First Regular Session Seventy-fifth General Assembly STATE OF COLORADO

PREAMENDED

This Unofficial Version Includes Committee Amendments Not Yet Adopted on Second Reading

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

House Committees

Finance Appropriations

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 http://leg.colorado.gov.)

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

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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

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1	HEAT, STE	AM,	PRESSURIZATION,	IRRADIATION,	OR	OTHER	STANDARD
2	TREATMEN	T AP	PLIED TO A FOOD II	NGREDIENT.			

- (7) "KRATOM LEAF EXTRACT" MEANS THE MATERIAL EXTRACTED

 FROM A KRATOM LEAF THROUGH THE APPLICATION OF A SOLVENT

 CONSISTING OF WATER, ETHANOL, FOOD-GRADE CARBON DIOXIDE, OR

 ANOTHER SOLVENT ALLOWED BY FEDERAL OR STATE LAW TO BE USED IN

 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.

- (9) "PROCESSOR" MEANS A PERSON THAT MANUFACTURES, PACKAGES, LABELS, OR DISTRIBUTES KRATOM PRODUCTS OR ADVERTISES OR REPRESENTS ITSELF AS A MANUFACTURER, PACKAGER, LABELER, OR DISTRIBUTOR OF KRATOM PRODUCTS.
- (10) "SEMI-SYNTHESIZED ALKALOID" MEANS AN ALKALOID OR ALKALOID DERIVATIVE CONTAINED IN A KRATOM LEAF EXTRACT THAT HAS BEEN EXPOSED TO CHEMICALS OR PROCESSES THAT WOULD CONFER A STRUCTURAL CHANGE IN THE ALKALOIDS, SUCH AS OXIDATION, REDUCTION, AND RING OPENING AND CLOSING, RESULTING IN MATERIAL 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

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1	EXTRACTING.
2	44-15-102. Registration - suspension or revocation. (1) $\underline{(a)}$ A
3	PROCESSOR SHALL NOT MANUFACTURE, PACKAGE, LABEL, OR DISTRIBUTE
4	A KRATOM PRODUCT IN THE STATE UNLESS THE MANUFACTURER OF THE
5	KRATOM PRODUCT HAS OBTAINED A REGISTRATION OF THE KRATOM
6	PRODUCT FROM THE EXECUTIVE DIRECTOR. \underline{A} MANUFACTURER MAY
7	INCLUDE IN AND OBTAIN A SINGLE REGISTRATION FOR MULTIPLE KRATOM
8	PRODUCTS THAT CONTAIN THE SAME KRATOM INGREDIENTS AND THAT ARE
9	IN THE SAME DELIVERY FORM BUT THAT ARE IN DIFFERENT CONTAINERS,
10	PACKAGES, OR VOLUMES.
11	(b) A REGISTRATION IS VALID FOR ONE YEAR FROM THE DATE OF
12	ISSUANCE BY THE EXECUTIVE DIRECTOR AND IS NONTRANSFERABLE.
13	(2) THE EXECUTIVE DIRECTOR SHALL NOT ISSUE A REGISTRATION
14	FOR A KRATOM PRODUCT UNLESS THE MANUFACTURER PAYS THE FEE
15	DESCRIBED IN SECTION 44-15-103 AND PROVIDES TO THE EXECUTIVE
16	DIRECTOR:
17	(a) Proof of a current good manufacturing practices
18	CERTIFICATE FROM AN AUDITOR ACCREDITED BY THE AMERICAN
19	NATIONAL STANDARDS INSTITUTE (ANSI), OR ITS SUCCESSOR
20	ORGANIZATION, FOR ANY FACILITY THAT MANUFACTURES THE KRATOM
21	PRODUCT;
22	(b) PROOF OF A CURRENT FOOD FACILITY REGISTRATION FROM THE
23	FEDERAL FOOD AND DRUG ADMINISTRATION FOR ANY FACILITY THAT
24	MANUFACTURES, PACKAGES, LABELS, OR DISTRIBUTES THE KRATOM
25	PRODUCT;
26	(c) A COPY OF THE KRATOM PRODUCT'S LABEL TO DEMONSTRATE
27	COMPLIANCE WITH SECTION 6-1-737 (2)(b); AND

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1	(d) PROOF OF A CERTIFICATE OF ANALYSIS FROM AN INDEPENDENT
2	LABORATORY CONFIRMING THE ALKALOID CONTENT OF THE KRATOM
3	PRODUCT, WHICH CERTIFICATE OF ANALYSIS MUST CONFIRM THAT:
4	(I) THE KRATOM PRODUCT HAS A LEVEL OF
5	7-HYDROXYMITRAGYNINE IN THE ALKALOID FRACTION THAT IS TWO
6	PERCENT OR LESS OF THE ALKALOID COMPOSITION OF THE KRATOM
7	PRODUCT; AND
8	(II) THERE ARE NO SYNTHESIZED ALKALOIDS OR
9	SEMI-SYNTHESIZED ALKALOIDS IN THE KRATOM PRODUCT.
10	(3) If the executive director receives evidence that a
11	KRATOM PRODUCT REGISTERED PURSUANT TO THIS SECTION MAY BE
12	ADULTERATED IN VIOLATION OF SECTION 6-1-737 (2)(a)(I), THE
13	EXECUTIVE DIRECTOR MAY REQUIRE A THIRD-PARTY TEST OF THE KRATOM
14	PRODUCT BY AN INDEPENDENT LABORATORY CHOSEN BY THE EXECUTIVE
15	DIRECTOR.
16	(4) (a) The executive director may suspend or revoke a
17	REGISTRATION ISSUED PURSUANT TO THIS SECTION IN THE EVENT OF A
18	VIOLATION OF:
19	(I) This section or the rules adopted pursuant to this
20	SECTION; OR
21	(II) SECTION 6-1-737.
22	(b) A MANUFACTURER THAT REGISTERS A KRATOM PRODUCT
23	PURSUANT TO THIS SECTION IS RESPONSIBLE FOR THE DIRECT COSTS
24	ASSOCIATED WITH A THIRD-PARTY TEST DESCRIBED IN SUBSECTION (3) OF
25	THIS SECTION OR ENFORCEMENT ACTION RELATED TO THE KRATOM
26	PRODUCT IF THE THIRD-PARTY TEST OR ENFORCEMENT ACTION LEADS TO
2.7	THE SUSPENSION OR REVOCATION OF THE KRATOM PRODUCT'S

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1	REGISTRATION OR THE ASSESSMENT OF A CIVIL PENALTY PURSUANT TO
2	SECTION 44-15-104.
3	44-15-103. Annual fee - cash fund. (1) THE EXECUTIVE
4	DIRECTOR SHALL ESTABLISH AN ANNUAL FEE PAID BY A MANUFACTURER
5	OF A KRATOM PRODUCT THAT IS MANUFACTURED, PACKAGED, LABELED,
6	OR DISTRIBUTED IN THE STATE. THE STATE TREASURER SHALL CREDIT THE
7	ANNUAL FEES TO THE FUND.
8	(2) (a) THE KRATOM CONSUMER PROTECTION CASH FUND IS
9	CREATED IN THE STATE TREASURY. THE FUND CONSISTS OF ANNUAL FEES
10	CREDITED TO THE FUND PURSUANT TO SUBSECTION (1) OF THIS SECTION,
11	CIVIL PENALTIES CREDITED TO THE FUND PURSUANT TO SECTION 44-15-104
12	(3), AND ANY OTHER MONEY THAT THE GENERAL ASSEMBLY MAY
13	APPROPRIATE OR TRANSFER TO THE FUND.
14	(b) The state treasurer shall credit all interest and
15	INCOME DERIVED FROM THE DEPOSIT AND INVESTMENT OF MONEY IN THE
16	FUND TO THE FUND.
17	(c) Subject to annual appropriation by the general
18	ASSEMBLY, THE EXECUTIVE DIRECTOR MAY EXPEND MONEY FROM THE
19	Fund for the administration and enforcement of this article 15 .
20	44-15-104. Civil penalty. (1) A MANUFACTURER OF A KRATOM
21	PRODUCT THAT IS MANUFACTURED, PACKAGED, LABELED, OR DISTRIBUTED
22	IN THE STATE WITHOUT A REGISTRATION ISSUED PURSUANT TO SECTION
23	44-15-102 (1) IS SUBJECT TO A CIVIL PENALTY OF:
24	(a) No more than one thousand dollars for the first
25	VIOLATION;
26	(b) No more than five thousand dollars for the second
27	VIOLATION; AND

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1	(c) At least five thousand dollars and no more than
2	TWENTY THOUSAND DOLLARS FOR A THIRD OR SUBSEQUENT VIOLATION.
3	(2) IN THE EVENT OF A THIRD OR SUBSEQUENT VIOLATION, THE
4	MANUFACTURER IS PROHIBITED FROM MANUFACTURING OR DISTRIBUTING
5	KRATOM PRODUCTS IN THE STATE FOR THREE YEARS AFTER THE DATE THE
6	CIVIL PENALTY IS ASSESSED.
7	(3) THE STATE TREASURER SHALL CREDIT THE CIVIL PENALTIES TO
8	THE FUND.
9	44-15-105. Compliance with federal law - rules. (1) A KRATOM
10	PRODUCT SOLD, OFFERED FOR SALE, OR INTRODUCED INTO COMMERCE IN
11	THE STATE MUST BE MANUFACTURED, PACKAGED, LABELED, AND
12	DISTRIBUTED IN COMPLIANCE WITH 21 CFR 111, AS THAT PART EXISTED
13	on July 1, 2025, or as updated by the executive director by rule.
14	(2) A PROCESSOR SHALL HOLD A CURRENT FOOD FACILITY
15	REGISTRATION FROM THE FEDERAL FOOD AND DRUG ADMINISTRATION.
16	44-15-106. Rules. The executive director may adopt rules
17	THAT ARE NECESSARY FOR THE ADMINISTRATION AND ENFORCEMENT OF
18	THIS ARTICLE 15.
19	44-15-107. Local government regulation. NOTHING IN THIS
20	ARTICLE 15 OR RULES ADOPTED BY THE EXECUTIVE DIRECTOR PURSUANT
21	TO THIS ARTICLE 15 LIMITS THE ABILITY OF A LOCAL GOVERNMENT TO
22	ENACT OR ENFORCE AN ORDINANCE, RESOLUTION, REGULATION, OR OTHER
23	LAW RELATING TO THE MANUFACTURE, SALE, OFFER FOR SALE, TRANSFER,
24	POSSESSION, OR USE OF ANY KRATOM PRODUCT WITHIN THE LOCAL
25	GOVERNMENT'S JURISDICTION SO LONG AS THE LOCAL GOVERNMENT
26	ORDINANCE, RESOLUTION, REGULATION, OR LAW IS NO LESS RESTRICTIVE
27	THAN THE REQUIREMENTS OF THIS ARTICLE 15.

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1	SECTION 3. In Colorado Revised Statutes, add 6-1-737 as
2	follows:
3	6-1-737. Kratom - deceptive trade practice - definitions.
4	(1) Unless the context otherwise requires, the definitions in
5	SECTION 44-15-101 APPLY TO THIS SECTION.
6	(2) A PERSON SHALL NOT:
7	(a) Knowingly prepare, distribute, advertise, sell, or offer
8	TO SELL A KRATOM PRODUCT:
9	(I) THAT IS ADULTERATED;
10	(II) TO A PERSON UNDER TWENTY-ONE YEARS OF AGE;
11	(III) THAT CONTAINS A LEVEL OF 7-HYDROXYMITRAGYNINE IN THE
12	ALKALOID FRACTION THAT IS GREATER THAN TWO PERCENT OF THE
13	ALKALOID COMPOSITION OF THE KRATOM PRODUCT;
14	(IV) THAT IS A CONFECTION; MIMICS A CANDY PRODUCT; OR IS
15	MANUFACTURED, PACKAGED, LABELED, OR DISTRIBUTED IN A WAY THAT
16	IS APPEALING TO CHILDREN, INCLUDING IN THE DISTINCT SHAPE OF A
17	HUMAN, AN ANIMAL, OR FRUIT; OR
18	(V) That is combustible or intended for vaporization;
19	(b) Prepare, distribute, advertise, sell, or offer to sell a
20	KRATOM PRODUCT THAT DOES NOT HAVE A LABEL THAT CLEARLY AND
21	CONSPICUOUSLY SETS FORTH ON EACH RETAIL PACKAGE:
22	(I) THE IDENTITY AND ADDRESS OF ANY PROCESSOR INVOLVED IN
23	MANUFACTURING, PACKAGING, LABELING, OR DISTRIBUTING THE KRATOM
24	PRODUCT;
25	(II) THE FULL LIST OF INGREDIENTS IN THE KRATOM PRODUCT;
26	(III) A RECOMMENDATION:
27	(A) AGAINST USE BY INDIVIDUALS WHO ARE UNDER TWENTY-ONE

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1	YEARS OF AGE, PREGNANT, OR BREASTFEEDING; AND
2	(B) TO CONSULT A HEALTH-CARE PROFESSIONAL PRIOR TO USE;
3	(IV) AN ADVISEMENT THAT KRATOM MAY:
4	(A) BE HABIT FORMING OR CREATE A RISK OF ADDICTION; AND
5	(B) Interact with certain <u>medications</u> , <u>drugs</u> , <u>and</u>
6	CONTROLLED SUBSTANCES;
7	(V) THE FOLLOWING <u>STATEMENTS:</u>
8	(A) "THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE _
9	FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO
10	DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE."; AND
11	(B) "KEEP OUT OF REACH OF CHILDREN."; AND
12	(VI) DIRECTIONS FOR USE THAT INCLUDE:
13	(A) A RECOMMENDED AMOUNT OF THE KRATOM PRODUCT PER
14	SERVING;
15	(B) THE NUMBER OF RECOMMENDED SERVINGS PER PACKAGE;
16	(C) A RECOMMENDED NUMBER OF SERVINGS OF THE KRATOM
17	PRODUCT THAT CAN BE SAFELY CONSUMED IN A TWENTY-FOUR-HOUR
18	PERIOD; AND
19	(D) QUANTITATIVE DECLARATIONS OF THE AMOUNT OF
20	MITRAGYNINE AND THE AMOUNT OF 7-HYDROXYMITRAGYNINE PER
21	SERVING OF THE KRATOM PRODUCT;
22	(c) DISPLAY OR STORE KRATOM PRODUCTS IN A RETAIL LOCATION
23	IN A MANNER THAT WILL ALLOW THE PRODUCTS TO BE ACCESSED BY
24	INDIVIDUALS UNDER TWENTY-ONE YEARS OF AGE; OR
25	(d) Manufacture, package, label, or distribute a kratom
26	PRODUCT THAT:
7	(I) CONTAINS SYNTHESIZED ALKALOIDS OF SEMI-SYNTHESIZED

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1	ALKALOIDS; OR
2	(II) HAS A LEVEL OF 7-HYDROXYMITRAGYNINE IN THE ALKALOID
3	FRACTION THAT IS GREATER THAN TWO PERCENT OF THE ALKALOID
4	COMPOSITION OF THE PRODUCT.
5	(3) A PERSON THAT CONDUCTS THE ACTIVITIES DESCRIBED IN
6	SUBSECTION (2) OF THIS SECTION ENGAGES IN A DECEPTIVE TRADE
7	PRACTICE.
8	SECTION 4. In Colorado Revised Statutes, 18-13-132, amend
9	(3) as follows:
10	18-13-132. Furnishing kratom products to persons under
11	twenty-one years of age. (3) As used in this section, "kratom product"
12	has the meaning set forth in section 44-1-105 (1) 44-15-101 (8).
13	SECTION 5. Applicability. This act applies to conduct occurring
14	on or after the effective date of this act.
15	SECTION 6. Safety clause. The general assembly finds,
16	determines, and declares that this act is necessary for the immediate
17	preservation of the public peace, health, or safety or for appropriations for
18	the support and maintenance of the departments of the state and state
19	institutions.

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