

1 H.416

2 Introduced by Representatives Headrick of Burlington and Gregoire of
3 Fairfield

4 Referred to Committee on

5 Date:

6 Subject: Health; labeling of food, drugs, cosmetics, and hazardous substances;
7 kratom

8 Statement of purpose of bill as introduced: This bill proposes to require the
9 Department of Health to develop and maintain a registry for kratom products
10 prepared, manufactured, sold, distributed, or maintained in the State. It further
11 proposes labeling requirements for kratom products prepared, sold, delivered,
12 or maintained in the State and enforcement standards for violations of the
13 proposed provisions.

14 An act relating to the regulation of kratom products

15 It is hereby enacted by the General Assembly of the State of Vermont:

16 Sec. 1. SHORT TITLE

17 This act may be cited as the “Kratom Consumer Protection Act.”

18 Sec. 2. 18 V.S.A. chapter 82, subchapter 3 is added to read:

19 Subchapter 3. Kratom Consumer Protection Act

1 § 4091. DEFINITIONS

2 As used in this subchapter:

3 (1) “Attractive to children” means the preparation, manufacturing, or
4 packaging of a kratom product in a manner that bears any reasonable
5 resemblance to an existing candy product or branded food product so as to be
6 easily mistaken for the candy product or the branded product, especially by
7 children.

8 (2) “Department” means the Department of Health.

9 (3) “Distributor” means a person that sells, distributes, or maintains
10 kratom products in the State or a person who advertises, represents, or holds
11 themselves out as selling, distributing, or maintaining kratom products in the
12 State.

13 (4) “Extract” means a substance or compound obtained by extraction of
14 the leaf of the plant *Mitragyna speciosa*, intended for ingestion, which contains
15 more than trace amounts of *Mitragyna speciosa* and other alkaloids of the plant
16 and does not contain any controlled substances or levels of residual solvents
17 higher than permitted by the U.S. Pharmacopeia 467.

18 (5) “Independent laboratory testing” means a laboratory that is
19 accredited by a third-party accrediting body as a competent testing laboratory
20 pursuant to ISO/IEC 17025 of the International Organization for
21 Standardization.

1 (6) “Kratom” means the plant Mitragyna speciosa or any part of the
2 plant.

3 (7) “Kratom food service establishment” means a food service
4 establishment licensed pursuant to chapter 85 of this title that sells or
5 distributes:

6 (A) kratom as a beverage prepared on-site; or

7 (B) a prepackaged kratom beverage or finished kratom product.

8 (8) “Kratom product” or “product” means a finished article containing
9 any part of the leaf of the plant Mitragyna speciosa in fresh, dehydrated, or
10 dried form, or a kratom extract.

11 (9) “Processor” means a person who prepares, manufactures, sells, or
12 maintains kratom products in the State or a person who advertises, represents,
13 or holds themselves out as preparing, manufacturing, selling, or maintaining
14 kratom products in the State.

15 (10) “Retailer” means a person who sells, distributes, advertises, or
16 represents kratom products or a person who holds themself out as selling,
17 distributing, advertising, or representing kratom products.

18 (11) “Synthesized material” means an alkaloid, metabolite, or alkaloid
19 derivative that has been created by chemical synthesis or biosynthetic means,
20 including fermentation, recombinant techniques, yeast-derived, and enzymatic
21 techniques, rather than traditional food preparation techniques, such as heating

1 or extracting, that synthetically alters the composition of any kratom alkaloid
2 or constituent.

3 § 4092. KRATOM PRODUCT PROHIBITIONS

4 A processor or distributor shall not prepare, manufacture, sell, offer for sale,
5 distribute, or maintain in the State any kratom product that:

6 (1) contains or is adulterated with a dangerous non-kratom substance,
7 including a poisonous or otherwise deleterious non-kratom ingredient or
8 substance listed as a controlled substance under State or federal law;

9 (2) is mixed with another compound that is known to inhibit key
10 cytochrome P450 enzymes, including CYP3A4 or CYP2D6, or both, unless a
11 specific mixture is scientifically validated safe under the intended conditions of
12 use and are permitted by the Department by rule;

13 (3) is a kratom extract product that contains levels of residual solvents
14 exceeding those allowed in the U.S. Pharmacopeia;

15 (4) contains synthesized material;

16 (5) is in a form that is combustible, intended to be used for vaporization,
17 or injectable;

18 (6) is prepared, manufactured, or packaged in a manner that is attractive
19 to children; and

20 (7) is not registered on the Department's registry pursuant to section
21 4093 of this subchapter.

1 § 4093. KRATOM PRODUCT REGISTRATION

2 (a) A processor or distributor shall register annually with the Department
3 any kratom product that is in an approved kratom delivery form intended to be
4 offered for sale or distributed to a consumer in the State. The registering
5 processor or distributor shall pay a fee to the Department, subject to annual
6 adjustment, to cover all administrative costs for processing and administering
7 registrations and developing and maintaining a kratom product registry web
8 page on the Department’s website. The processor or distributor’s registration
9 application shall include:

10 (1) sworn assurances from the processor or distributor that any facility
11 in which the kratom product was prepared, manufactured, or maintained has a
12 valid food facility registration with the U.S. Food and Drug Administration;

13 (2) evidence demonstrating that the processor or distributor has a
14 reasonable basis for believing the kratom product is safe for consumption
15 under the conditions of use set forth on the product’s label;

16 (3) a certificate of analysis from an independent testing laboratory
17 showing compliance with the requirements for kratom products in accordance
18 with this subchapter; and

19 (4) sworn assurances that the processor or distributor has a reasonable
20 basis for believing the kratom product complies with the prohibitions listed in
21 section 4092 of this title.

1 (b) A kratom product containing the same kratom ingredients in the same
2 approved kratom delivery form, but in a different container, package, or
3 volume, shall be included in a single registration.

4 (c) The Department shall publish and maintain a kratom registry page on its
5 website listing all kratom products currently registered for sale in the State to
6 enable retailers to verify whether a kratom product is permissible for sale or
7 distribution to consumers.

8 § 4094. KRATOM PRODUCT LABELING

9 (a) Unless otherwise preempted under federal law, a kratom product
10 prepared, manufactured, sold, delivered, offered for sale, or maintained in the
11 State shall bear a conspicuous label on the packaging with the following:

12 (1) a recommendation against the use of the kratom product by
13 individuals under 21 years of age or who are pregnant or breastfeeding;

14 (2) a recommendation that an individual consult with a health care
15 professional prior to use;

16 (3) a statement that kratom may be habit forming;

17 (4) a statement in accordance with 21 C.F.R. § 101.93 that “These
18 statements have not been evaluated by the Food and Drug Administration.

19 This product is not intended to diagnose, treat, cure, or prevent disease.”;

20 (5) the name and place of business of the processor or distributor
21 registering the kratom product; and

1 (6) instructions for use of the kratom product, including;

2 (A) the recommended amount of the kratom product per serving for
3 the specific approved product form, including capsules, gummies, beverages,
4 liquids, and loose powders;

5 (B) the recommended number of servings that can be safely
6 consumed in a 24-hour period;

7 (C) a listing of servings per container; and

8 (D) a listing of kratom alkaloids and other ingredients in the product,
9 including quantities not to exceed declarations of the amount per serving for
10 Mitragynine speciosa and 7-hydroxymitragynine.

11 (b) A kratom food service establishment serving kratom as a beverage
12 prepared on-site shall provide the information listed in subsection (a) of this
13 section to the customer by supplying a written document directly to the
14 customer or by prominently displaying the information near the point of sale
15 device.

16 (c) A kratom product containing a level of 7-hydroxymitragynine greater
17 than the two percent limit shall not be marketed or labeled on its packaging as
18 a kratom product or as a derivative of the alkaloid Mitragynine.

19 § 4095. ENFORCEMENT

20 (a)(1) No person shall knowingly sell, distribute, offer for sale, hold for
21 sale, or give away a kratom product that is not registered with the Department.

1 (2) A person who violates this subsection shall:

2 (A) be fined not more than \$5,000.00 for each unregistered product;

3 (B) be fined not more than \$10,000.00 for a second or subsequent
4 violation relating to the same product; and

5 (C) be prohibited from selling a kratom product for a period of two
6 years for a third or subsequent violation relating to the same product.

7 (b)(1) No person shall knowingly sell kratom product intended for human
8 ingestion to an individual 21 years of age or younger.

9 (2) A person who violates this subsection shall:

10 (A) be imprisoned not more than one year or fined not more than
11 \$1,000.00, or both, for a first offense; or

12 (B) be imprisoned not more than two years or fined not more than
13 \$2,000.00, or both, for a second or subsequent offense.

14 (c)(1) No person shall knowingly prepare, sell, deliver, offer for sale, hold
15 for sale, or give away a kratom product that contains a controlled substance
16 under the Controlled Substances Act, 21 U.S.C. §§ 801–904, or a regulated
17 drug as defined in section 4201 of this title.

18 (2) A person who knowingly violates this subsection shall be
19 imprisoned not more than three years or fined not more than \$3,000.00, or
20 both. These penalties shall be in addition to any other provision in law.

1 (d)(1) No person shall knowingly prepare, sell, deliver, offer for sale, hold
2 for sale, or give away a kratom product that contains synthetic mitragynine,
3 synthetic 7-hydroxymitragynine, or any other synthetically derived compound
4 of the plant Mitragyna speciosa.

5 (2) A person who knowingly violates this subsection shall be
6 imprisoned not more than two years or fined not more than \$2,000.00, or both.
7 These penalties shall be in addition to any other provision in law.

8 (e) Upon receipt of a report of an alleged violation regarding any kratom
9 product offered for sale, the Department shall require the registrant to produce
10 an updated and current certificate of analysis in a reasonable time frame from a
11 certified independent third-party laboratory showing compliance with the
12 requirements of this subchapter for safe kratom products and include copies of
13 all product labels. If the registrant does not provide the certificate of analysis
14 in the specified time frame, the registration for that product shall be revoked
15 and a stop sales order will be issued for products covered by this registration.

16 (f) If the Department has a reasonable basis to require an independent third-
17 party test of a registered kratom product by a laboratory of the Department's
18 choice, the registrant shall be required to submit payment to the Department
19 for the test within a reasonable time frame. If the registrant does not tender
20 payment to the Department within 30 days following receipt of the invoice for

1 the testing, the Department shall revoke the registration for that product and a
2 stop sales order will be issued for products covered by this registration.

3 (g) A retailer that relied in good faith upon the representations of a
4 processor or distributor of a kratom product shall not be in violation of this
5 section.

6 § 4096. RULEMAKING

7 The Department shall adopt rules pursuant to 3 V.S.A. chapter 25 for the
8 implementation of this subchapter, including:

9 (1) a process registering a kratom product by a processor or distributor;

10 (2) approved kratom product delivery forms;

11 (3) approved extraction methods used in the preparation or
12 manufacturing of kratom products; and

13 (4) contents of a certificate of analysis from an ISO 17025 laboratory
14 representing the product does not contain levels of residual solvents, biological
15 contaminants, or heavy metal contaminants that meet the standard for dietary
16 supplement products.

17 Sec. 3. EFFECTIVE DATE

18 This act shall take effect on July 1, 2025.