

JAN 16 2025

A BILL FOR AN ACT

RELATING TO CONSUMER PROTECTION.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

1 SECTION 1. Chapter 328, Hawaii Revised Statutes, is
2 amended by adding a new part to be appropriately designated and
3 to read as follows:

4 **"PART . HAWAII KRATOM CONSUMER PROTECTION ACT**

5 **§328-A Short title.** This part shall be known and may be
6 cited as the Hawaii Kratom Consumer Protection Act.

7 **§328-B Definitions.** As used in this chapter:

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

15 "Independent testing laboratory" means a laboratory
16 accredited by a third-party accrediting body as a competent
17 testing laboratory pursuant to standard 17025 of the



1 International Organization for Standardization and International
2 Electrotechnical Commission specialized system for worldwide
3 standardization, commonly abbreviated as ISO/IEC 17025.

4 "Kratom" means the plant *Mitragyna speciosa* or any part of
5 that plant, including all components present in the natural
6 plant.

7 "Kratom extract" means a substance or compound obtained by
8 extraction of the *Mitragyna speciosa* leaf, intended for
9 ingestion, containing more than trace amounts of *Mitragyna*
10 *speciosa* and contains other alkaloids of the kratom plant, which
11 does not contain any controlled substances or levels of residual
12 solvents greater than is allowed in the U.S. Pharmacopeia
13 General Chapter 467.

14 "Kratom food service establishment" means a person who
15 sells kratom as a beverage prepared on-site, or sells pre-
16 packaged kratom beverages or finished kratom products, at a food
17 service establishment licensed by the department.

18 "Kratom product" means a food, food ingredient, dietary
19 ingredient, dietary supplement, or beverage intended for human
20 consumption that contains any part of the leaf of the plant
21 *Mitragyna speciosa* or an extract of the *Mitragyna speciosa* leaf



1 and is manufactured or served as a powder, capsule, pill,
2 beverage, liquid, or other edible form.

3 "Synthesized material" means an alkaloid or alkaloid
4 derivative that has been created by chemical synthesis or
5 biosynthetic means, including fermentation, recombinant
6 techniques, yeast derived, and enzymatic techniques, rather than
7 traditional food preparation techniques, such as heating or
8 extracting, that synthetically alters the composition of any
9 kratom alkaloid or constituent.

10 **§328-C Kratom products; limitations.** (a) No person shall
11 sell, offer for sale, advertise, distribute, produce, or
12 manufacture any of the following:

13 (1) A kratom product that contains:

14 (A) A level of 7-hydroxymitragynine in the alkaloid
15 fraction that is more than two per cent of the
16 alkaloid composition of the kratom product;
17 provided that any product that contains a level
18 of 7-hydroxymitragynine in the alkaloid fraction
19 more than two per cent of the alkaloid
20 composition cannot be marketed, labeled, or
21 contain any reference on its packaging, that it



- 1 is a kratom product or referenced that it is
2 derived from the alkaloid mitragynine;
- 3 (B) Kratom extract and that contains levels of
4 residual solvents greater than is allowed in the
5 U.S. Pharmacopeia General Chapter 467; or
- 6 (C) Dangerous psychoactive compounds, including but
7 not limited to synthetic cannabinoids or
8 synthetic cathinones, or any other compound that
9 significantly alters the safety profile of the
10 kratom product;
- 11 (2) A kratom product that is adulterated;
- 12 (3) A kratom product produced or manufactured in a manner
13 that is attractive to children;
- 14 (4) A kratom product in any form that is combustible,
15 intended to be used for vaporization, or injectable;
16 or
- 17 (5) A product that contains any part of the leaf of the
18 plant *Mitragyna speciosa* or an extract of the
19 *Mitragyna speciosa* leaf and that does not conform to
20 the definition of kratom product.



1 (b) For purpose of this section, a kratom product shall be
2 deemed adulterated if:

3 (1) The kratom product contains a poisonous or otherwise
4 deleterious non-kratom ingredient, including but not
5 limited to substances listed as a controlled substance
6 under federal law or chapter 329;

7 (2) The kratom product contains any synthesized material
8 or alkaloids or other plant constituents that have
9 been isolated or manipulated to artificially increase
10 their potency through a method other than traditional
11 food preparation techniques, unless the manufacturer
12 has safety data to support the increased potency
13 according to the conditions for use on the label in
14 the populations the data supports; or

15 (3) A kratom product is combined with another compound
16 that is known to inhibit key cytochrome P450 enzymes,
17 including CYP3A4 and CYP2D6, unless such specific
18 product mixtures are scientifically validated as safe
19 under the intended conditions of use and are
20 specifically permitted by the department by rules
21 adopted pursuant to chapter 91.



1 **§328-D Kratom product registration; required.** (a) No
2 person shall place a kratom product into commerce in the State
3 unless the person has registered the kratom product with the
4 department on a form prescribed by the department with a fee as
5 provided under subsection (b) and the sworn certifications under
6 subsection (d).

7 (b) The registration fee shall be determined by department
8 by rule adopted pursuant to chapter 91. The fee shall be
9 adjusted annually to cover all administrative costs for
10 processing and administering the registration, including the
11 necessary personnel and the publication and maintenance of a
12 kratom registration webpage as provided in this section.

13 (c) A person registering a kratom product under section
14 328-C(b)(2) or (3) shall pay an additional fee determined by the
15 department pursuant to chapter 91 based on the costs incurred to
16 retain the services of qualified experts to review the safety
17 data provided by the person to allow the department to conduct a
18 review and make a final decision.

19 (d) Applications for registration shall include sworn
20 certifications from the kratom product's producer or
21 manufacturer of the following:



1 (1) The kratom product was manufactured, processed, or
2 held in a facility that is in compliance with current
3 good manufacturing practices that meet requirements of
4 title 21 Code of Federal Regulations section 111;

5 (2) A statement that the producer or manufacturer has a
6 reasonable basis that the product is safe for
7 consumption under the conditions of use set forth on
8 the label; provided that the person registering the
9 kratom product shall assume responsibility and
10 liability for the kratom product; and

11 (3) A certificate of analysis from a certified third-party
12 independent testing laboratory showing compliance with
13 the requirements of this chapter for residual
14 solvents, 7-hydroxymitragynine content, contaminants,
15 and synthesized materials.

16 (e) Products that contain identical kratom ingredients in
17 identical kratom delivery forms shall be included in a single
18 registration regardless of whether the containers, packages, or
19 volumes are identical.

20 (f) Each registration shall expire on December 31 of each
21 year. Before December 31 of each year, the person shall renew



1 the registration on a form prescribed by the department with a
2 fee as provided under subsection (b).

3 (g) The department shall publish and maintain a kratom
4 registration page on the department's website listing all
5 registered kratom products available to be sold, offered for
6 sale, or distributed in the State.

7 **§328-E Kratom products; labeling.** A kratom product sold,
8 offered for sale, advertised, distributed, produced, or
9 manufactured in the State shall have a label that clearly and
10 conspicuously provides all of the following information on each
11 retail package:

12 (1) A statement against the use by individuals who are
13 under eighteen years of age, who are pregnant, or who
14 are breastfeeding;

15 (2) A recommendation to consult a health care professional
16 prior to use;

17 (3) A statement that kratom may be habit forming;

18 (4) The following statement: "These statements have not
19 been evaluated by the United States Food and Drug
20 Administration. This product is not intended to
21 diagnose, treat, cure, or prevent any disease.";



- 1 (5) The name and the address for the place of business of
2 the registrant; and
- 3 (6) Directions for use that includes the following:
- 4 (A) A recommended amount of the kratom product per
5 serving that is:
- 6 (i) Clearly described on the label for product
7 forms, such as capsules, gummies,
8 prepackaged single serving units, and
9 similar product forms; or
- 10 (ii) For beverages, liquids, or loose powders, a
11 clear instruction or a mark on the package
12 or container that clearly informs the
13 consumer on the recommended serving size;
- 14 (B) A recommended number of servings that can be
15 safely consumed in a twenty-four-hour period;
- 16 (C) A listing of the servings per container;
- 17 (D) A listing of kratom alkaloids and other
18 ingredients in the product, including
19 quantitative not to exceed declarations of the
20 amount per serving of mitragynine and 7-
21 hydroxymitragynine;



1 (E) A kratom food service establishment that sells
2 kratom as a beverage prepared on-site shall
3 provide an equivalent label in card form or
4 prominently display the required language in a
5 location next to the point-of-sale device to the
6 customer at the time the beverage is purchased by
7 the consumer; and

8 (F) For any kratom product that contains psychoactive
9 compounds otherwise permitted shall be clearly
10 labeled with a full disclosure of all active
11 ingredients, the exact concentration of each
12 compound, and adequate warning statements about
13 the potential interactions and risks associated
14 with the combined use of these substances.

15 **§328-F Enforcement.** (a) Each kratom product without a
16 valid registration shall be seized and destroyed, and the costs
17 associated with the enforcement shall be assessed to the person
18 selling, offering for sale, advertising, or distributing the
19 kratom product.

20 (b) No person shall sell or offer for sale a kratom
21 product intended to a person under eighteen years of age. A



1 person who knowingly commits a second or subsequent violation of
2 this subsection within one year after the initial violation
3 shall be guilty of a misdemeanor.

4 (c) A person who knowingly sells, offers for sale,
5 advertises, distributes, produces, or manufactures a kratom
6 product containing any substance listed as a controlled
7 substance under federal law or chapter 329 shall be guilty of a
8 class C felony.

9 (d) A person who knowingly sells, offers for sale,
10 advertises, distributes, produces, or manufactures a kratom
11 product containing any synthesized material, including synthetic
12 mitragynine, synthetic 7-hydroxymitragynine, or any other
13 synthetically derived compound of the plant *Mitragyna speciosa*,
14 or alkaloids or other plant shall constitute a violation of
15 section 328-C(b)(2). A violation of this subsection shall
16 result in the immediate seizure and destruction of the kratom
17 products and may result in the penalties under section 328-29.
18 Any person who, within five years of the instant offense, has
19 convictions of two or more violations of this subsection shall
20 be guilty of a class C felony.



1 (e) A person who violates section 328-C(b), except as
2 provided under subsection (d), shall be subject to the penalties
3 under section 328-29.

4 (f) Upon receipt of a violation report on any kratom
5 product sold, offered for sale, advertised, distributed,
6 produced, or manufactured, the department shall require the
7 person to produce an updated and current certificate of analysis
8 in a reasonable time frame from a certified third-party
9 independent testing laboratory showing compliance with the
10 requirements of this part for safe kratom products. If the
11 person does not provide the certificate of analysis in the
12 specified time frame, the registration for that product shall be
13 revoked and a stop sale order shall be issued for products
14 covered by the registration.

15 (g) If the department has a reasonable basis to require an
16 independent third-party test of a registered kratom product by
17 an independent testing laboratory of the department's choice,
18 the person shall be required to submit payment for the test
19 within a reasonable time frame. If the person does not tender
20 payment to the department within thirty days of receipt of the
21 invoice for the testing, the department shall revoke the



1 registration for that product and a stop sale order shall be
2 issued for products covered by the registration.

3 (h) No person shall be in violation of this part for any
4 kratom product that has been reviewed and approved by the
5 department for safe consumption in combination with psychoactive
6 compounds under clearly defined conditions of use.

7 (i) No person shall be in violation of this part if it is
8 shown by a preponderance of the evidence that the person relied
9 in good faith upon the representations of a manufacturer,
10 producer, or distributor of food represented to be a kratom
11 product.

12 **§328-G Rules.** The department shall adopt rules pursuant
13 to chapter 91 to effectuate this part. The rules shall provide:

14 (1) The process for a registration of a kratom product by
15 a person;

16 (2) The requirements for enforcing the restriction on the
17 sale of any kratom product to a person under the age
18 of eighteen; and

19 (3) Proof of appropriate quality testing from an
20 independent testing laboratory in the form of a
21 certificate of analysis representing the product does



1 not contain levels of residual solvents, biological
2 contaminants or heavy metal contaminants that violates
3 the standard for dietary supplement products.

4 **§328-H Federal preemption.** If at any time on or after the
5 effective date of this part, the federal government or any
6 department or agency thereof, including but not limited to the
7 federal Drug Enforcement Administration or United States Food
8 and Drug Administration, regulates 7-hydroxymitragynine, 7-
9 hydroxymitragynine extracts, 7-hydroxymitragynine products, any
10 other derivative of the plant *Mitragyna speciosa*, 7-
11 hydroxymitragynine processors, or 7-hydroxymitragynine
12 retailers, including the acceptance by the United States Food
13 and Drug Administration of a new dietary ingredient
14 notification, those federal regulations shall supersede and take
15 precedence over any provision of this part and any
16 administrative regulation promulgated thereunder to the contrary
17 that is addressed by the federal action."

18 SECTION 2. In codifying the new sections added by section
19 1 of this Act, the revisor of statutes shall substitute
20 appropriate section numbers for the letters used in designating
21 the new sections in this Act.

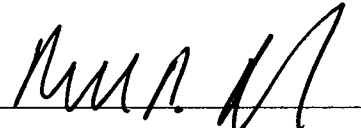


1 SECTION 3. This Act does not affect rights and duties that
2 matured, penalties that were incurred, and proceedings that were
3 begun before its effective date.

4 SECTION 4. This Act shall take effect on January 1, 2026.

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INTRODUCED BY:



By Request



S.B. NO. 463

Report Title:

Hawaii Kratom Consumer Protection Act; Kratom Products;
Registration

Description:

Beginning 1/1/2026, requires kratom products to be registered with the Department of Health and imposes labeling requirements.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.

