SENATE DOCKET, NO. 806 FILED ON: 1/14/2025

SENATE . . . . . No.

The Commonwealth of Massachusetts

PRESENTED BY:

Jacob R. Oliveira

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act concerning the regulation of Kratom.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Jacob R. Oliveira	*Hampden, Hampshire and Worcester*

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SENATE . . . . . No.

[Pin Slip]

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE DOCKET, NO. *2956* OF 2023-2024.]

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Fourth General Court
(2025-2026)

An Act concerning the regulation of Kratom.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1: Chapter 94 of the general laws shall be amended by inserting the following new chapter at the end thereof:

Chapter 94J: Kratom

Section 1. As used in this chapter the following words shall, unless the context clearly requires otherwise, have the following meanings:

"Attractive to children", 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.

"Department", the department of agricultural resources

"Distributor", a person that sells, prepares, distributes, or maintains kratom products, or advertises, represents, or holds itself out as selling, preparing, or maintaining kratom products.

"Independent testing laboratory", means a laboratory that is accredited by a third-party accrediting body as a competent testing laboratory pursuant to ISO/IEC 17025 of the International Organization for Standardization.

"Kratom", the plant Mitragyna speciosa or any part of that plant, including all components present in the natural plant.

"Kratom food service establishment", means any person who sells kratom as a beverage prepared on-site, or sells pre-packaged kratom beverages or finished kratom products, at a licensed food service establishment.

"Kratom product", a food, food ingredient, dietary ingredient, dietary supplement, or beverage intended for human consumption which contains any part of the leaf of the plant Mitragyna speciosa or an extract of the Mitragyna speciosa leaf and is manufactured or served as a powder, capsule, pill, beverage, liquid, or other edible form.

"Kratom extract", a substance or compound obtained by extraction of the Mitragyna speciosa leaf, intended for ingestion, containing more than trace amounts of Mitragyna speciosa and contains 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 467.

"Registrant", a person or processor that sells, prepares, manufactures, distributes, or maintains kratom products, or advertises, represents, or holds itself out as selling, preparing, or maintaining kratom products.

“Retailer”, any person that sells, distributes, advertises, represents, or holds itself out as selling kratom products.

"Synthesized material", 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 composition of any kratom alkaloid or constituent.

Section 2. Kratom Product Limitations.

A registrant shall not prepare, distribute, sell, or expose for sale any of the following:

(1) A product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 2% of the alkaloid composition of the kratom product.

a. Any product that contains a level of 7-hydroxymitragynine greater than the two percent (2%) limit as provided in Section 3(1) cannot be marketed, labeled, or contain any reference on its packaging, that it is a kratom product or referenced that it is derived from the alkaloid mitragynine.

(2) No registrant, distributor, or retailer shall offer for sale any kratom product that contains or is adulterated with any of the following:

a. A kratom product is adulterated with a dangerous non-kratom substance if it contains a poisonous or otherwise deleterious non-kratom ingredient, including, but not limited to, the substances listed as a controlled substances under state or federal law.

b. Contains dangerous psychoactive compounds, which include but are not limited to synthetic cannabinoids, synthetic cathinones, or any other compound that significantly alters the safety profile of the kratom product.

c. The kratom product is mixed with another compound that is known to inhibit key cytochrome P450 enzymes, including CYP3A4 and/or CYP2D6, shall be deemed to be adulterated unless such specific product mixtures are scientifically validated as safe under the intended conditions of use and are specifically permitted by the Department.

d. A kratom product in any form that is combustible, intended to be used for vaporization, or injectable.

e. Products that do not fall into the definition of a kratom product as provided in Section 2(3) are prohibited.

(3) The kratom product is not manufactured in a manner that is attractive to children.

(4) The kratom product does not contain any synthesized material as provided in Section 2(5) or that contains alkaloids or other plant constituents that have been isolated or manipulated to artificially increase their potency, other than using the approved extraction method provided herein, unless the manufacturer has safety data to support the increased potency according to the conditions for use on the label in the populations the data supports.

(5) A kratom extract product that contains levels of residual solvents higher than is allowed in Section 2(4).

Section 3. Kratom product registration.

(1) The party responsible for placing a kratom product into commerce in the 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 all administrative costs for processing and administering such registrations, including the necessary staff and the publication and maintenance of a kratom registration webpage as provided in Section 4(5).

(2) Parties seeking to register a product under Section 3(2) or (3)(3)(c) shall be required to pay a fee based on the costs the Department incurs to retain the services of qualified experts to review the safety data provided by the registrant to allow the Department to conduct a review and make a final decision.

(3) The registration shall include the following sworn certifications from the processor:

a. The kratom product was manufactured, processed, or held in a facility that is in compliance with current good manufacturing practices that meet requirements of 21 CFR 111.

b. A statement the processor has a reasonable basis that the product is safe for consumption under the conditions of use set forth on the label. The registrant assumes responsibility and liability for any such products offered for sale.

c. The submission of a certificate of analysis (COA) from a certified independent third-party laboratory showing compliance with the requirements of this chapter for residual solvents, 7-hydroxymitragynine content, contaminants, and synthesized materials.

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

(5) The department shall publish and maintain a kratom registration page on its official website listing all currently registered kratom products for sale by retailers that allows retailers to verify registered kratom products they are permitted to sell to consumers.

Section 4. Labeling.

(1) A kratom product produced, manufactured, distributed, offered, sold or offered for sale shall have a label that clearly and conspicuously provides all of the following information on each retail package:

a. A statement against the use by individuals who are under 18 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 United States 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 registrant.

f. Directions for use that include the following:

i. A recommended amount of the kratom product per serving that is (1) clearly described on the label for product forms such as capsules, gummies, prepackaged single serving units, and similar product forms; or (2) for beverages, liquids, or loose powders, a clear

instruction or a mark on the package or container that clearly informs the consumer on the recommended serving size.

ii. A recommended number of servings that can be safely consumed in a 24-hour period.

iii. A listing of the servings per container.

iv. A listing of kratom alkaloids and other ingredients in the product, including quantitative not to exceed declarations of the amount per serving of each of the following:

1. Mitragynine.

2. 7-hydroxymitragynine.

v. A kratom food service establishment who sells kratom as a beverage prepared on-site shall provide an equivalent label in card form or prominently display the required language in a location next to the point-of-sale device to the customer at the time the beverage is purchased by the consumer.

vi. Labeling and Disclosure Requirements

1. Any kratom product that contains psychoactive compounds otherwise permitted must be clearly labeled with a full disclosure of all active ingredients, the exact concentration of each compound, and adequate warning statements about the potential interactions and risks associated with the combined use of these substances.

Section 5. Enforcement.

(1) A registrant is prohibited from selling any kratom product; a distributor is prohibited from distributing any kratom product; and a retailer is prohibited from selling any kratom product that does not have a current registration with the department. Any kratom product not registered shall be seized and destroyed, and the costs associated with such enforcement shall be assessed to the party responsible for its availability for sale in the state.

(2) Kratom products that are intended for human ingestion may not be sold in this state to a person who is under 18 years of age. A person who knowingly and willfully violates this paragraph commits a misdemeanor, punishable as provided in state law. A person who knowingly and willfully commits a second or subsequent violation of this paragraph within one (1) year after the initial violation commits a misdemeanor of the first degree, punishable as provided in state law.

(3) A registrant that knowingly and willfully manufactures, delivers, holds, offers for sale, distributes or sells a kratom product that contains any controlled substance listed in state or federal law shall be guilty of a felony as provided in state law.

(4) A registrant that knowingly and willfully manufactures, delivers, holds, offers for sale, distributes or sells a kratom product that contains synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compound of the plant Mitragyna speciosa commits a misdemeanor, punishable as provided in state law.

a. Any violation of Section 6(4) shall result in the immediate seizure and destruction of the adulterated kratom products and may result in civil or criminal penalties as provided in state law. Repeat offenders shall be subject to enhanced penalties, including permanent revocation of licenses to sell or distribute kratom products.

(5) Product non-compliance reports. Upon receipt of a violation report on any kratom product offered for sale, the department shall require the registrant to produce an updated and current certificate of analysis in a reasonable time frame from a certified independent third-party laboratory showing compliance with the requirements of this chapter for safe kratom products. 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 will be issued for products covered by this registration.

(6) Third-party verification. 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 (30) days of receipt of the invoice for the testing, the department shall revoke the registration for that product and a stop sales order will be issued for products covered by this registration

(7) A processor does not violate this Section for any kratom product that has been reviewed and approved by the Department for safe consumption in combination with psychoactive compounds under clearly defined conditions of use.

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

Section 6. Rules.

(1) The department shall adopt regulations to administer provisions of this Chapter. The regulation must provide for:

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

b. The requirements for enforcing the restriction on the sale of any kratom product to a person under the age of 18.

c. 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.

Section 7. Federal Preemption.

If at any time on or after the effective date of this act, the federal government or any department or agency thereof, including but not limited to the federal Drug Enforcement Agency or Food and Drug Administration, regulates 7-hydroxymitragynine, 7-hydroxymitragynine extracts, 7-hydroxymitragynine products, any other derivative of the plant Mitragyna speciosa, 7-hydroxymitragynine processors, or 7-hydroxymitragynine retailers, including the acceptance by the Food and Drug Administration of a new dietary ingredient notification, those federal regulations shall supersede and take precedence over any provision of this act and any administrative regulation promulgated thereunder to the contrary that is addressed by the federal action.

Section 8. Enactment Date.

This act would take effect 180 days after passage.