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S.128

Introduced by Senators Vyhovsky, Gulick, White and Wrenner

Referred to Committee on

Date:

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

Statement of purpose of bill as introduced: This bill proposes to regulate
kratom products for labeling consumable products for marketing and sale and
to establish an age requirement for the purchase of kratom products.

An act relating to the regulation of kratom products

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

Sec. 1. SHORT TITLE

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

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

Subchapter 3. Kratom Consumer Protection Act

§ 4091. DEFINITIONS

As used in this subchapter:

(1) “Dangerous non-kratom substance” means a substance that has been
determined to be an imminent hazard to the public health, safety, and welfare.

1 (2) “Food” means a food, food product, food ingredient, dietary
2 ingredient, dietary supplement, or beverage for human consumption.

3 (3) “Kratom” means any parts of the plant Mitragyna speciosa, whether
4 growing or not, and any compound, manufacture, salt, derivative, mixture, or
5 preparation of the plant, including mitragynine and the metabolite 7-
6 hydroxymitragynine.

7 (4) “Kratom extract” means a food product or dietary ingredient
8 containing any part of the leaf of the plant Mitragyna speciosa that has been
9 extracted in order to provide standardized dosing.

10 (5) “Kratom product” means a food product or dietary ingredient
11 containing any part of the leaf of the plant Mitragyna speciosa.

12 (6) “Processor” means a person who sells, prepares, manufactures,
13 distributes, or maintains kratom products, or advertises, represents, or holds
14 itself out as selling, preparing, or maintaining kratom products.

15 (7) “Retailer” means a person that sells, distributes, advertises,
16 represents, or holds itself out as selling or maintaining kratom products.

17 § 4092. AGE REQUIREMENT

18 (a) No person shall sell a kratom product to a person under 18 years of age.

19 (b) A violation of this section shall be subject to the penalties in section
20 4054 of this chapter.

1 § 4093. KRATOM PRODUCT LIMITATIONS

2 (a) A kratom product shall include on its package or label the amount of
3 mitragynine and 7-hydroxymitragynine contained in the product.

4 (b) A processor shall not sell, deliver, offer for sale, hold for sale, or give
5 away any of the following:

6 (1) A kratom product that is adulterated with a dangerous non-kratom
7 substance. A kratom product is adulterated with a dangerous non-kratom
8 substance if the kratom product is mixed or packed with a non-kratom
9 substance and that substance affects the quality or strength of the kratom
10 product to such a degree as to render the kratom product injurious to a
11 consumer.

12 (2) A kratom product that is contaminated with a dangerous non-kratom
13 substance. A kratom product is contaminated with a dangerous non-kratom
14 substance if the kratom product contains a poisonous or otherwise deleterious
15 non-kratom ingredient, including the substances listed in the State's controlled
16 substance list.

17 (3) A kratom extract that contains levels of residual solvents higher than
18 is allowed in the U.S. Pharmacopeia chapter 467.

19 (4) A kratom product containing a level of 7-hydroxymitragynine in the
20 alkaloid fraction that is greater than one percent of the overall alkaloid
21 composition of the product.

1 (5) A kratom product containing any synthetic alkaloids including
2 synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other
3 synthetically derived compounds of the kratom plant.

4 (6) A kratom product that does not provide adequate labeling directions
5 necessary for safe use by consumers, including a recommended serving size,
6 the recommended number of servings per day, and the number of servings that
7 is in the package.

8 (c) A violation of this section shall be subject to the penalties in section
9 4054 of this chapter.

10 § 4094. KRATOM PRODUCT REGISTRATION

11 (a) A processor shall register annually any kratom product intended to be
12 offered for sale to a consumer that is in an approved kratom delivery form and
13 pay a fee, subject to annual adjustment, to cover all administrative costs for
14 processing and administering such registrations. The registration shall include
15 a certificate of analysis (COA) from a certified independent third-party
16 laboratory showing compliance with the requirements for kratom products in
17 this subchapter.

18 (b) Upon receipt of noncompliance with the provisions of this subchapter,
19 the Department shall require the processor to produce a current COA within
20 45 days following a certified independent third-party laboratory showing
21 compliance with this subchapter. If the processor does not provide the COA in

1 the specified time frame, the Department shall revoke the registration for that
2 product.

3 (c) Upon receipt of notification of any adverse event related to a registered
4 kratom product, the processor shall be required to submit to the Department via
5 certified mail a copy of the processor's adverse event report that is required to
6 be submitted to the U.S. Food and Drug Administration as outlined in the
7 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 379aa-1. The Department
8 shall revoke a product's registration if the processor fails to report an adverse
9 event as required by this section.

10 (d) If the Department has a reasonable basis to require an independent
11 third-party test of a registered kratom product by a laboratory of the
12 Department's choice, the processor shall submit a payment to the Department
13 for the test within 45 days. If the processor does not tender payment to the
14 Department within 45 days following receipt of the invoice for testing, the
15 Department shall revoke the registration for that product.

16 (e) The Department may adopt rules in accordance with this subchapter.
17 § 4095. ADMINISTRATIVE PENALTY

18 (a) A processor who violates this chapter shall be subject to an
19 administrative penalty of not more than \$500.00 for the first violation, and of
20 not more than \$1,000.00 for a second violation. If the Commissioner
21 determines that a violation is continuing, each day's continuance may be

1 deemed a separate violation beginning on the date the violator is served with
2 notice of the violation.

3 (b) The Department may use the enforcement powers as set forth in chapter
4 3 of this title to enforce any violations of this chapter or of any related rules,
5 permits, or orders issued.

6 (c) A retailer who relies in good faith upon the representations of a
7 manufacturer, processor, packer, or distributor of food represented to be a
8 kratom product shall not be found in violation of this subchapter.

9 Sec. 3. 18 V.S.A. § 4201 is amended to read:

10 § 4201. DEFINITIONS

11 (a) As used in this chapter, unless the context otherwise requires:

12 * * *

13 (29)~~(A)~~ “Regulated drug” means:

14 ~~(A)~~(i) a narcotic drug;

15 ~~(B)~~(ii) a depressant or stimulant drug, other than methamphetamine;

16 ~~(C)~~(iii) a hallucinogenic drug;

17 ~~(D)~~(iv) Ecstasy;

18 ~~(E)~~(v) cannabis; or

19 ~~(F)~~(vi) methamphetamine.

20 (B) “Regulated drug” does not mean any parts of the plant *Mitragyna*
21 *speciosa*, whether growing or not, and any compound, manufacture, salt,

1 derivative, mixture, or preparation of the plant, including but not limited to
2 mitragynine and the metabolite 7-hydroxymitragynine.

3 * * *

4 Sec. 4. EFFECTIVE DATE

5 This act shall take effect on July 1, 2023