STATE OF NEW YORK

10969

IN ASSEMBLY

April 14, 2026

Introduced by M. of A. BLUMENCRANZ -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to prohibiting harmful synthetic and adulterated kratom products, and requiring testing, labeling, and enforcement for natural kratom products

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. This act shall be known and may be cited as the "synthetic kratom kills act".

§ 2. Legislative intent. The legislature hereby finds and declares that:

1. Kratom (Mitragyna speciosa), a plant-based product, is used by many New Yorkers for potential benefits such as pain relief, mood support, and aid for conditions like PTSD among veterans, when derived from natural leaf in moderate forms.

2. However, dangerous synthetic or semi-synthetic kratom products, including those with elevated levels of 7-hydroxymitragynine (7-OH) or chemical alterations, have been linked to serious adverse events, including deaths and overdoses, as reported in public health data.

3. Existing mechanisms, including recent prohibitions on sales to those under 21 and mandatory warning labels, are important but insufficient to fully address adulteration, untested potency, misleading marketing, and youth appeal in synthetic variants.

4. Evidence from other jurisdictions demonstrates that unregulated synthetics pose significant risks, while regulated natural leaf with quality controls reduces harm without eliminating access.

5. Modern testing capabilities, including third-party laboratories, allow for verification of alkaloid content, absence of contaminants, and product safety prior to sale.

6. At the same time, consumer education through detailed labeling is essential to promote safe, informed use and prevent interactions or misuse.

7. It is the intent of the legislature to ban harmful synthetics and adulterated products outright, while regulating natural kratom through

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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testing, labeling, age restrictions, and local enforcement to protect public health, ensure consumer safety, and preserve access to beneficial natural forms.

8. The legislature further intends to focus on civil enforcement tools, avoiding criminalization of natural products, to deter violations effectively while supporting responsible commerce.

§ 3. The public health law is amended by adding a new section 1399-mmmm to read as follows:

§ 1399-mmmm. Kratom consumer protection and regulation. 1. For the purposes of this section, the following terms shall have the following meanings:

(a) "Kratom leaf" means the leaf of the kratom plant, also known as Mitragyna speciosa, in fresh, dehydrated, or dried form that undergoes no postharvest processing other than drying or size reduction, by cutting, milling, or similar procedure or by cleaning or sterilization through application of heat, steam, pressurization, irradiation, or other standard treatments applied to food ingredients. Nothing in this paragraph shall be construed to limit the naturally occurring total alkaloid content of kratom leaf, provided that alkaloid levels are verified as naturally occurring and unadulterated through third-party laboratory testing as required under subdivision three of this section.

(b) "Kratom product" means a product marketed for human consumption containing any part of the leaf of the plant Mitragyna speciosa, including any such product sold or marketed under an alternative name, trade name, or labeling that does not identify the product as kratom, and does not contain any synthesized kratom material.

(c) "Synthesized kratom material" means: (i) an alkaloid or alkaloid derivative that has been created by chemical synthesis or biosynthetic means (including but not limited to: fermentation, recombinant techniques, yeast derived, enzymatic techniques), rather than traditional food preparation techniques such as heating or extracting that synthetically alters the molecular structure of any kratom alkaloid or constituent; or (ii) an alkaloid or alkaloid derivative contained in kratom that has been exposed to chemicals or processes that would confer a structural change in the alkaloids.

(d) "Adulterated kratom product" means a kratom product that is adulterated with a dangerous substance other than kratom or with a substance that affects the quality or strength of the kratom product to a degree as to render the kratom product injurious to a consumer.

(e) "Manufacturer" means a person or business that produces, prepares, compounds, or processes kratom products, including any person or business packaging, repackaging, labeling, or relabeling of kratom products.

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

(g) "Distributor" means any person or business entity engaged in the business of purchasing kratom products from a manufacturer and selling or otherwise distributing such products to retailers or other persons for resale. A common carrier shall not be considered a distributor solely by virtue of transporting kratom products in the ordinary course of business.

(h) "Third-party laboratory" means a laboratory that has no direct interest in a manufacturer or distributor of kratom products, that is accredited pursuant to ISO/IEC 17025 or an equivalent standard recognized by the department of health, and that can perform mandated testing utilizing validated methods.

(i) "Total alkaloids" means the aggregate concentration of all alkaloids present in a kratom product, measured in milligrams per gram of product, as determined by third-party laboratory testing conducted pursuant to subdivision three of this section.

(j) "Alkaloid" means a naturally occurring nitrogen-containing organic compound produced by or derived from the kratom plant that has pharmacological activity, including but not limited to mitragynine and 7-hydroxymitragynine.

2. No person, manufacturer, retailer, or other entity shall manufacture, distribute, sell, or offer for sale:

(a) Synthesized kratom material;

(b) Any adulterated kratom product;

(c) A kratom product that is combustible or intended to be used for vaporization, aerosolization, or injection;

(d) A kratom product that is incorporated into, or marketed or labeled as, a conventional food or beverage product; provided, however, that kratom leaf prepared as an aqueous infusion or traditional tea preparation, without added food ingredients beyond those otherwise permitted under this section, shall not be considered a conventional food or beverage for the purposes of this paragraph;

(e) A kratom product that contains flavoring agents or additives specifically designed or marketed to appeal to individuals under twenty-one years of age;

(f) A kratom product not contained in child-resistant packaging that meets standards set forth in 16 C.F.R. 1700.15(b) when tested in accordance with 16 C.F.R. 1700.20;

(g) A kratom product that mimics a candy product or is manufactured, packaged, or advertised in a way that can be reasonably considered to appeal to individuals under twenty-one years of age; or

(h) Any kratom product in which the concentration of 7-hydroxymitragynine exceeds two percent of the concentration of total alkaloids, as determined by third-party laboratory testing conducted pursuant to subdivision three of this section.

3. All kratom products sold or otherwise distributed in this state must be tested by a third-party laboratory prior to the sale or distribution of each batch or lot, and found to be free from: (i) heavy metals at levels exceeding applicable United States Food and Drug Administration food safety thresholds; (ii) microbial contamination, including Salmonella, E. coli O157:H7, and total combined yeast and mold, at levels exceeding applicable federal food safety thresholds; (iii) pesticide residues at levels exceeding applicable federal food safety thresholds; (iv) fentanyl and other controlled substances as defined under New York law; and (v) synthesized kratom material as defined in paragraph (c) of subdivision one of this section. Such testing shall further include quantification of total alkaloid content, mitragynine concentration, and 7-hydroxymitragynine concentration in milligrams per gram of product, to verify compliance with paragraph (h) of subdivision two of this section and to support the labeling requirements of paragraph (b) of subdivision four of this section. All such products shall be affixed with a label verifying such testing and the information listed in subdivision four of this section. Manufacturers shall maintain certificates of analysis and make them available upon request.

4. All kratom products sold or otherwise distributed in this state shall be accompanied by a clear label that provides adequate information for safe and effective use by consumers that includes but is not limited to:

(a) A list of ingredients used in the manufacturing of the kratom product;

(b) The amount of mitragynine and 7-hydroxymitragynine contained in the kratom product, expressed in milligrams per serving and milligrams per container;

(c) The recommended serving size of the kratom product;

(d) The manufacturer's recommended maximum number of servings per twenty-four-hour period;

(e) The number of servings per container of the kratom product;

(f) The name and principal street address of the manufacturer of the kratom product;

(g) A unique batch or lot number specifically linking each kratom product to a specific batch or lot manufactured by the kratom manufacturer;

(h) A recommendation to consult a healthcare professional prior to use;

(i) A statement that kratom is not safe for use while pregnant or breastfeeding;

(j) A statement that the kratom product should be stored safely and out of the reach of children;

(k) A statement that the sale or transfer of possession to another person under twenty-one years of age is prohibited;

(l) A warning that the product may result in dangerous medication interactions; and

(m) A disclaimer that the kratom product is not intended to diagnose, treat, cure, or prevent any medical condition or disease.

If there is not sufficient room on the kratom product label, the kratom product shall display on the label a scannable bar code, QR code, or web address linked to a document containing the information required in this subdivision.

5. Kratom products shall not be sold through vending machines or other automated self-service devices.

6. (a) The department of health, county and municipal health departments, and law enforcement shall have authority to inspect establishments, investigate complaints, seize prohibited products, and conduct hearings.

(b) Any person or entity violating this section shall receive a notice of violation. It shall be the responsibility of the owner and/or the owner's manager or business agent to ensure compliance; the owner shall be liable for violations committed by employees or agents acting within the scope of their employment or agency. It shall be an affirmative defense that the owner maintained written compliance policies, conducted training of employees regarding the requirements of this section, and that the specific violation occurred without the owner's knowledge despite such policies and training.

(c) Penalties shall be as follows:

(1) First violation: civil fine of five hundred dollars plus confiscation of all involved products.

(2) Second violation within thirty-six months: civil fine of one thousand dollars, seven-day suspension of any applicable state or local business license or permit, plus confiscation.

(3) Third or subsequent violation within thirty-six months: civil fine of five thousand dollars, thirty-day suspension of any applicable state or local business license or permit, plus confiscation.

(4) Four or more violations within thirty-six months or two or more violations involving the sale of synthesized kratom material, adulterat-

ed kratom products, or kratom products to individuals under twenty-one years of age (each constituting an "egregious violation"): referral to the applicable licensing authority for permanent revocation of any applicable state or local business license or permit, following notice and a hearing before the department or local board of health.

(d) Each day a violation exists shall constitute a separate offense. Separate but simultaneous violations shall be treated as separate violations provided, however, that the total civil fines imposed upon any single person or entity for continuing violations of the same provision shall not exceed twenty-five thousand dollars within any thirty-six month period.

(e) Before suspending or revoking any applicable business license or permit pursuant to this section, the department or board shall provide notice and an opportunity for a hearing.

(f) Affirmative defense for age verification. It shall be an affirmative defense to a charge of violating paragraph (h) of subdivision two of this section that the seller in good faith demanded and examined a government-issued photographic identification document indicating that the purchaser was twenty-one years of age or older, and that the identification document presented by the purchaser reasonably appeared to be genuine and valid at the time of sale.

7. Manufacturers, distributors, and retailers shall maintain certificates of analysis and written records of adverse events, consumer complaints, and product safety concerns (collectively, "incident reports") for a period of not less than three years and shall make such records available for inspection upon request by the department, county or municipal health department, or law enforcement authority. The department is authorized to promulgate rules and regulations as needed to implement this section; however, implementation shall be accomplished utilizing existing departmental resources and personnel, and no new program, office, or additional appropriation shall be required solely by reason of this section. The department is further authorized to promulgate rules updating testing standards, contaminant thresholds, or the list of prohibited substances under this section as scientific or public health evidence warrants, provided that any such updates shall be accomplished within existing appropriations.

8. If any provision of this section is held invalid, the remainder shall continue in full force and effect.

9. Nothing in this section shall be construed to preempt any county, city, town, or village from enacting local laws or ordinances that impose restrictions on the sale or distribution of kratom products that are more stringent than those provided in this section.

10. Manufacturers of kratom products already in commercial distribution prior to the effective date of this section shall have one hundred eighty days from such effective date to achieve compliance with the testing requirements of subdivision three of this section.

§ 4. This act shall take effect ninety days after it shall have become a law, provided that the commissioner of health is authorized to promulgate any necessary rules and regulations prior to such effective date.