REQUIRES TWO-THIRDS MAJORITY VOTE
(§§ 6, 6.5)

(Reprinted with amendments adopted on April 24, 2023)

FIRST REPRINT **A.B. 322**

ASSEMBLY BILL NO. 322–ASSEMBLYMEN NGUYEN, YEAGER, GONZÁLEZ; BROWN-MAY, DICKMAN, D'SILVA AND GALLANT

MARCH 16, 2023

JOINT SPONSORS: SENATORS HANSEN; AND NGUYEN

Referred to Committee on Commerce and Labor

SUMMARY—Revises provisions relating to kratom products. (BDR 52-763)

FISCAL NOTE: Effect on Local Government: Increases or Newly Provides for Term of Imprisonment in County or City Jail or Detention Facility.
Effect on the State: Yes.

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EXPLANATION – Matter in ***bolded italics*** is new; matter between brackets [~~omitted material~~] is material to be omitted.

AN ACT relating to public health; prohibiting a person from selling or offering to sell a kratom product to an end user unless the kratom product has been registered with the State Department of Agriculture; setting forth requirements for the registration of a kratom product with the Department; requiring a person who registers a kratom product to pay certain expenses and report certain information relating to the kratom product to the Department; authorizing the Department to adopt certain regulations governing kratom products; revising provisions establishing certain prohibited acts relating to kratom products; exempting a person who engages in certain acts relating to kratom products from certain criminal or legal penalties if certain substances in those products are designated as controlled substances; prohibiting the State Board of Pharmacy from including certain substances on a schedule of controlled substances; providing penalties; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law defines "kratom product" to mean, in general, any product or ingredient containing any part of the leaf of the *Mitragyna Speciosa* plant if the plant contains the alkaloid mitragynine or 7-hydroxymitragynine, or any synthetic material that contains the alkaloid mitragynine or 7-hydroxymitragynine. Existing law prohibits a person from: (1) selling or offering to sell any material, compound, mixture or preparation containing a kratom product to a child under the age of 18 years; (2) preparing, distributing, advertising, selling or offering to sell a kratom product that is adulterated with certain substances; and (3) selling a kratom product that does not have a label that meets certain requirements. Existing law provides for the imposition of a civil penalty of not more than $1,000 against a person who violates those prohibitions. (NRS 597.998)

Section 5 of this bill revises the definition of kratom product to mean food containing any part of the leaf of the *Mitragyna Speciosa* plant. **Section 9** of this bill revises the prohibited acts relating to kratom products set forth under existing law to revise: (1) requirements relating to the type of kratom products that a person is prohibited from preparing, distributing, advertising, selling or offering to sell; and (2) the information that must be included on a label for a kratom product. **Section 9** eliminates the civil penalty imposed for engaging in such prohibited acts and instead provides for the imposition of administrative fines by the State Department of Agriculture for certain violations relating to kratom products.

Section 6 of this bill prohibits a person from selling or offering to sell a kratom product to an end user unless the kratom product has been registered with the Department. **Section 6** sets forth certain requirements for a person to register a kratom product with the Department.

Sections 6.5 and 8 of this bill set forth circumstances under which the Department may require a person who registers a kratom product to submit the kratom product to a laboratory for certain additional testing. **Section 7.5** of this bill requires a person who registers a kratom product to submit to the Department a copy of certain reports concerning the kratom product that are required to be submitted to the United States Food and Drug Administration.

Section 7 of this bill authorizes the Board to adopt certain regulations to carry out the provisions of this bill.

Existing law authorizes the State Board of Pharmacy to adopt regulations to add, delete or reschedule substances as controlled substances in schedules I, II, III, IV or V pursuant to the Uniform Controlled Substances Act. (NRS 453.146) Existing law prohibits certain substances from being included on such a schedule. (NRS 453.2186) **Section 9.5** of this bill prohibits the Board from including mitragynine or any of its constituent alkaloids on any schedule unless the substance is designated as a controlled substance pursuant to federal law. **Section 8.3** of this bill provides that if mitragynine or any of its constituent alkaloids is added to a schedule of controlled substances, a person who engages in the possession, delivery, production, sale or use of a kratom product that meets the requirements of this bill and who confines his or her activities to those authorized by this bill does not commit a violation of any law, ordinance, rule or regulation of this State or any political subdivision of this State and any such conduct must not constitute the basis for any investigation, detention, search, seizure, arrest, prosecution or other legal penalty against the person.

Sections 2.5-4.5 of this bill define certain other words and terms for the purposes of this bill.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Chapter 597 of NRS is hereby amended by adding thereto the provisions set forth as sections 2 to 8.7, inclusive, of this act.

Sec. 2. *As used in NRS 597.998 and sections 2 to 8.7, inclusive, of this act, unless the context otherwise requires, the words and terms defined in sections 2.5 to 5, inclusive, of this act have the meanings ascribed to them in those sections.*

Sec. 2.5. *"Certificate of analysis" means a document produced by a laboratory describing the results of the laboratory's testing of a kratom product.*

Sec. 3. *"Department" means the State Department of Agriculture.*

Sec. 4. *"Food" means any food, food product, food ingredient, dietary ingredient, dietary supplement or beverage intended for ultimate human consumption.*

Sec. 4.5. *"Kratom extract" means a kratom product containing any part of the leaf of the Mitragyna Speciosa plant that has been extracted and concentrated to provide a dosage that is more standardized.*

Sec. 5. *"Kratom product" means food containing any part of the leaf of the Mitragyna Speciosa plant, or an extract thereof, which is manufactured as a powder, capsule, pill or other edible form.*

Sec. 6. *1. A person shall not sell or offer to sell a kratom product to an end user unless the kratom product has been registered with the Department pursuant to this section.*

2. A person who wishes to register a kratom product must submit to the Department:

(a) An application on a form prescribed by the Department;

(b) A fee in an amount established by the Department by regulation;

(c) A certificate of analysis for the kratom product which:

(1) Is produced by an independent laboratory that meets any requirements set forth in regulations adopted by the Department pursuant to section 7 of this act; and

(2) Provides sufficient information about the kratom product to enable the Department to determine whether the kratom product complies with the provisions of NRS 597.998 and sections 2 to 8.7, inclusive, of this act; and

(d) Any other information and documentation that the Department deems necessary to ensure that the kratom product

meets the requirements of NRS 597.998 and sections 2 to 8.7, inclusive, of this act and the regulations adopted pursuant thereto.

3. A registration issued pursuant to this section expires 1 year after issuance and may be renewed by submitting to the Department an application for renewal and the same fees and materials required by paragraphs (b), (c) and (d) of subsection 2 for an initial registration.

Sec. 6.5. *1. If the Department has reasonable cause to believe that the information contained on the label of, or the certificate of analysis for, a kratom product is inaccurate, the Department may require the person who registered the kratom product to send the kratom product to a laboratory selected by the Department to conduct testing on the kratom product.*

2. After the testing conducted pursuant to subsection 1 is completed, the Department shall send the person who registered the kratom product a bill for the costs of the testing. If the person fails to pay those costs within a period of time after the receipt of the bill established by the Department by regulation, the Department shall revoke the registration of the kratom product.

Sec. 7. *The Department may adopt regulations as it determines to be necessary or advisable to carry out the provisions of NRS 597.998 and sections 2 to 8.7, inclusive of this act.*

Sec. 7.5. *1. If a person submits to the United States Food and Drug Administration a report pursuant to 21 U.S.C. § 379aa-1 concerning a serious adverse event involving a kratom product that the person has registered pursuant to section 6 of this act, the person shall send a copy of that report to the Department by certified mail within a period of time established by the Department by regulation.*

2. Failure to send to the Department a copy of the report described in subsection 1 within the time required by subsection 1, constitutes grounds for the revocation of the registration of the kratom product about which the report relates.

Sec. 8. *1. Any person may report to the Department on a form prescribed by the Department a suspected violation of NRS 597.998 or sections 2 to 8.7, inclusive, of this act.*

2. If the Department determines that the allegations in a complaint are credible and relate to the content or labeling of, or a certificate of analysis for, a kratom product, the Department shall require the person who committed the alleged violation to obtain and provide to the Department, within a period of time prescribed by the Department by regulation, a new certificate of analysis which complies with paragraph (c) of subsection 2 of section 6 of this act for the kratom product.

3. If a person fails to provide the Department with a certificate of analysis pursuant to subsection 2, the Department shall revoke the registration for the kratom product.

Sec. 8.3. ***Notwithstanding any other provision of law, if mitragynine or any of its constituent alkaloids are added to schedule I, II, III, IV or V by the State Board of Pharmacy by regulation pursuant to NRS 453.146, a person who engages in the possession, delivery, production, sale or use of a kratom product that meets the requirements of NRS 597.998 and sections 2 to 8.7, inclusive, of this act and who confines his or her activities to those authorized by NRS 597.998 and sections 2 to 8.7, inclusive, of this act does not violate any law, ordinance, rule or regulation of this State or any political subdivision of this State and such conduct may not constitute the basis for any investigation, detention, search, seizure, arrest, prosecution or other legal penalty against the person.***

Sec. 8.7. ***1. A person who violates any provision of NRS 597.998 and sections 2 to 8.7, inclusive, of this act is subject to an administrative fine in an amount not to exceed $500 for a first offense and $1,000 for a second or subsequent offense.***

2. Upon the request of a person to whom an administrative fine is issued, the Department shall provide notice of and conduct a hearing in accordance with the provisions of chapter 233B of NRS.

Sec. 9. NRS 597.998 is hereby amended to read as follows:

597.998 1. A person shall not knowingly ***distribute,*** sell or offer to sell any material, compound, mixture or preparation containing a kratom product to a child under the age of 18 years.

2. A person shall not knowingly prepare, distribute, advertise, sell or offer to sell a kratom product that ~~[is]~~ ***:***

(a) Is combined, packaged or adulterated with ~~[a]~~ ***:***

(1) A controlled substance or a dangerous drug, as defined in chapter 454 of NRS, or any poisonous or deleterious substance; or

(2) Any 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 ~~[. A person has not violated the provisions of this subsection if he or she can show by a preponderance of evidence that he or she relied in good faith upon the representations of a manufacturer, processor, packer or distributor of the kratom product.~~

~~3. A person shall not sell a kratom product that does not have a label that clearly sets forth the ingredients and directions for the safe and effective use of the kratom product.~~

~~4. A person who violates any provision of this section is subject to a civil penalty of not more than $1,000 for each violation.~~

~~5. As used in this section, "kratom product" means any product or ingredient containing:~~

~~(a) Any part of the leaf of the Mitragyna Speciosa plant if the plant contains the alkaloid mitragynine or 7-hydroxymitragynine; or~~

~~(b) A synthetic material that contains the alkaloid mitragynine or 7-hydroxymitragynine,~~

~~➥ regardless of whether the product or ingredient is labeled or sold for human consumption.]~~ ***;***

(b) Contains a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 1 percent of the alkaloid composition of the kratom product;

(c) Contains a synthetic alkaloid, including, without limitation, synthetic mitragynine, synthetic 7-hydroxymitragynine or any synthetically derived compound of the Mitragyna Speciosa plant;

(d) Does not include a label that clearly sets forth:

(1) The recommended size of an individual serving;

(2) The maximum limits for individual servings per day;

(3) The number of servings equal to the size of one recommended individual serving that are contained in the package; and

(4) Directions for the safe and effective use of the kratom product.

(e) A kratom extract which contains levels of residual solvents that exceed the levels authorized by chapter 467 of the United States Pharmacopeia-National Formulary, published by the United States Pharmacopeial Convention.

Sec. 9.5. NRS 453.2186 is hereby amended to read as follows:

453.2186 1. Authority to control pursuant to NRS 453.146, 453.218, 453.2182 and 453.2184 does not extend to distilled spirits, wine, malt beverages or tobacco.

2. ***The Board shall not include mitragynine or any of its constituent alkaloids on any schedule unless the substance is designated as a controlled substance pursuant to federal law.***

3. The Board shall not include any nonnarcotic substance on any schedule if that substance is in a form suitable for final dosage and has been approved by the Food and Drug Administration for sale over the counter without a prescription, unless the Board affirmatively finds that:

(a) The substance itself or one or more of its active ingredients is an immediate precursor of a controlled substance; and

(b) The substance is materially misbranded or mislabeled, or the public interest requires the scheduling of the substance as a controlled substance in schedule I, II, III or IV.

~~[3.]~~ ***4.*** In determining whether the public interest requires the scheduling of the substance, the Board shall consider:

(a) Whether the customary methods of marketing and distributing the substance are likely to lead to its unlawful distribution or use, including any relevant information with regard to a manufacturer or distributor of the substance concerning:

(1) His or her record of compliance with applicable federal, state and local statutes, ordinances and regulations;

(2) His or her past experience in the manufacture and distribution of controlled substances, and the existence in his or her establishment of effective controls against the unlawful distribution or use of the substance;

(3) Whether he or she has ever been convicted under any federal or state law relating to a controlled substance; and

(4) Whether he or she has ever furnished materially falsified or fraudulent material in any application filed pursuant to NRS 453.011 to 453.552, inclusive;

(b) Whether the substance is controlled under the federal Controlled Substances Act;

(c) The status of any pending proceeding to determine whether the substance should be controlled or exempted from control;

(d) Any history of abuse or misuse of the substance in this State; and

(e) Any other factors which are relevant to the public health and safety.

~~[4.]~~ ***5.*** In determining whether a substance is misbranded or mislabeled, the Board shall consider the requirements of the federal Food, Drug, and Cosmetic Act and the Code of Federal Regulations concerning indications for its use and any advertising for a use not so indicated.

Sec. 10. 1. This section becomes effective upon passage and approval.

2. Sections 1 to 9.5, inclusive, of this act become effective:

(a) Upon passage and approval for the purpose of adopting any regulations and performing any other preparatory administrative tasks that are necessary to carry out the provisions of this act; and

(b) On January 1, 2024, for all other purposes.

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