doses of kratom are said to produce a stimulant effect, while higher doses may produce an opioid-like effect.⁵ Additionally, research points to the potential for

¹ Drug Enforcement Administration, *Kratom* (April 2020), <u>https://www.dea.gov/sites/default/files/2020-06/Kratom-2020_0.pdf</u> (last visited Mar. 28, 2025).

 $^{^{2}}$ Id.

 $^{^{3}}$ Id.

 ⁴ See Dimy Fluyau and Neelambika Revedigar, *Biochemical Benefits, Diagnosis, and Clinical Risks Evaluation of Kratom*, FRONTIERS IN PSYCH. J. VOL. 8 (April 24, 2017) <u>https://www.frontiersin.org/articles/10.3389/fpsyt.2017.00062/full</u> (last visited Mar. 25, 2025).
 ⁵ Fluyau and Neelambika, *supra* note 6.

further development of mitragynine and the use of kratom as a harm reduction agent.⁶ Even so, the toxicity of kratom remains a topic of discussion, as well as its potential to cause herb-drug interactions and even be involved in fatalities.⁷ While research on kratom is in early stages, kratom itself has the potential to be addictive and has not been shown to be safe or effective for any medical use.⁸

According to the FDA, kratom is not appropriate for use as a dietary supplement. The FDA has concluded from available information, including scientific data, that kratom is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury and, therefore, dietary supplements that are or contain kratom are adulterated under the FD&C Act. Further, FDA has determined that kratom, when added to food, is an unsafe food additive. Based on these determinations by FDA, kratom is not lawfully marketed as a dietary supplement and cannot be lawfully added to conventional foods.⁹

Florida Kratom Consumer Protection Act of 2023

In 2023, the Legislature enacted the Florida Kratom Consumer Protection Act,¹⁰ which made it unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, any kratom product to a person under 21 years of age. Violations are a second degree misdemeanor, punishable as provided in <u>s. 775.082</u> or <u>s. 775.083, F.S. ¹¹</u>

The Florida Department of Agriculture and Consumer Services (DACS) is required to adopt rules to implement the act. The rules include the following requirements:¹²

- Each establishment distributing products consisting of or containing Kratom Products must be permitted as a Food Establishment pursuant under the Florida Food Safety Act.
- Kratom Products must be packaged and labeled as required by the Florida Food Safety Act.
- Retailers that sell Kratom must display signs regarding the age limit for purchasing Kratom.
- Food Establishments must obtain confirmation that the purchaser is 21 years of age or older before mailing the product.
- Food Establishments must require proof of age from a purchaser of any Kratom product before selling the product to that person.
- Kratom products shall not be offered for sale by means of vending machines.

The rule authorizes DACS to enforce violations by imposing stop-sale/stop-use orders, administrative fines of up to \$5,000 per violation, permit suspensions, and/or revocations, and other administrative disciplinary procedures.¹³

State and Federal Prohibitions

Currently, kratom is not listed as a controlled substance under federal law or Florida law. In 2016, the U.S. Drug Enforcement Administration (DEA) submitted a notice of intent to place kratom into Schedule I of the Controlled Substances Act (CSA) based on abuse potential and risk to public health.¹⁴ However, the DEA withdrew the notice a few months later based on public comments.¹⁵ In a letter obtained by an industry group, U.S. Health and Human Services appeared to rescind their recommendation to the DEA to place kratom on Schedule I of the CSA in 2018,

⁶ See Charles Veltri and Oliver Grundmann, *Current Perspectives on the Impact of Kratom Use*, SUBSTANCE ABUSE AND REHAB. J. VOL. 10, 23-31 (July 1, 2019) <u>https://pubmed.ncbi.nlm.nih.gov/31308789/</u> (last visited Mar. 25, 2025).

 ⁷ Id.; see also FLORIDA DEPT. LAW ENF'T, Drugs <u>https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2021-Interim-Drug-Report-FINAL.aspx</u> (last visited Mar. 25, 2025). In May of 2022 the Florida Department of Law Enforcement published its 2021 Interim Report, which found a 36% rise in kratom-involved deaths over the first half of 2021.
 ⁸ NAT'L CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH, *Kratom*, <u>https://www.nccih.nih.gov/health/kratom</u> (last visited Mar. 25, 2025).

⁹ U.S. Food & Drug Administration, *FDA and Kratom*, <u>https://www.fda.gov/news-events/public-health-focus/fda-and-kratom</u> (last visited Mar. 25, 2025).

¹⁰ Ch. 2023-182, Laws of Fla.

¹¹ S. <u>500.92, F.S.</u>

¹² R. 5K-4.030, F.A.C.

¹³ *Id*.

¹⁴ 81 FR 59929. ¹⁵ 81 FR 70652

stating that such action should wait until it is supported by further research on kratom uses, abuse, and risks.¹⁶ The DEA continues to label kratom as a drug of concern.¹⁷

The U.S. Food and Drug Administration (FDA) has stated that there is substantial concern regarding the safety of kratom and the risk it may pose to public health, and indicated that there are currently no FDA-approved uses for kratom.¹⁸ The FDA is actively evaluating all available scientific information on the safety and effects of kratom and continues to warn consumers not to use any kratom products, but has made no official findings.¹⁹

In 2015, the FDA issued an import alert²⁰ that labels kratom as an adulterating ingredient.²¹ As a result, the FDA seized imports of kratom-containing dietary supplements and bulk dietary ingredients. In May of 2021, the FDA announced the seizure of around 37,500 tons of adulterated kratom in Fort Myers, Florida, worth an estimated \$1.3 million.²² On October 26, 2021, a consent decree of condemnation and destruction against the seized articles by the FDA was entered, which required the claimants to pay a penal bond and destroy all seized articles.²³

Generally, the official federal legal and regulatory status of kratom or kratom included in food products is still being decided.

In 2014, Sarasota County banned kratom, labeling it as a designer drug.²⁴ With the exception of Sarasota County, in Florida, all parts of the plant and its extracts are legal to cultivate, buy, possess, and distribute without a license or prescription.

Kratom is illegal in Alabama,²⁵ Arkansas,²⁶ Indiana,²⁷ Rhode Island,²⁸ Vermont,²⁹ and Wisconsin.³⁰ Other states such as Arizona,³¹ Georgia,³² Texas,³³ and Utah³⁴ regulate kratom under their state's version of the Kratom Consumer Protection Act. A total of sixteen states regulate the sale of kratom products in some fashion. The state laws are not uniform. Their differences arise in their handling of particular issues relating to kratom products. These issues include:³⁵

²² U.S. Food and Drug Administration, *FDA Announces Seizure of Adulterated Dietary Supplements Containing Kratom*, May 21, 2021, <u>https://www.fda.gov/news-events/press-announcements/fda-announces-seizure-adulterated-dietary-supplements-containing-kratom</u> (last visited Mar. 25, 2025).

 23 *Id*.

https://www.alabamapublichealth.gov/blog/assets/controlledsubstanceslist.pdf (last visited Mar. 25, 2025).

²⁶ See Arkansas Department of Health, List of Controlled Substances, available at https://healthy.arkansas.gov/wp-

content/uploads/Controlled Substances List.pdf (last visited Mar. 25, 2025).

²⁷ See IC 35-31.5-2-321.

https://docs.wixstatic.com/ugd/9ba5da_9836aee2b9f04a30b55fe480fe3c6ff4.pdf (last visited Mar. 30, 2025).

²⁹ See Vt. Admin. Code 12-5-23:4.0.

- ³² See GA Code § 16-13-121.
- ³³ Texas Health and Safety Code Ann. Ch. 444 (2023).

BILL HISTORY

¹⁶ Josh Long, *HHS in 2018 rescinded recommendation to schedule kratom as a drug*, Jan. 28, 2021,

https://www.naturalproductsinsider.com/regulatory/hhs-2018-rescinded-recommendation-schedule-kratom-drug (last visited Mar. 28, 2025).

¹⁷ U.S. Drug Enforcement Administration, *Kratom*, <u>https://www.dea.gov/factsheets/kratom</u> (last visited Mar. 28, 2025).

¹⁸ U.S. Food and Drug Administration, *FDA and Kratom*, <u>https://www.fda.gov/news-events/public-health-focus/fda-and-kratom</u> (last visited Mar. 25, 2025).

¹⁹ Id.

²⁰ U.S. Food and Drug Administration, Import Alert 54-15, Import Alert 54-15 (fda.gov) (last visited Mar. 25, 2025).

²¹ *Id.* The FDA labeled kratom as adulterating based on the absence of a history of use or other evidence of safety establishing that kratom will reasonably be expected to be safe as a dietary ingredient, kratom and kratom-containing dietary supplements and bulk dietary ingredients are adulterated because they contain a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

²⁴ See Sarasota, FL., Code of Ordinances, Sec. 62-351 (2014).

²⁵ See Alabama Public Health, Controlled Substance List (Jan. 20, 2021),

²⁸ Rhode Island Department of Health, Designation of Controlled Substance (Apr. 10, 2017),

³⁰ See W.S.A. 961.14.

³¹ See AZ Rev Stat § 36-795.02.

³⁴ See UT Code § 4-45-101.

³⁵ Congressional Research Service, *Kratom Regulation: Federal Status and State Approaches*, <u>https://www.congress.gov/crs-product/LSB11082</u> (last visited Mar. 30, 2025).

- Age restrictions
- Marketing to children.
- Adulteration and contamination.
- Strength.
- Labeling.
- Testing and sampling.
- Registration and permitting.
- Synthetic alkaloids.
- Local authority.
- Private right of action.
- Taxation.

Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act (FDCA) is a federal law which establishes the legal framework within which the FDA operates.³⁶ The FDA develops regulations under the FDCA for the safety of foods, drugs, and cosmetics based on the laws set forth in the FDCA, including when a food is adulterated.³⁷ Instances where a food must be determined to be adulterated include when it:³⁸

- Bears or contains any poisonous or deleterious substance which may render it injurious to health; such as consisting in whole or in part of any filthy, putrid, or decomposed substance;
- Is a dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under use pursuant to the label;
- Is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.

When a food is determined to be adulterated, the FDA may take the following compliance measures:³⁹

- Warning and untitled letters,
- Import alerts,
- Recalls,
- Debarment,
- Civil money penalties,
- Seizure of products,
- Injunctions, and
- Criminal prosecution.

Florida Food Safety Act

The purpose of the Florida Food Safety Act (Act)⁴⁰ is to safeguard and protect the consuming public from product use and merchandising deceit regarding the intrastate commerce of food. The Act is also meant to promote conformance with the Federal Food, Drug, and Cosmetic Act,⁴¹ Agriculture Marketing Act of 1946,⁴² and Federal Trade Commission Act.⁴³⁴⁴

DACS is the agency responsible for the enforcement of the production, manufacture, transportation, and sale of food through the Act. The <u>DACS Division of Food Safety (Division</u>) is directly responsible for assuring the public of a safe, wholesome, and properly represented food supply.⁴⁵ The division accomplishes this through the

³⁶ 21 U.S.C. 301.

³⁷ See 21 C.F.R. §§ 1-1299.

³⁸ 21 U.S.C. 342.

³⁹ CRS Report R43609, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues*, February 9, 2018, <u>https://www.everycrsreport.com/reports/R43609.html#fn96</u> (last visited Mar. 25, 2025).

⁴⁰ See <u>ch. 500, F.S.</u>

⁴¹ 21 U.S.C. §§ 301-399d.

⁴² 7 U.S.C. §§ 1621-1629.

^{43 5} U.S.C. §§ 41-58, as amended.

⁴⁴ S. <u>500.02, F.S.</u>

⁴⁵ FDACS, Division of Food Safety, <u>https://www.fdacs.gov/Divisions-Offices/Food-Safety</u> (last visited March 8, 2025).

permitting⁴⁶ and inspection⁴⁷ of food establishments,⁴⁸ the inspection and evaluation of food products, and the performance of specialized laboratory testing on a variety of food products sold or produced in Florida.⁴⁹ The Division also proactively monitors food from manufacturing and distribution to retail.⁵⁰

As part of its responsibilities, DACS can impose a variety of <u>disciplinary actions</u> against food establishments for specified violations.⁵¹ This includes, but is not limited to, revoking or suspending⁵² the permit of a food establishment or imposing Class II⁵³ administrative fines.⁵⁴ DACS, or its duly authorized agent, can also issue and enforce a stop-sale, stop-use, removal, or hold order if DACS or its agent finds any food, food processing equipment, area, or food storage area is in violation of the Florida Food Safety Act.⁵⁵

Many FDA regulations have been adopted as rules of the division.⁵⁶

The following are examples when food is deemed adulterated: 57

- Food that bears or contains any poisonous or deleterious substance which may render it injurious to health;
- Food that bears or contains any added poisonous or added deleterious substance; a food additive; or a color additive, which is unsafe;
- Food that is or bears or contains any food additive which is unsafe;
- Food whose container is composed, in whole or in part, of any poisonous or deleterious substance;
- Food where any substance has been substituted wholly or in part therefor;
- Food where damage or inferiority has been concealed in any manner; and
- A dietary supplement or its ingredients that present a significant risk of illness or injury due to certain labeling and ingredient requirements.

Misbranded food includes food offered for sale and its label or labeling does not comply with the requirements of 21 U.S.C. s. 343(r) pertaining to nutritional content claims and health claims. Labels for supplements may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.⁵⁸

DACS may inspect food that may be adulterated or misbranded;⁵⁹ seize food that is adulterated or misbranded;⁶⁰ suspend permits of those who sell food that is adulterated or misbranded, adulterate or misbrand food, or receive food in commerce that is adulterated or misbranded;⁶¹ and impose a fine for adulterated or misbranded food, not to exceed \$5,000⁶² per violation.⁶³

Florida Contraband Forfeiture Act

- ⁴⁹ S. <u>500.09(6), F.S.</u>
- ⁵⁰ S. <u>500.81(3)(b)1.</u>, F.S.
- ⁵¹ S. <u>500.121, F.S.</u>
- ⁵² *Id*.

- ⁵⁴ S. <u>500.121, F.S.</u>
- ⁵⁵ S. <u>500.172, F.S.</u>
- ⁵⁶ R. 5K-4.002, F.A.C.
- ⁵⁷ S. <u>500.10, F.S.</u>
- ⁵⁸ S. <u>500.11(1)(n), F.S.</u>; 21 U.S.C. s. 343 (r)(6)(C.
- ⁵⁹ S. <u>500.147(1), F.S.</u>
- ⁶⁰ S. <u>500.173, F.S.</u>
- ⁶¹ S. <u>500.12(4), F.S.</u>
- ⁶² S. <u>570.971(1)(b), F.S.</u>
- ⁶³ S. <u>500.121, F.S.</u>

⁴⁶ S. <u>500.12, F.S.</u>

⁴⁷ S. <u>500.147, F.S.</u>

⁴⁸ S. <u>500.03(1)(p)</u>, F.S., defines "food establishment" as a factory, food outlet, or other facility manufacturing, processing, packing, holding, storing, or preparing food or selling food at wholesale or retail. The term does not include a business or activity regulated under s. 413.051, s. 500.80, chapter 509, or chapter 601. The term includes tomato packinghouses and repackers but does not include any other establishments that pack fruits and vegetables in their raw or natural states, including those fruits or vegetables that are washed, colored, or otherwise treated in their unpeeled, natural form before they are marketed.

⁵³ The fine for each Class II violation cannot exceed \$5,000. S. <u>570.971(1)(b), F.S.</u>

The Florida Contraband Forfeiture Act⁶⁴ prescribes procedures for law enforcement agencies to follow when seizing, forfeiting, and disposing of property under the act. Property may only be seized if the owner of the property is arrested for a criminal offense that forms the basis for determining that the property is a contraband article, or if one of the following circumstances apply:⁶⁵

- The owner of the property cannot be identified after a diligent search, or the person in possession of the property denies ownership and the owner of the property cannot be identified by means that are available to the employee or agent of the seizing agency at the time of the seizure;
- The owner of the property is a fugitive from justice or is deceased;
- An individual who does not own the property is arrested for a criminal offense that forms the basis for determining that the property is a contraband article and the owner of the property had actual knowledge of the criminal activity;
- The owner of the property agrees to be a confidential informant; or
- The property is a monetary instrument.

Florida Clean Indoor Air ACT

The FCIAA prohibits any person under the age of 21 from smoking tobacco or vaping within 1,000 feet of a public or private elementary, middle, or secondary school between the hours of 6 a.m. and midnight. A violation of this prohibition is punishable by a maximum noncriminal civil penalty not to exceed \$25, 50 hours of community service or, where available, successful completion of a school-approved anti-tobacco "alternative to suspension."⁶⁶

Division of Alcoholic Beverages and Tobacco

The Division of Alcoholic Beverages and Tobacco (ABT) within the Department of Business and Professional Regulation (DBPR) is the state agency responsible for the regulation and enforcement of alcoholic beverages, tobacco products, and nicotine products. Alcoholic beverages are regulated by the Beverage Law,⁶⁷ which governs the manufacture, distribution, and sale of wine, beer, and liquor by manufacturers, distributors, and vendors.⁶⁸ Tobacco and nicotine products are regulated by the tobacco and nicotine products law, which governs the purchasing, possessing, and regulation of the marketing, sale, or delivery by manufacturers and dealers.⁶⁹

Tobacco and Nicotine Product Retailers

In order to sell tobacco products or nicotine products at retail in Florida, a person must obtain a retail tobacco products dealer permit or retail nicotine products dealer permit from the Division. A person must obtain a permit for each place of business or premises where tobacco or nicotine products are sold.⁷⁰

The Division may discipline a tobacco retailer or nicotine product retailer's permit for violating any of the provisions relating to the retail sale of such products. Such discipline includes administrative fines up to \$1,000 and suspension or revocation of a permit.⁷¹

However, the Division may not discipline a tobacco retailer or nicotine product retailer's permit for other violations of the law, including violating the state hemp program.

Package Stores

A package store is a vendor operating a place of business where beverages are sold only in sealed containers for consumption off the premises.⁷² Package stores may not sell, offer, or expose for sale any merchandise other than such beverages, and such places of business must be devoted exclusively to such sales. However, package stores may sell, in addition to alcoholic beverages:⁷³

- ⁶⁵ S. <u>932.703(1), F.S.</u>
- ⁶⁶ S. <u>386.212, F.S.</u>

- ⁶⁸ See <u>s. 561.14, F.S.</u>
- ⁶⁹ See <u>ch. 569, F.S.</u>

⁷⁰ Ss. <u>569.003</u> and <u>569.32</u>, F.S. ⁷¹ Ss. <u>569.006</u> and <u>569.35</u>, F.S.

⁷² S. <u>565.02(1)(a), F.S.</u>

⁷³ S. <u>565.04, F.S.</u>

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J. <u>505.04, 1.5.</u>
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⁶⁴ Ss. <u>932.701</u>-<u>932.7062, F.S.</u>,

⁶⁷ S. <u>561.01(6)</u>, F.S., provides that the "The Beverage Law" means chs. 561, 562, 563, 564, 565, 567, and 568, F.S.

- bitters,
- grenadine,
- nonalcoholic mixer-type beverages,
- fruit juices produced in this state,
- home bar, and party supplies and equipment,
- miniatures of no alcoholic content, and
- tobacco products.

Quota Licensees

Currently, there is not a limit on the number of licenses the Division may issue to businesses selling malt beverages or wine. However, the law limits the number of licenses for selling distilled spirits to one license per 7,500 residents within the county with a minimum of three licenses per county for counties that have approved the sale of intoxicating liquors. These licenses are known as quota licenses and are the only type of alcoholic beverage license that is limited in number.⁷⁴

Current law limits the types of items quota licensees may sell. Currently, quota licensees may only sell alcoholic beverages, bitters, grenadine, nonalcoholic mixer-type beverages, fruit juices, party supplies, party-type foods, miniatures of no alcoholic content, nicotine products, and tobacco products. If the quota licensee allows for the consumption of alcohol on the licensee's establishment then they may also sell items customarily sold in a restaurant.⁷⁵

Current law does not prohibit quota licensees from selling products containing kratom; however, it also does not specifically allow it.

RECENT LEGISLATION:

| YEAR | EAR BILL # HOUSE SPONSOR(S) | | SENATE SPONSOR | OTHER INFORMATION | |
|------|-----------------------------|---------|----------------|---------------------------------------|--|
| 2023 | <u>CS/HB 179</u> | Andrade | Gruters | The bill became law on July 1, 202 | |

OTHER RESOURCES:

United States Drug Enforcement Administration, Kratom

United States Food & Drug Administration, FDA and Kratom

University of Florida College of Pharmacy, Kratom Resources

Cleveland Clinic, Is Kratom Safe To Use?

| BILL HISTORY | | | | | | | | |
|--|------------------|----------|------------------------------------|-------------------------|--|--|--|--|
| COMMITTEE REFERENCE | ACTION | DATE | STAFF DIRECTOR/ POLICY CHIEF | ANALYSIS PREPARED BY | | | | |
| Industries & Professional Activities Subcommittee | 16 Y, 2 N, As CS | 4/1/2025 | Anstead | Thompson | | | | |
| THE CHANGES ADOPTED BY THE COMMITTEE: The PCS revised various provisions in the bill, including those that address: • Certification of laboratories by DACS. • Distribution and sales. • Labeling and consumption. • Registration, reporting, and testing. • Violations and penalties. • Violations to the bill, including those that address: • Mail order, Internet, and remote sales. • Seizure and destruction. • Use near school property. • DBPR's Division of Alcoholic Beverages and Tobacco. • The PCS removed a provision from the bill that provided funding and position to DACS. | | | | | | | | |

THIS BILL ANALYSIS HAS BEEN UPDATED TO INCORPORATE ALL OF THE CHANGES DESCRIBED ABOVE.
