

**SENATE . . . . . No. 1609**

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**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:	
<i>Jacob R. Oliveira</i>	<i>Hampden, Hampshire and Worcester</i>	
<i>Colleen M. Garry</i>	<i>36th Middlesex</i>	<i>2/12/2025</i>
<i>Edward J. Kennedy</i>	<i>First Middlesex</i>	<i>4/16/2025</i>
<i>Paul R. Feeney</i>	<i>Bristol and Norfolk</i>	<i>12/9/2025</i>

**SENATE . . . . . No. 1609**

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By Mr. Oliveira, a petition (accompanied by bill, Senate, No. 1609) of Jacob R. Oliveira and Colleen M. Garry for legislation relative to the regulation of Kratom. Public Health.

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

**The Commonwealth of Massachusetts**

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**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:*

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

3 Chapter 94J: Kratom

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

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

10 “Department”, the department of agricultural resources

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

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

16 “Kratom”, the plant *Mitragyna speciosa* or any part of that plant, including all  
17 components present in the natural plant.

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

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

25 “Kratom extract”, a substance or compound obtained by extraction of the *Mitragyna*  
26 *speciosa* leaf, intended for ingestion, containing more than trace amounts of *Mitragyna speciosa*  
27 and contains other alkaloids of the kratom plant, which does not contain any controlled  
28 substances or levels of residual solvents higher than is allowed in the U.S. Pharmacopeia 467.

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

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

34           "Synthesized material", an alkaloid or alkaloid derivative that has been created by  
35 chemical synthesis or biosynthetic means, including but not limited to; fermentation,  
36 recombinant techniques, yeast derived, enzymatic techniques, rather than traditional food  
37 preparation techniques, such as heating or extracting that synthetically alters the composition of  
38 any kratom alkaloid or constituent.

39           Section 2. Kratom Product Limitations.

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

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

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

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

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

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

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

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

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

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

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

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

71 Section 3. Kratom product registration.

72 (1) The party responsible for placing a kratom product into commerce in the state  
73 shall register annually to offer for sale kratom products manufactured in an approved kratom  
74 delivery form and pay a fee, adjusted annually, to cover all administrative costs for processing  
75 and administering such registrations, including the necessary staff and the publication and  
76 maintenance of a kratom registration webpage as provided in Section 4(5).

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

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

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

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

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

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

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

96           Section 4. Labeling.

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

100           a.       A statement against the use by individuals who are under 18 years of age, who are  
101 pregnant, or who are breastfeeding.

102           b.       A recommendation to consult a health care professional prior to use.

103           c.       A statement that kratom may be habit forming.

104           d.       The following statement: “These statements have not been evaluated by the  
105 United States Food and Drug Administration. This product is not intended to diagnose, treat,  
106 cure, or prevent any disease.”

107           e.       The name and the address for the place of business of the registrant.

- 108 f. Directions for use that include the following:
- 109 i. A recommended amount of the kratom product per serving that is (1) clearly  
110 described on the label for product forms such as capsules, gummies, prepackaged single serving  
111 units, and similar product forms; or (2) for beverages, liquids, or loose powders, a clear  
112 instruction or a mark on the package or container that clearly informs the consumer on the  
113 recommended serving size.
- 114 ii. A recommended number of servings that can be safely consumed in a 24-hour  
115 period.
- 116 iii. A listing of the servings per container.
- 117 iv. A listing of kratom alkaloids and other ingredients in the product, including  
118 quantitative not to exceed declarations of the amount per serving of each of the following:
- 119 1. Mitragynine.
- 120 2. 7-hydroxymitragynine.
- 121 v. A kratom food service establishment who sells kratom as a beverage prepared on-  
122 site shall provide an equivalent label in card form or prominently display the required language  
123 in a location next to the point-of-sale device to the customer at the time the beverage is  
124 purchased by the consumer.
- 125 vi. Labeling and Disclosure Requirements
- 126 1. Any kratom product that contains psychoactive compounds otherwise permitted  
127 must be clearly labeled with a full disclosure of all active ingredients, the exact concentration of

128 each compound, and adequate warning statements about the potential interactions and risks  
129 associated with the combined use of these substances.

130 Section 5. Enforcement.

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

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

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

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

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

153           (5)     Product non-compliance reports. Upon receipt of a violation report on any kratom  
154 product offered for sale, the department shall require the registrant to produce an updated and  
155 current certificate of analysis in a reasonable time frame from a certified independent third-party  
156 laboratory showing compliance with the requirements of this chapter for safe kratom products. If  
157 the registrant does not provide the certificate of analysis in the specified time frame, the  
158 registration for that product shall be revoked and a stop sales order will be issued for products  
159 covered by this registration.

160           (6)     Third-party verification. If the department has a reasonable basis to require an  
161 independent third-party test of a registered kratom product by a laboratory of the department's  
162 choice, the registrant shall be required to submit payment for the test within a reasonable time  
163 frame. If the registrant does not tender payment to the department within thirty (30) days of  
164 receipt of the invoice for the testing, the department shall revoke the registration for that product  
165 and a stop sales order will be issued for products covered by this registration

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

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

172 Section 6. Rules.

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

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

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

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

183 Section 7. Federal Preemption.

184 If at any time on or after the effective date of this act, the federal government or any  
185 department or agency thereof, including but not limited to the federal Drug

186 Enforcement Agency or Food and Drug Administration, regulates 7-hydroxymitragynine,  
187 7-hydroxymitragynine extracts, 7-hydroxymitragynine products, any other derivative of the plant  
188 *Mitragyna speciosa*, 7-hydroxymitragynine processors, or 7-hydroxymitragynine retailers,

189 including the acceptance by the Food and Drug Administration of a new dietary ingredient  
190 notification, those federal regulations shall supersede and take precedence over any provision of  
191 this act and any administrative regulation promulgated thereunder to the contrary that is  
192 addressed by the federal action.

193 Section 8. Enactment Date.

194 This act would take effect 180 days after passage.