STATE OF NEW YORK

8136

2025-2026 Regular Sessions

IN SENATE

May 15, 2025

Introduced by Sen. COMRIE -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law and the tax law, in relation to enacting the "New York state kratom consumer protection act"

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

Section 1. Short title. This act shall be known and may be cited as the "New York state kratom consumer protection act".

§ 2. The article heading of article 13-F of the public health law, as amended by chapter 448 of the laws of 2012, is amended to read as follows:

REGULATION OF TOBACCO PRODUCTS, HERBAL CIGARETTES, **KRATOM** AND SMOKING PARAPHERNALIA; DISTRIBUTION TO MINORS

§ 3. Section 1399-aa of the public health law is amended by adding eleven new sections, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28 and 29 to read as follows:

19. "Kratom" means the plant Mitragyna speciosa or any part of that plant.

20. "Kratom product" means a finished article containing: (a) any part of a leaf of the plant Mitragyna speciosa in fresh, dehydrated, or dried form; or (b) a kratom extract.

21. "Kratom processor" means a person who:

(a) manufactures, distributes, or warehouses a kratom product; or

(b) advertises, represents, or holds oneself out as manufacturing, distributing, or warehousing a kratom product.

22. "Kratom extract" means a substance or compound obtained by extraction of the Mitragyna speciosa leaf, intended for ingestion, containing more than trace amounts of Mitragyna speciosa and containing other alkaloids of the kratom plant, which does not contain any controlled substances or levels of residual solvents higher than is allowed in the U.S. Pharmacopeia (USP) 467.

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

LBD00486-04-5

23. "Alkaloid" means a compound found in the Mitragyna speciosa leaf including but not limited to mitragynine, paynantheine, speciociliatine, or speciogynine.

24. "Synthesized material" means an alkaloid, metabolite of 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, oxidation, rather than traditional food preparation techniques, such as heating or extracting.

25. "Semi-synthetic alkaloid" means a substance derived from an alkaloid naturally occurring in kratom that has been chemically altered through chemical reactions such as, but not limited to: oxidation, reduction, acetylation, or other processes to change the structure or pharmacological activity of the naturally occurring kratom alkaloid. This includes but is not limited to the synthesis of 7-hydroxymitragynine when produced by chemical alteration of mitragynine.

26. "Synthetic kratom-like compound" means a substance that is not found naturally in the Mitragyna speciosa plant and is created entirely through laboratory synthesis to mimic the pharmacological effects of kratom alkaloids.

27. "Retailer" means any person that sells or advertises itself as selling kratom products directly to consumers, except that a retailer shall not include any facility that prepares a kratom or kratom product extract onsite and offers onsite sale of that kratom or kratom raw leaf or extract product shall have a restaurant license in the jurisdiction where they operate and shall be exempt from registration requirements and labeling provisions provided herein, including as a processor or retailer.

28. "Attractive to children" means kratom products manufactured in the shape of cartoons, or animals or is manufactured or packaged in a form that bears any reasonable resemblance to an existing candy product that is familiar to the public as a widely distributed, branded food product such that a product could be mistaken for the branded product, especially by children.

29. "Current certificate of analysis (COA)" means a test completed within twelve months of submission.

§ 4. The public health law is amended by adding a new section 1399-gg-1 to read as follows:

§ 1399-gg-1. Kratom product limitations. 1. A processor or a retailer shall not prepare, distribute, sell, or offer for sale any of the following:

(a) Any product containing a synthesized, semi-synthesized, or synthetic kratom like-compound as follows:

(i) A product that contains synthesized material as provided in subdivision twenty-four, twenty-five, or twenty-six of section thirteen hundred ninety-nine-aa of this article; or

(ii) A product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than two percent of total alkaloids in a container; or

(iii) A product with a single serving of a product exceeding 1mg/serving of 7-hyroxymitragynine.

(b) A product that contains or is adulterated with any of the following:

(i) A kratom product contains a dangerous poisonous or otherwise deleterious non-kratom ingredient, including, but not limited to, the substances listed as a controlled substance under state or federal law;

(ii) A kratom product in any form that is combustible, intended to be used for vaporization, or as an injectable;

(iii) A kratom product manufactured in a manner that is attractive to children; or

(iv) A kratom extract product that contains levels of residual solvents higher than is allowed in subdivision twenty-two of section thirteen hundred ninety-nine-aa of this article.

§ 5. The public health law is amended by adding a new section 1399-gg-2 to read as follows:

§ 1399-gg-2. Kratom product registration. 1. A kratom processor may not knowingly prepare, distribute, sell, or offer for sale a kratom product in this state that is not registered with the department.

2. A kratom retailer may not sell, distribute, advertise, represent, or hold itself out as selling a kratom product in this state that is not registered with the department.

3. The person responsible for knowingly placing a kratom product into commerce directly in this state shall register annually to offer for sale kratom products manufactured in an approved kratom delivery form and pay a fee, adjusted annually, to cover the administrative costs specifically required for processing and administering such registrations, including the necessary staff and the publication and maintenance of a kratom registration webpage on the department's website.

4. The registration shall include the following documentation from the processor:

(a) A sworn declaration from the registrant that the product registered is compliant with the requirements of this section;

(b) A certification from a third-party independent auditor that the processor's operations are generally consistent with appropriate guidelines of the FDA GMP requirements found in 21 CFR Part 111 or 117 that would apply to kratom products allowed by this chapter for any facility that manufactures, processes, packs, or holds such a kratom product as being registered;

(c) Proof of current U.S. Food and Drug Administration food facility registration for all of the processor's facility that manufactures, processes, packs, or holds the kratom product being registered;

(d) A sworn declaration from the registrant that the processor has the evidence required to meet the federal requirement for having a reasonable expectation of the safety of the product under the conditions of use set forth on the label. The registrant assumes responsibility and liability for any such products offered for sale; and

(e) The submission of a current COA from a certified independent third-party laboratory showing compliance with the requirements of USP 467 for residual solvents, 7-hydroxymitragynine content, and the USP 2232 standard for heavy metal contaminants.

5. A kratom product that contains the same kratom ingredients in the same kratom delivery form, but in a different container, package, or volume, shall be included in a single registration.

6. The department shall maintain a kratom registration database listing all currently registered kratom products.

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

§ 1399-gg-3. Labeling of kratom. 1. A kratom product produced, manufactured, distributed, offered, sold or offered for sale shall have a label that clearly and conspicuously provides the following information on each retail package, including, but not limited to:

(a) A statement against the use by individuals who are under twenty-one years of age, who are pregnant, or who are breastfeeding;

(b) A recommendation to consult a health care professional prior to use;

(c) A statement that kratom may be habit forming;

(d) The following statement: "These statements have not been evaluated by the U.S. Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.";

(e) The name and the address for the place of business of the manufacturor or distributor; and

(f) Directions for use that include, but are not limited to, the following:

(i) A recommended amount of the kratom product per serving that is: (A) clearly described on the label for product forms such as capsules, gummies, prepackaged single serving units, and similar product forms; or

(B) for beverages, liquids, or loose powders, a clear instruction or a mark on the package or container that clearly informs the consumer regarding the recommended serving size and servings per twenty-four hour period;

(ii) A recommended maximum number of servings that should be consumed in a twenty-four hour period;

(iii) A listing of the servings per container;

(iv) A listing of all the ingredients in the product; and

(v) the amount per serving of each of the following kratom compounds:

(A) Mitragynine; and

(B) 7-hydroxymitragynine.

§ 7. The public health law is amended by adding a new section 1399-mm-4 to read as follows:

§ 1399-mm-4. Sale of unregistered kratom products prohibited. 1. No person shall knowingly sell, distribute, advertise, represent, or hold any kratom product that does not have a current registration with the department. A retailer knowingly selling any kratom product not registered with the department that is not on the list of registered products published on the department's website shall be subject to the following civil penalties:

(a) A fine of one thousand dollars for each instance in which product has been found to be sold;

(b) A fine of up to five thousand dollars for a second violation; and

(c) A fine of up to ten thousand dollars for a third violation and the retailer shall be prohibited from the sale of any kratom product in the state for a period of two years.

2. No kratom processor shall knowingly sell, distribute, advertise, represent, or hold any kratom product in this state that is noncompliant with the requirements of this article.

(a) A fine of ten thousand dollars for each such noncompliant product offered for sale;

(b) A fine of twenty thousand dollars and such kratom processor is prohibited from selling any kratom product in the state for two years;

(c) Upon a third violation, the processor, distributor, or retailer shall be prohibited from the sale of any kratom product in the state for ten years; and

(d) Any direct to consumer business model would be subject to the same fines issued pursuant to subdivision one of this section.

3. No seller shall knowingly sell or provide kratom products to any person under twenty-one years of age.

(a) A person who knowingly and willfully commits a first violation of this subdivision shall be guilty of a class A misdemeanor.

(b) A person who knowingly and willfully commits a second or subsequent violation of this paragraph within two years after the initial violation, shall be guilty of a class E felony.

4. A registrant or retailer who knowingly and willfully manufactures, delivers, holds, offers for sale, distributes or sells a kratom product in this state that contains any controlled substance listed in this state or in federal law shall be guilty of a class A misdemeanor.

5. A person who knowingly and willfully manufactures, delivers, holds, offers for sale, distributes or sells a product that contains synthesized material, semi-synthetic alkaloid, or synthetic kratom-like compound as defined in this article commits a class A misdemeanor.

6. Upon receipt of a credible violation report on any kratom product offered for sale, the department shall require the registrant to produce an updated and current COA from a certified independent third-party laboratory within thirty days establishing compliance with the requirements of this chapter for kratom products, including copies of all product labels. If the registrant does not provide the certificate of analysis in the specified time frame, the registration for that product shall be revoked and a stop sales order shall be issued for all products covered by such registration.

7. If the department has a reasonable basis to require an independent third-party test of a registered kratom product by a laboratory of the department's choice, the registrant shall be required to submit payment for the test within a reasonable time frame. If the registrant does not tender payment to the department within thirty days of receipt of the invoice for the testing, the department shall revoke the registration for that product and a stop sales order shall be issued for all products covered by such registration.

8. It is an affirmative defense if the retailer shows by a preponderance of the evidence that such retailer relied in good faith upon the representations of a processor of food represented to be a kratom product.

§ 8. The tax law is amended by adding a new section 471-f to read as follows:

§ 471-f. Imposition of kratom and kratom products tax. 1. There is hereby imposed and shall be paid a tax on all kratom and kratom products possessed in this state by any person.

2. It is intended that the ultimate incidence of and liability for the tax shall be upon the consumer, and that any agent or dealer who shall pay the tax to the commissioner shall collect the tax from the purchaser or consumer.

§ 9. The tax law is amended by adding a new section 471-g to read as follows:

§ 471-g. Excise tax on kratom and kratom products. 1. There is hereby imposed an excise tax on the gross receipts from the sale of kratom or kratom products by a kratom retailer to a retail customer at the rate of five percent. The tax imposed by this article shall be charged against and be paid by the retail customer and shall not be added as a separate charge or line item on any sales slip, invoice, receipt or other statement or memorandum of the price given to the retail customer.

2. The commissioner may make, adopt and amend rules, regulations, procedures and forms necessary for the proper administration of this article.

3. Every registered kratom retailer that makes sales of kratom and kratom products subject to the tax imposed by this article shall, on or before the twentieth date of each month, file with the commissioner a return on forms to be prescribed by the commissioner, showing its receipts from the retail sale of kratom and kratom products during the preceding calendar month and the amount of tax due thereon. Such returns shall contain such further information as the commissioner may require. Every registered kratom retailer required to file a return under this section shall, at the time of filing such return, pay to the commissioner the total amount of tax due on its retail sales of kratom and kratom products for the period covered by such return. If a return is not filed when due, the tax shall be due on the day on which the return is required to be filed.

4. Whenever the commissioner shall determine that any moneys received under the provisions of this article were paid in error, they may cause the same to be refunded, with interest, in accordance with such rules and regulations as they may prescribe, except that no interest shall be allowed or paid if the amount thereof would be less than one dollar. Such interest shall be at the overpayment rate set by the commissioner pursuant to subdivision twenty-sixth of section one hundred seventy-one of this chapter, or if no rate is set, at the rate of six percent per annum, from the date when the tax, penalty or interest to be refunded was paid to a date preceding the date of the refund check by not more than thirty days. Provided, however, that for the purposes of this subdivision, any tax paid before the last day prescribed for its payment shall be deemed to have been paid on such last day. Such moneys received under the provisions of this article which the commissioner shall determine were paid in error, may be refunded out of funds in the custody of the comptroller to the credit of such taxes provided an application therefor is filed with the commissioner within two years from the time the erroneous payment was made.

5. The provisions of article twenty-seven of this chapter shall apply to the tax imposed by this article in the same manner and with the same force and effect as if the language of such article had been incorporated in full into this section and had expressly referred to the tax imposed by this article, except to the extent that any provision of such article is either inconsistent with a provision of this article or is not relevant to this article.

§ 10. Rules and regulations. The department of health shall adopt any necessary rules and regulations to administer provisions of this act. Such rules and regulations shall include, but not be limited to:

1. The process for a registration of a kratom product by a processor, distributor, or a retailer;

2. The requirements for enforcing the restriction on the sale of any kratom product to a person under the age of 21; and

3. Proof of appropriate quality testing from an ISO 17025 laboratory in the form of a Certificate of Analysis (COA) representing the product does not contain levels of residual solvents, biological contaminants or heavy metal contaminants that meet the standard for dietary supplement products.

§ 11. This act shall take effect on the one hundred eightieth day after it shall have become a law. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized to be made and completed on or before such effective date.