
HOUSE COMMITTEE AMENDMENTS

2023 Regular Session

Substitute for Original House Bill No. 572 by Representative Goudeau as proposed by the House Committee on Health and Welfare

This document reflects the content of a substitute bill but is not in a bill form; page numbers in this document DO NOT correspond to page numbers in the substitute bill itself.

To amend the heading of Part XI of Chapter 4 of Title 40 of the Louisiana Revised Statutes of 1950 and to enact Part X-G of Chapter 4 of Title 40 of the Louisiana Revised Statutes of 1950, to be comprised of R.S. 40:1051 through 1056, relative to kratom products; to provide for definitions; to prohibit distribution of kratom products to minors; to provide for kratom product registration; to require a registration fee; to provide for enforcement; to provide for violations and penalties; to provide for seizure of certain kratom products; to provide for a termination clause; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. Part XI of Chapter 4 of Title 40 of the Louisiana Revised Statutes of 1950 is hereby amended and reenacted and R.S. 40:1051 through 1056 is hereby enacted to read as follows:

~~PART XI. LOUISIANA NARCOTICS REHABILITATION COMMISSION~~ PART

X-G. KRATOM CONSUMER PROTECTION ACT

§1051. Short title

This Part shall be known and may be cited as the "Kratom Consumer Protection Act".

§1052. Definitions

As used in this Part, the following terms have the meaning ascribed to them in this Section unless context clearly indicates otherwise:

(1) "Commissioner" means the commissioner of the alcohol and tobacco control.

(2) "Department" means the Louisiana Department of Health

(3) "Kratom product" means a food product or dietary ingredient containing any part of the leaf of the plant *Mitragyna speciosa* or an extract of it, manufactured as a powder, capsule, pill, beverage, extract, or other edible form. For purposes of the provisions of this Part, all kratom products are considered food.

(4) "Processor" means a person or entity that sells, prepares, manufactures, distributes, or maintains kratom products or advertises, represents, or holds itself out as selling, preparing, or maintaining kratom products.

(5) "Retailer" means a person that sells, distributes, advertises, represents, or holds itself out as selling or maintaining kratom products.

§1053. Kratom products; criteria

A. Any kratom product that is manufactured, distributed, imported, or sold for use in this state shall satisfy with all of the following criteria:

(1) Be registered by the commissioner.

(2)(a) Contain no dangerous nonkratom substance.

(b) For purposes of this Part, a kratom product is adulterated with a dangerous nonkratom substance if the kratom product is mixed or packed with a nonkratom substance that affects the quality or strength of the kratom product to such a degree as to render the kratom product injurious to a consumer.

(3) Contain levels of residual solvents below the amount that is allowed by the United States Pharmacopeia Monograph 467.

(4) Contain a concentration of 7-hydroxymitragynine not exceeding one percent of the overall alkaloid composition of the kratom product.

(5) Contain synthetic alkaloids including synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compounds of the kratom plant.

B. The package of a kratom product shall contain all of the following information:

(1) A recommended serving size.

(2) A recommended number of daily servings.

(3) The number of servings in a package.

(4) A disclaimer stating that the product has not been evaluated by the United States Food and Drug Administration and is not intended to diagnose, treat, cure, or prevent any disease.

(5) The name, address, and phone number of the manufacturer or processor of the kratom product.

§1054. Prohibition of sale to minors

A processor or retailer shall not distribute or sell a kratom product to an individual under eighteen years of age.

§1055. Kratom product registration

A. Processor registration. A processor shall register each kratom product intended to be offered for sale to an end consumer. A kratom product registration is valid for one year. A processor shall pay a registration fee, adjusted annually, to cover all administrative costs for processing and administering the registration program. A processor shall obtain a certificate of analysis for a product from a certified, independent third-party laboratory showing that the kratom product complies with the requirements of this Part in order to be registered. If the kratom product does not comply with the requirements of this Subsection, it shall not be registered.

B. Product noncompliance reports. The commissioner shall give notice to a processor of a credible report of noncompliance with the requirements of this Part. The commissioner may require the processor to obtain a certificate of analysis from a certified, independent third-party laboratory showing compliance with the requirements of this Part. If a processor fails to obtain and provide a certificate of analysis within ninety days from the date of the notice and request by the commissioner, the registration for that kratom product shall be revoked.

C. Adverse events reports. Upon report of an adverse event related to a registered kratom product, a processor shall submit an adverse event report via certified mail to the department and the United States Food and Drug Administration in accordance with federal law. Any failure to report an adverse event to the department shall authorize the commissioner to revoke a product's registration.

§1056. Violations

A. A processor that violates the provisions of this Part shall be subject to the following:

(1) For a first offense, an administrative fine of not more than five hundred dollars.

(2) For a second or subsequent offense, an administrative fine of not more than one thousand dollars.

(3) For a third offense, in addition to an administrative fine of not more than one thousand dollars, the commission shall revoke the registration for the noncomplaint kratom product for a period of not less than one year. The registration may be reinstated only if the processor pays the registration fee and all administrative costs incurred by the department and the office of alcohol and tobacco control arising out of the revocation of sale of the kratom product.

B. Upon the request of a person to whom an administrative fine is issued, the commissioner shall conduct a hearing in accordance with the Administrative Procedure Act.

C. A retailer does not violate the provisions of this Part if it is shown, by a preponderance of the evidence, that the retailer relied in good faith upon the representations of a manufacturer, processor, or distributor of food represented to be a kratom product.

D. Any kratom product found in this state in violation of this Part shall be considered contraband and any property interest in the kratom product is vested in the state of Louisiana and is subject to seizure and destruction.

E. Any certified law enforcement officer in this state may enforce the administrative provisions of this Part.

F. The provisions of this Act shall be null and void and have no effect if the United States Drug Enforcement Administration places mitragynine on the Controlled Substance Schedule.

Section 2. Any local governmental subdivision that has, prior to May 1, 2023, enacted a more restrictive provision relative to kratom products than provided by this Act shall be exempt from the provisions of this Act.

Section 3. This Act shall become effective upon signature by the governor or, if not signed by the governor, upon expiration of the time for bills to become law without signature by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If vetoed by the governor and subsequently approved by the legislature, this Act shall become effective on the day following such approval.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB Draft

2023 Regular Session

Abstract: Establishes a regulatory process for sale of kratom containing products.

Proposed law creates the "Kratom Consumer Protection Act" to regulate the preparation, distribution, sale, or exposure for sale of kratom.

Proposed law establishes the following criteria for kratom containing products to be sold in Louisiana. Kratom products:

- (1) Must be registered in with the commissioner of the office of alcohol and tobacco control.
- (2) Cannot be adulterated with a dangerous nonkratom substance that renders the product injurious to a consumer.
- (3) Must contain levels of residual solvents less than is allowed by the United States Pharmacopeia standards
- (4) Must not contain 7-hydroxymitragynine in excess of one percent of the overall alkaloid composition.
- (5) Must not contain any synthetic alkaloids.

Proposed law establishes the requirements for the packaging of kratom products including, the manufacturer recommended serving size, number of servings, and recommended daily serving amount.

Proposed law requires kratom packages to include the disclaimer that the product has not been evaluated by the United States Food and Drug Administration, and that the drug has not been approved to treat, cure, diagnose, or prevent any disease.

Proposed law prohibits the sale of kratom products to anyone under the age of 18.

Proposed law requires a processor to register each kratom product intended to be sold to a end consumer on an annual basis. Proposed law further provides that the processor must pay

a registration fee and obtain a certificate of analysis to evidence the product's compliance the requirements of proposed law.

Proposed law establishes a mechanism for the commissioner to test kratom products after a reliable report of noncompliance with the requirements of proposed law. A processor shall pay the costs associated with testing.

Proposed law establishes a procedure for reporting adverse events related to a registered product and method of testing at the cost of the processor.

Proposed law provides for administrative fines for violations of proposed law. The penalties are as follows:

- (1) On a first offense, the fine is not more than \$500.
- (2) On a second offense, the fine is not more than \$1000.
- (3) On a third offense, in addition to the fine, the product's registration is revoked for not less than one year and additional fees.

Proposed law provides that if by preponderance of the evidence the facts show that the violation occurred by a good faith error or mistake, the penalties will not be enforced.

Proposed law provides proposed law shall not apply to any local governmental entity that passed more strict rules regarding kratom products than are provided by this section.

Proposed law will become effective on the signature of the governor.

Proposed law provides that kratom products that do not comply with proposed law may be seized and destroyed by law enforcement.

Proposed law establishes that the proposed law shall be null and void if the United States Drug Enforcement Administration adds mitragynine to the Controlled Substance Schedule.

Effective upon signature of the governor.

(Adds R.S. 40:1051-1056)