

2023 Regular Session

HOUSE BILL NO. 655 (Substitute for House Bill No. 572 by Representative Goudeau)

BY REPRESENTATIVE GOUDEAU

CONSUMERS/PROTECTION: Provides relative to kratom products

1 AN ACT

2 To amend and reenact the heading of Part XI of Chapter 4 of Title 40 of the Louisiana
3 Revised Statutes of 1950 and to enact Part X-G of Chapter 4 of Title 40 of the
4 Louisiana Revised Statutes of 1950, to be comprised of R.S. 40:1051 through 1056,
5 relative to kratom products; to provide for definitions; to prohibit sale or distribution
6 of kratom products to minors; to provide for kratom product registration; to require
7 registration with the office of alcohol and tobacco control; to require a registration
8 fee; to provide for enforcement; to provide for violations and penalties; to provide
9 for seizure of certain kratom products; to provide for termination; and to provide for
10 related matters.

11 Be it enacted by the Legislature of Louisiana:

12 Section 1. Part XI of Chapter 4 of Title 40 of the Louisiana Revised Statutes of 1950
13 is hereby amended and reenacted and Part X-G of Chapter 4 of Title 40 of the Louisiana
14 Revised Statutes of 1950, comprised of R.S. 40:1051 through 1056, is hereby enacted to read
15 as follows:

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

17 X-G. KRATOM CONSUMER PROTECTION ACT

18 §1051. Short title

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

1 §1052. Definitions

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

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

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

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

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

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

16 (6) "University laboratory" is a laboratory operated by the University of
17 Louisiana at Monroe, Southern University, or Louisiana State University.

18 §1053. Kratom products; criteria

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

21 (1) Be registered by the commissioner.

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

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

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

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

3 (5) Contain synthetic alkaloids including synthetic mitragynine, synthetic
4 7-hydroxymitragynine, or any other synthetically derived compounds of the kratom
5 plant.

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

8 (1) A recommended serving size.

9 (2) A recommended number of daily servings.

10 (3) The number of servings in a package.

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

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

16 §1054. Prohibition of sale to minors

17 A processor or retailer shall not distribute or sell a kratom product to an
18 individual under twenty-one years of age.

19 §1055. Kratom product registration

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

28 B. Product noncompliance reports. The commissioner shall give notice to
29 a processor of a credible report of noncompliance with the requirements of this Part.

1 The commissioner may require the processor to obtain a certificate of analysis from
2 a university laboratory showing compliance with the requirements of this Part. If a
3 processor fails to obtain and provide a certificate of analysis within ninety days from
4 the date of the notice and request by the commissioner, the registration for that
5 kratom product shall be revoked.

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

11 §1056. Violations

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

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

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

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

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

27 C. A retailer does not violate the provisions of this Part if it is shown, by a
28 preponderance of the evidence, that the retailer relied in good faith upon the

1 representations of a manufacturer, processor, or distributor of food represented to be
2 a kratom product.

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

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

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

11 Section 2. The provisions of this Act shall not apply to any local governmental
12 subdivision that enacts a more restrictive ordinance relative to kratom products than required
13 by this Act.

14 Section 3. In order to implement the provisions of this Act, the laboratories of the
15 University of Louisiana at Monroe, Southern University, and Louisiana State University
16 shall not be required to begin testing kratom products until July 1, 2024.

17 Section 4. This Act shall become effective upon signature by the governor or, if not
18 signed by the governor, upon expiration of the time for bills to become law without signature
19 by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If
20 vetoed by the governor and subsequently approved by the legislature, this Act shall become
21 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 655 Engrossed

2023 Regular Session

Goudeau

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 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 U.S. 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 U.S. Food and Drug Administration (FDA), 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 21.

Proposed law requires a processor to register with the commissioner of alcohol and tobacco control each kratom product intended to be sold to an end consumer on an annual basis. Proposed law further provides that the processor must pay a registration fee and obtain a certificate of analysis from a university-run laboratory to evidence the product's compliance with 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 requires the report to go the La. Dept. of Health and the FDA.

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 and subsequent offense, the fine is not more than \$1,000.
- (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, a retailer shows 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 passes more strict rules regarding kratom products than are provided by proposed law.

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 proposed law shall be null and void if the U.S. Drug Enforcement Administration adds mitragynine to the Controlled Substance Schedule.

Effective upon signature of governor or a lapse of time for gubernatorial action.

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