## First Regular Session Seventy-fifth General Assembly STATE OF COLORADO

# **INTRODUCED**

LLS NO. 25-0580.02 Christy Chase x2008

SENATE BILL 25-072

SENATE SPONSORSHIP

Mullica and Pelton B.,

### **HOUSE SPONSORSHIP**

Lindsay and Soper,

Senate Committees Finance **House Committees** 

## A BILL FOR AN ACT

### 101 **CONCERNING THE REGULATION OF KRATOM.**

#### **Bill Summary**

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <u>http://leg.colorado.gov.</u>)

Section 1 of the bill repeals certain provisions regarding the regulation of kratom that are included in sections 2 and 3 with amendments.

Section 2 prohibits a processor from manufacturing, packaging, labeling, or distributing in the state a food or dietary supplement that consists of kratom leaf or kratom leaf extract (kratom product) unless the manufacturer of the kratom product has obtained a registration of the kratom product (registration) from the executive director of the department of revenue (executive director). The manufacturer must pay a fee and provide proof of certain certificates and a registration from the federal food and drug administration to receive a registration for the kratom product from the executive director.

The executive director is required to establish an annual fee paid by manufacturers of kratom products that are manufactured, packaged, labeled, or distributed in the state. The fees are credited to the kratom consumer protection cash fund, which is created in **section 2** and may be used by the executive director for the administration and enforcement of state laws regulating kratom.

A manufacturer of a kratom product that is manufactured, packaged, labeled, or distributed in the state without a registration is subject to a civil penalty of:

- No more than \$1,000 for the first violation;
- No more than \$5,000 for the second violation; and
- At least \$5,000 and no more than \$20,000 for a third or subsequent violation.

In the event of a third or subsequent violation, the manufacturer is prohibited from manufacturing or distributing kratom products in the state for 3 years after the date the civil penalty is assessed.

**Section 3** prohibits a person from:

- Knowingly preparing, distributing, advertising, selling, or offering to sell a kratom product under certain circumstances;
- Preparing, distributing, advertising, selling, or offering to sell a kratom product that does not clearly and conspicuously set forth certain information on the kratom product's label;
- Displaying or storing kratom products in a retail location in a manner that will allow the products to be accessed by individuals under 21 years of age; or
- Manufacturing, packaging, labeling, or distributing a kratom product that contains synthesized or semi-synthesized kratom alkaloids or has a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 2% of the alkaloid composition of the product.

A person that conducts these prohibited activities engages in a deceptive trade practice.

1 Be it enacted by the General Assembly of the State of Colorado:

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- **SECTION 1.** In Colorado Revised Statutes, repeal 44-1-105.
- 3 SECTION 2. In Colorado Revised Statutes, add article 15 to title

1 44 as follows:

2 **ARTICLE 15** 3 **Kratom Regulation** 4 **44-15-101. Definitions.** As used in this article 15, unless the 5 CONTEXT OTHERWISE REQUIRES: 6 (1) "ADULTERATED" MEANS THE ADDITION OF FENTANYL OR ANY 7 OTHER CONTROLLED SUBSTANCE, A SYNTHESIZED ALKALOID OR 8 SEMI-SYNTHESIZED ALKALOID, OR ANOTHER SUBSTANCE PROHIBITED BY 9 LAW. 10 (2) "ALKALOID FRACTION" MEANS A PORTION OF A PLANT OR 11 PLANT EXTRACT THAT CONTAINS PRIMARILY ALKALOID COMPOUNDS. 12 (3) "CONTROLLED SUBSTANCE" MEANS A SUBSTANCE LISTED IN 13 PART 2 OF ARTICLE 18 OF TITLE 18. 14 (4) "FUND" MEANS THE KRATOM CONSUMER PROTECTION CASH 15 FUND CREATED IN SECTION 44-15-103 (2). 16 (5) "INDEPENDENT LABORATORY" MEANS A LABORATORY THAT IS 17 ACCREDITED UNDER THE STANDARDS OF THE INTERNATIONAL 18 ORGANIZATION FOR STANDARDIZATION 17025.2017 ACCREDITATION OR 19 FROM AN ACCREDITATION BODY THAT IS A SIGNATORY TO THE 20 INTERNATIONAL LABORATORY ACCREDITATION COOPERATION MUTUAL 21 **RECOGNITION ARRANGEMENT.** 22 (6) "KRATOM LEAF" MEANS THE LEAF OF THE MITRAGYNA 23 SPECIOSA PLANT, IN FRESH OR DEHYDRATED FORM, THAT IS SUBJECT TO NO 24 POSTHARVEST PROCESSING OTHER THAN: 25 (a) DRYING OR SIZE REDUCTION BY CUTTING, MILLING, OR OTHER 26 SIMILAR PROCEDURE; OR 27 (b) CLEANING OR STERILIZATION THROUGH THE APPLICATION OF

-3-

HEAT, STEAM, PRESSURIZATION, IRRADIATION, OR OTHER STANDARD
 TREATMENT APPLIED TO A FOOD INGREDIENT.

3 (7) "KRATOM LEAF EXTRACT" MEANS THE MATERIAL EXTRACTED
4 FROM A KRATOM LEAF THROUGH THE APPLICATION OF A SOLVENT
5 CONSISTING OF WATER, ETHANOL, FOOD-GRADE CARBON DIOXIDE, OR
6 ANOTHER SOLVENT ALLOWED BY FEDERAL OR STATE LAW TO BE USED IN
7 THE MANUFACTURING OF A FOOD INGREDIENT.

8 (8) "KRATOM PRODUCT" MEANS A FOOD OR DIETARY SUPPLEMENT 9 THAT CONSISTS OF, OR CONTAINS, KRATOM LEAF OR KRATOM LEAF 10 EXTRACT AND DOES NOT INCLUDE ANY SYNTHESIZED ALKALOIDS OR 11 SEMI-SYNTHESIZED ALKALOIDS.

12 (9) "PROCESSOR" MEANS A PERSON THAT MANUFACTURES,
13 PACKAGES, LABELS, OR DISTRIBUTES KRATOM PRODUCTS OR ADVERTISES
14 OR REPRESENTS ITSELF AS A MANUFACTURER, PACKAGER, LABELER, OR
15 DISTRIBUTOR OF KRATOM PRODUCTS.

16 (10) "SEMI-SYNTHESIZED ALKALOID" MEANS AN ALKALOID OR
17 ALKALOID DERIVATIVE CONTAINED IN A KRATOM LEAF EXTRACT THAT HAS
18 BEEN EXPOSED TO CHEMICALS OR PROCESSES THAT WOULD CONFER A
19 STRUCTURAL CHANGE IN THE ALKALOIDS, SUCH AS OXIDATION,
20 REDUCTION, AND RING OPENING AND CLOSING, RESULTING IN MATERIAL
21 THAT HAS BEEN CHEMICALLY ALTERED.

(11) "SYNTHESIZED ALKALOID" MEANS AN ALKALOID OR
ALKALOID DERIVATIVE OF THE KRATOM LEAF THAT HAS BEEN CREATED BY
CHEMICAL SYNTHESIS OR BIOSYNTHETIC MEANS, INCLUDING
FERMENTATION, RECOMBINANT TECHNIQUES, YEAST-DERIVED
TECHNIQUES, AND ENZYMATIC TECHNIQUES, RATHER THAN BY
TRADITIONAL FOOD PREPARATION TECHNIQUES SUCH AS HEATING OR

-4-

1 EXTRACTING.

44-15-102. Registration - suspension or revocation. (1) A
PROCESSOR SHALL NOT MANUFACTURE, PACKAGE, LABEL, OR DISTRIBUTE
A KRATOM PRODUCT IN THE STATE UNLESS THE MANUFACTURER OF THE
KRATOM PRODUCT HAS OBTAINED A REGISTRATION OF THE KRATOM
PRODUCT FROM THE EXECUTIVE DIRECTOR. A REGISTRATION IS VALID FOR
ONE YEAR FROM THE DATE OF ISSUANCE BY THE EXECUTIVE DIRECTOR AND
IS NONTRANSFERABLE.

9 (2) THE EXECUTIVE DIRECTOR SHALL NOT ISSUE A REGISTRATION 10 FOR A KRATOM PRODUCT UNLESS THE MANUFACTURER PAYS THE FEE 11 DESCRIBED IN SECTION 44-15-103 AND PROVIDES TO THE EXECUTIVE 12 DIRECTOR:

(a) PROOF OF A CURRENT GOOD MANUFACTURING PRACTICES
CERTIFICATE FROM THE AMERICAN NATIONAL STANDARDS INSTITUTE
(ANSI), OR ITS SUCCESSOR ORGANIZATION, FOR ANY FACILITY THAT
MANUFACTURES THE KRATOM PRODUCT;

17 (b) PROOF OF A CURRENT FOOD FACILITY REGISTRATION FROM THE
18 FEDERAL FOOD AND DRUG ADMINISTRATION FOR ANY FACILITY THAT
19 MANUFACTURES, PACKAGES, LABELS, OR DISTRIBUTES THE KRATOM
20 PRODUCT;

21 (c) A COPY OF THE KRATOM PRODUCT'S LABEL TO DEMONSTRATE
 22 COMPLIANCE WITH SECTION 6-1-737 (2)(b); AND

(d) PROOF OF A CERTIFICATE OF ANALYSIS FROM AN INDEPENDENT
LABORATORY CONFIRMING THE ALKALOID CONTENT OF THE KRATOM
PRODUCT, WHICH CERTIFICATE OF ANALYSIS MUST CONFIRM THAT:

26 (I) THE KRATOM PRODUCT HAS A LEVEL OF 27 7-HYDROXYMITRAGYNINE IN THE ALKALOID FRACTION THAT IS TWO

-5-

PERCENT OR LESS OF THE ALKALOID COMPOSITION OF THE KRATOM
 PRODUCT; AND

3 (II) THERE ARE NO SYNTHESIZED ALKALOIDS OR
4 SEMI-SYNTHESIZED ALKALOIDS IN THE KRATOM PRODUCT.

5 (3) IF THE EXECUTIVE DIRECTOR RECEIVES EVIDENCE THAT A 6 KRATOM PRODUCT REGISTERED PURSUANT TO THIS SECTION MAY BE 7 ADULTERATED IN VIOLATION OF SECTION 6-1-737 (2)(a)(I), THE 8 EXECUTIVE DIRECTOR MAY REQUIRE A THIRD-PARTY TEST OF THE KRATOM 9 PRODUCT BY AN INDEPENDENT LABORATORY CHOSEN BY THE EXECUTIVE 10 DIRECTOR.

11 (4) (a) THE EXECUTIVE DIRECTOR MAY SUSPEND OR REVOKE A
12 REGISTRATION ISSUED PURSUANT TO THIS SECTION IN THE EVENT OF A
13 VIOLATION OF:

14 (I) This section or the rules adopted pursuant to this15 section; or

16 (II) SECTION 6-1-737.

17 (b) A MANUFACTURER THAT REGISTERS A KRATOM PRODUCT 18 PURSUANT TO THIS SECTION IS RESPONSIBLE FOR THE DIRECT COSTS 19 ASSOCIATED WITH A THIRD-PARTY TEST DESCRIBED IN SUBSECTION (3) OF 20 THIS SECTION OR ENFORCEMENT ACTION RELATED TO THE KRATOM 21 PRODUCT IF THE THIRD-PARTY TEST OR ENFORCEMENT ACTION LEADS TO 22 THE SUSPENSION OR REVOCATION OF THE KRATOM PRODUCT'S 23 REGISTRATION OR THE ASSESSMENT OF A CIVIL PENALTY PURSUANT TO 24 SECTION 44-15-104.

44-15-103. Annual fee - cash fund. (1) The executive
Director shall establish an annual fee paid by a manufacturer
OF A KRATOM PRODUCT THAT IS MANUFACTURED, PACKAGED, LABELED,

-6-

OR DISTRIBUTED IN THE STATE. THE STATE TREASURER SHALL CREDIT THE
 ANNUAL FEES TO THE FUND.

3 (2) (a) THE KRATOM CONSUMER PROTECTION CASH FUND IS
4 CREATED IN THE STATE TREASURY. THE FUND CONSISTS OF ANNUAL FEES
5 CREDITED TO THE FUND PURSUANT TO SUBSECTION (1) OF THIS SECTION,
6 CIVIL PENALTIES CREDITED TO THE FUND PURSUANT TO SECTION 44-15-104
7 (3), AND ANY OTHER MONEY THAT THE GENERAL ASSEMBLY MAY
8 APPROPRIATE OR TRANSFER TO THE FUND.

9 (b) THE STATE TREASURER SHALL CREDIT ALL INTEREST AND
10 INCOME DERIVED FROM THE DEPOSIT AND INVESTMENT OF MONEY IN THE
11 FUND TO THE FUND.

12 (c) SUBJECT TO ANNUAL APPROPRIATION BY THE GENERAL
13 ASSEMBLY, THE EXECUTIVE DIRECTOR MAY EXPEND MONEY FROM THE
14 FUND FOR THE ADMINISTRATION AND ENFORCEMENT OF THIS ARTICLE 15.

44-15-104. Civil penalty. (1) A MANUFACTURER OF A KRATOM
PRODUCT THAT IS MANUFACTURED, PACKAGED, LABELED, OR DISTRIBUTED
IN THE STATE WITHOUT A REGISTRATION ISSUED PURSUANT TO SECTION
44-15-102 (1) IS SUBJECT TO A CIVIL PENALTY OF:

19 (a) NO MORE THAN ONE THOUSAND DOLLARS FOR THE FIRST20 VIOLATION;

(b) NO MORE THAN FIVE THOUSAND DOLLARS FOR THE SECONDVIOLATION; AND

(c) AT LEAST FIVE THOUSAND DOLLARS AND NO MORE THAN
TWENTY THOUSAND DOLLARS FOR A THIRD OR SUBSEQUENT VIOLATION.
(2) IN THE EVENT OF A THIRD OR SUBSEQUENT VIOLATION, THE

26 MANUFACTURER IS PROHIBITED FROM MANUFACTURING OR DISTRIBUTING

27 KRATOM PRODUCTS IN THE STATE FOR THREE YEARS AFTER THE DATE THE

-7-

1 CIVIL PENALTY IS ASSESSED.

2 (3) THE STATE TREASURER SHALL CREDIT THE CIVIL PENALTIES TO
3 THE FUND.

4 44-15-105. Compliance with federal law - rules. (1) A KRATOM 5 PRODUCT SOLD, OFFERED FOR SALE, OR INTRODUCED INTO COMMERCE IN 6 THE STATE MUST BE MANUFACTURED, PACKAGED, LABELED, AND 7 DISTRIBUTED IN COMPLIANCE WITH 21 CFR 111, AS THAT PART EXISTED 8 ON JULY 1, 2025, OR AS UPDATED BY THE EXECUTIVE DIRECTOR BY RULE. 9 (2) A PROCESSOR SHALL HOLD A CURRENT FOOD FACILITY 10 REGISTRATION FROM THE FEDERAL FOOD AND DRUG ADMINISTRATION. 11 44-15-106. Rules. THE EXECUTIVE DIRECTOR MAY ADOPT RULES 12 THAT ARE NECESSARY FOR THE ADMINISTRATION AND ENFORCEMENT OF 13 THIS ARTICLE 15. 14 **SECTION 3.** In Colorado Revised Statutes, add 6-1-737 as 15 follows: 16 6-1-737. Kratom - deceptive trade practice - definitions. 17 (1) UNLESS THE CONTEXT OTHERWISE REQUIRES, THE DEFINITIONS IN 18 SECTION 44-15-101 APPLY TO THIS SECTION. 19 (2) A PERSON SHALL NOT: 20 (a) KNOWINGLY PREPARE, DISTRIBUTE, ADVERTISE, SELL, OR OFFER 21 TO SELL A KRATOM PRODUCT: 22 (I) THAT IS ADULTERATED; 23 (II) TO A PERSON UNDER TWENTY-ONE YEARS OF AGE; 24 (III) THAT CONTAINS A LEVEL OF 7-HYDROXYMITRAGYNINE IN THE 25 ALKALOID FRACTION THAT IS GREATER THAN TWO PERCENT OF THE 26 ALKALOID COMPOSITION OF THE KRATOM PRODUCT; 27 (IV) THAT IS A CONFECTION; MIMICS A CANDY PRODUCT; OR IS

-8-

1	MANUFACTURED, PACKAGED, LABELED, OR DISTRIBUTED IN A WAY THAT
2	IS APPEALING TO CHILDREN, INCLUDING IN THE DISTINCT SHAPE OF A
3	HUMAN, AN ANIMAL, OR FRUIT; OR
4	(V) THAT IS COMBUSTIBLE OR INTENDED FOR VAPORIZATION;
5	(b) PREPARE, DISTRIBUTE, ADVERTISE, SELL, OR OFFER TO SELL A
6	KRATOM PRODUCT THAT DOES NOT HAVE A LABEL THAT CLEARLY AND
7	CONSPICUOUSLY SETS FORTH ON EACH RETAIL PACKAGE:
8	(I) The identity and address of any processor involved in
9	MANUFACTURING, PACKAGING, LABELING, OR DISTRIBUTING THE KRATOM
10	PRODUCT;
11	(II) THE FULL LIST OF INGREDIENTS IN THE KRATOM PRODUCT;
12	(III) A RECOMMENDATION:
13	(A) AGAINST USE BY INDIVIDUALS WHO ARE UNDER TWENTY-ONE
14	YEARS OF AGE, PREGNANT, OR BREASTFEEDING; AND
15	(B) TO CONSULT A HEALTH-CARE PROFESSIONAL PRIOR TO USE;
16	(IV) AN ADVISEMENT THAT KRATOM MAY:
17	(A) BE HABIT FORMING; AND
18	(B) INTERACT WITH CERTAIN MEDICATIONS;
19	(V) The following statement: "These statements have not
20	BEEN EVALUATED BY THE UNITED STATES FOOD AND DRUG
21	ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT,
22	CURE, OR PREVENT ANY DISEASE."; AND
23	(VI) DIRECTIONS FOR USE THAT INCLUDE:
24	(A) A RECOMMENDED AMOUNT OF THE KRATOM PRODUCT PER
25	SERVING;
26	(B) A RECOMMENDED NUMBER OF SERVINGS OF THE KRATOM
27	PRODUCT THAT CAN BE SAFELY CONSUMED IN A TWENTY-FOUR-HOUR

1 PERIOD; AND

2 (C) QUANTITATIVE DECLARATIONS OF THE AMOUNT OF
3 MITRAGYNINE AND THE AMOUNT OF 7-HYDROXYMITRAGYNINE PER
4 SERVING OF THE KRATOM PRODUCT;

- 5 (c) DISPLAY OR STORE KRATOM PRODUCTS IN A RETAIL LOCATION
  6 IN A MANNER THAT WILL ALLOW THE PRODUCTS TO BE ACCESSED BY
  7 INDIVIDUALS UNDER TWENTY-ONE YEARS OF AGE; OR
- 8 (d) MANUFACTURE, PACKAGE, LABEL, OR DISTRIBUTE A KRATOM
  9 PRODUCT THAT:
- 10 (I) CONTAINS SYNTHESIZED ALKALOIDS OR SEMI-SYNTHESIZED
  11 ALKALOIDS; OR
- (II) HAS A LEVEL OF 7-HYDROXYMITRAGYNINE IN THE ALKALOID
  FRACTION THAT IS GREATER THAN TWO PERCENT OF THE ALKALOID
  COMPOSITION OF THE PRODUCT.
- 15 (3) A PERSON THAT CONDUCTS THE ACTIVITIES DESCRIBED IN
  16 SUBSECTION (2) OF THIS SECTION ENGAGES IN A DECEPTIVE TRADE
  17 PRACTICE.
- 18 SECTION 4. In Colorado Revised Statutes, 18-13-132, amend
  19 (3) as follows:
- 18-13-132. Furnishing kratom products to persons under
  twenty-one years of age. (3) As used in this section, "kratom product"
  has the meaning set forth in section 44-1-105 (1) 44-15-101 (8).
- 23 SECTION 5. Applicability. This act applies to conduct occurring
  24 on or after the effective date of this act.
- 25 SECTION 6. Safety clause. The general assembly finds, 26 determines, and declares that this act is necessary for the immediate 27 preservation of the public peace, health, or safety or for appropriations for

- 1 the support and maintenance of the departments of the state and state
- 2 institutions.