

**DRAFT REGULATION OF THE ASHLAND BOARD OF HEALTH: SALE OF
KRATOM PRODUCTS**

Regulating the Sale, Distribution, and Labeling of Kratom Products, and Prohibiting the Sale of Products Containing Excessive Levels of 7-Hydroxymitragynine or Synthetic Kratom Alkaloids.

WHEREAS, kratom (*Mitragyna speciosa*) is a tropical tree native to Southeast Asia, and its leaves are consumed in various forms including powdered leaf, extracts, capsules, and beverages; and

WHEREAS, the active compounds in kratom include mitragynine and 7-hydroxymitragynine, and the concentration of these alkaloids can vary significantly across commercially available kratom products; and

WHEREAS, kratom products are increasingly available for retail sale within the Commonwealth of Massachusetts, and consumers would benefit from consistent standards governing the quality, labeling, and composition of such products; and

WHEREAS, the Ashland Board of Health seeks to ensure that kratom products sold within the Town of Ashland are accurately labeled, free of adulteration and contamination, do not contain synthetic alkaloids, and maintain alkaloid concentrations within established limits; and

WHEREAS, the Ashland Board of Health further seeks to prevent the sale of kratom products to persons under twenty-one (21) years of age and to ensure that kratom products are not marketed in a manner attractive to children; and

WHEREAS, synthetic kratom alkaloids may also be manufactured and sold as standalone products containing no kratom plant material, presenting public health concerns equal to or greater than those of kratom products themselves; and

WHEREAS, this regulation is consistent with and complementary to pending state legislation (House Bill No. 4394), currently before the House Committee on Ways and Means, that would establish statewide standards for the sale of kratom products in the Commonwealth.

**THE ASHLAND BOARD OF HEALTH DOES HEREBY ADOPT THE FOLLOWING
REGULATION:**

Section 1. Recitals.

The recitals above are true and correct and are incorporated herein by this reference.

Section 2. Authority.

This regulation is promulgated pursuant to the authority granted to the Ashland Board of Health by Massachusetts General Laws Chapter 111, Section 31, which states “Boards of health may make reasonable health regulations.”

Section 3. Purpose.

This regulation is enacted pursuant to the Board of Health’s authority to protect public safety, health, and welfare. The express purpose of this regulation is to establish consumer protection standards for kratom products sold within the Town of Ashland, including requirements for accurate labeling, product composition limits, age verification, and appropriate packaging and display.

Section 4. Definitions.

For the purposes of this regulation, the following words shall, unless the context clearly requires otherwise, have the following meanings:

“Attractive to Children” means any of the following:

- (a) Use of images that are attractive to children, including, but not limited to, images of any of the following, except as part of required health warnings:
 - (i) Cartoons, toys, or robots.
 - (ii) Any real or fictional humans.
 - (iii) Fictional animals or creatures.
 - (iv) Fruits or vegetables, except when used to accurately describe ingredients or flavors contained in a product.
 - (v) Likeness to images, characters, or phrases that are popularly used to advertise to children.
- (b) Imitation of candy packaging or labeling, or other packaging and labeling of cereals, sweets, chips, or other food products typically marketed to children.
- (c) The terms “candy” or “candies” or variants in spelling, such as “kandy” or “kandee.”
- (d) Brand names or close imitations of brand names of candies, cereals, sweets, chips, or other food products typically marketed to children.
- (e) Any other image or packaging that is easily confused with commercially available foods that do not contain kratom and are typically marketed to children.
- (f) Any other packaging used that is attractive to children, considering all relevant facts and circumstances.

“Child-Resistant Packaging” means packaging that is designed or constructed to be significantly difficult for children under five (5) years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and that is not difficult for normal adults to use properly, as defined under the Poison Prevention Packaging Act (15 U.S.C. § 1471 et seq.) and its implementing regulations at 16 CFR § 1700.15.

“Kratom Extract” means the material obtained by extraction of kratom leaves by any means.

“Kratom Leaf” means the leaf of the kratom plant (*Mitragyna speciosa*) in any form.

“Kratom Product” means a product consisting of kratom leaf, kratom leaf extract, or both. A kratom product shall not:

- (a) Contain any synthesized kratom alkaloids or other synthesized kratom constituents, or synthesized metabolites of any kratom constituent; or

- (b) Contain a level of 7-hydroxymitragynine that is greater than two percent (2%) of the total kratom alkaloids in the product, or more than one milligram (1 mg) per serving of 7-hydroxymitragynine.
- (c) Be mixed into, or served as a component of, any food or beverage prepared or sold for immediate consumption.

A kratom product shall not be classified as a food, food product, food ingredient, dietary ingredient, or dietary supplement. For purposes of this regulation, a kratom product is regulated as a restricted botanical commodity under the Board's general authority pursuant to M.G.L. c. 111, § 31, and is independent of the State Sanitary Code (105 CMR 590).

“Kratom Retailer” means a person or entity who sells, maintains, or distributes kratom products, or advertises, represents, or holds itself out as selling, maintaining, or distributing kratom products.

“Manufacture” means the production, preparation, compounding, or processing of kratom, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes, but is not limited to, any packaging or repackaging of such substance or labeling or relabeling of its container.

“Person” means any individual, firm, partnership, association, corporation, company, or organization of any kind, including but not limited to an owner, operator, manager, proprietor, or person in charge of any establishment, business, or retail store.

“Total Kratom Alkaloids” means the sum of mitragynine, speciociliatine, speciogynine, paynantheine, and 7-hydroxymitragynine in a kratom product.

“Synthetic Kratom Alkaloid Product” means any product containing a synthesized kratom alkaloid, synthesized kratom constituent, or synthesized metabolite of any kratom constituent, that does not otherwise qualify as a Kratom Product under this regulation.

Section 5. Labeling Requirements.

A kratom retailer shall not sell, distribute, or offer for sale a kratom product without a label clearly stating:

- (1) The name and address of its manufacturer;
- (2) A full list of its ingredients;
- (3) Directions for its safe and effective use, including the recommended serving size.

Section 6. Product Restrictions.

- (a) A kratom retailer shall not distribute, advertise, sell, or offer for sale a kratom product that is adulterated with a dangerous non-kratom substance. A kratom product is adulterated with a dangerous non-kratom substance if the kratom product is mixed or packed with a non-kratom substance and that substance affects the quality or strength of the kratom product to such a degree as to render the kratom product injurious to a consumer.

- (b) A kratom retailer shall not distribute, advertise, sell, or offer for sale a kratom product that is contaminated with a dangerous non-kratom substance. A kratom product is contaminated with a dangerous non-kratom substance if the kratom product contains a poisonous or otherwise deleterious non-kratom ingredient, including, but not limited to, a controlled substance or controlled substance analogue as both are defined in Section 1 of Chapter 94C of the Massachusetts General Laws.
- (c) A kratom retailer shall not distribute, advertise, sell, or offer for sale a kratom product containing a level of 7-hydroxymitragynine that is greater than two percent (2%) of the total kratom alkaloids in the product, or more than one milligram (1 mg) per serving of 7-hydroxymitragynine.
- (d) A kratom retailer shall not distribute, advertise, sell, or offer for sale a kratom product containing any synthesized kratom alkaloids, including synthesized mitragynine, synthesized 7-hydroxymitragynine, any other synthesized kratom constituents, or synthesized metabolites of any kratom constituent.
- (e) An individual, business, or other entity shall not produce, sell, or distribute a kratom product that is Attractive to Children, as defined in Section 4 of this regulation.
- (f) All kratom products offered for retail sale within the Town of Ashland shall be packaged in Child-Resistant Packaging, as defined in Section 4 of this regulation, for the life of the product.
- (g) A person shall not distribute, advertise, sell, or offer for sale within the Town of Ashland a Synthetic Kratom Alkaloid Product.

Section 7. Sales Restrictions and Age Verification.

- (1) No person shall sell, offer for sale, provide, or distribute a kratom product to a person under twenty-one (21) years of age.
- (2) Each person selling or distributing kratom products shall verify the age of the purchaser by means of a valid government-issued photographic identification containing the bearer's date of birth, confirming that the purchaser is twenty-one (21) years of age or older. Verification is required for any person under the age of forty (40).
- (3) All retail sales of kratom products must be face-to-face between the seller and the buyer and occur at the retail location.
- (4) No person shall offer for sale a kratom product within the Town of Ashland unless such product is behind a counter in an area only accessible to store employees or in a secured display which is only accessible with the intervention of a store employee.

Section 8. Violations and Penalties.

- (a) A kratom retailer who violates Section 5 (Labeling Requirements) or Section 6 (Product Restrictions) of this regulation shall be subject to an administrative fine of not more than five hundred dollars (\$500) for the first offense and not more than one thousand dollars (\$1,000) for subsequent offenses. Upon the request of a person to

whom an administrative fine is issued, the Ashland Board of Health shall conduct a hearing in accordance with Massachusetts General Laws Chapter 30A.

- (b) A kratom retailer does not violate Section 5 or Section 6 of this regulation if the retailer can show by a preponderance of the evidence that the retailer relied in good faith upon the representations of a manufacturer, processor, packer, or distributor of a kratom product, or food represented to be a kratom product, that such product was in compliance with this regulation.
- (c) A kratom retailer who violates Section 7 (Sales Restrictions and Age Verification) of this regulation shall be punished by a fine of one thousand dollars (\$1,000) for the first offense, two thousand dollars (\$2,000) for a second offense, and five thousand dollars (\$5,000) for a third or subsequent offense.
- (d) Each day any violation exists shall be deemed to be a separate offense.

Section 9. Enforcement.

- (1) Enforcement of this regulation shall be by the Ashland Board of Health or its designated agent(s).
- (2) The Ashland Board of Health shall have the authority to inspect any retail establishment selling or offering for sale kratom products to ensure compliance with this regulation. Inspections may be conducted without prior notice.
- (3) Any resident who desires to register a complaint pursuant to this regulation may do so by contacting the Ashland Board of Health or its designated agent(s), and the Board shall investigate.
- (4) The Ashland Board of Health shall adopt standards for testing kratom products for safety and compliance with this regulation.

Section 10. Severability.

If any section, subsection, subdivision, sentence, clause, phrase, or portion of this regulation is, for any reason, held to be invalid or unconstitutional by the decision of any court of competent jurisdiction, such decision shall not affect the validity of the remaining portions of this regulation. The Ashland Board of Health hereby declares that it would have adopted this regulation and each section, subsection, subdivision, sentence, clause, phrase, or portion thereof, irrespective of the fact that any one or more sections, subsections, subdivisions, sentences, clauses, phrases, or portions thereof be declared invalid or unconstitutional.

Section 11. Effective Date.

This regulation shall take effect and be in force thirty (30) days after its adoption by the Ashland Board of Health.

ADOPTED by the Ashland Board of Health on this _____ day of _____, 20_____.

Chair, Ashland Board of Health

Member, Ashland Board of Health

Member, Ashland Board of Health

Date

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