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

## **INTRODUCED**

LLS NO. 23-0660.02 Sarah Lozano x3858

**SENATE BILL 23-147** 

#### **SENATE SPONSORSHIP**

Sullivan and Ginal,

#### **HOUSE SPONSORSHIP**

(None),

### **Senate Committees**

#### **House Committees**

Finance

#### A BILL FOR AN ACT

101 CONCERNING THE REGULATION OF PROCESSORS OF KRATOM PRODUCTS.

#### **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 <a href="http://leg.colorado.gov">http://leg.colorado.gov</a>.)

Effective July 1, 2024, the bill:

- Establishes the minimum standards and labeling requirements for kratom products;
- Requires that, prior to selling or offering for sale any kratom product, the processor of the kratom product

(processor) register the kratom product with the department of revenue (department) and provide a certificate of analysis for the kratom product to the department;

- Requires a processor to notify the department if an adverse event report is submitted to the federal food and drug administration for any of the processor's kratom products; and
- Allows the department, if there is a reasonable basis, to require a test for compliance of a processor's kratom product by a third-party laboratory, to coordinate with a third-party laboratory to conduct the test, and to require the processor to pay the department's cost for the test.

The executive director of the department is required to promulgate rules to administer and enforce the bill and is authorized to impose fines on processors that violate the bill.

Be it enacted by the General Assembly of the State of Colorado: 1 2 **SECTION 1.** In Colorado Revised Statutes, **repeal** 44-1-105. 3 **SECTION 2.** In Colorado Revised Statutes, **add** article 15 to title 4 44 as follows: 5 **ARTICLE 15** 6 Colorado Kratom Consumer Protection Act 7 **44-15-101. Short title.** THE SHORT TITLE OF THIS ARTICLE 15 IS 8 THE "COLORADO KRATOM CONSUMER PROTECTION ACT". 9 44-15-102. Definitions. AS USED IN THIS ARTICLE 15, UNLESS THE 10 CONTEXT OTHERWISE REQUIRES: 11 "CERTIFICATE OF ANALYSIS" MEANS A CERTIFICATE OF (1) 12 ANALYSIS: 13 (a) FROM A THIRD-PARTY LABORATORY SHOWING THAT A KRATOM 14 PRODUCT DOES NOT VIOLATE SECTIONS 44-15-103 (2)(b) AND (2)(c); AND 15 (b) THAT INCLUDES A BATCH NUMBER OR LOT NUMBER FOR THE 16 APPLICABLE KRATOM PRODUCT.

-2- SB23-147

1	(2) "FUND" MEANS THE KRATOM CONSUMER PROTECTION CASH
2	FUND CREATED IN SECTION 44-15-108 (1).
3	(3) "Kratom extract" means a product containing any
4	PART OF THE LEAF OF THE PLANT MITRAGYNA SPECIOSA THAT HAS BEEN
5	EXTRACTED THROUGH AN EXTRACTION PROCESS THAT MEETS THE
6	STANDARDS SET BY THE UNITED STATES PHARMACOPEIA.
7	(4) "Kratom product" or "product" means any part of the
8	LEAF OF THE PLANT MITRAGYNA SPECIOSA, OR A KRATOM EXTRACT,
9	MANUFACTURED AS A FOOD, POWDER, CAPSULE, PILL, BEVERAGE, OR ANY
10	OTHER EDIBLE PRODUCT.
11	(5) "LOCAL GOVERNMENT" MEANS A HOME RULE OR STATUTORY
12	COUNTY, MUNICIPALITY, OR CITY AND COUNTY.
13	(6) (a) "PROCESSOR" MEANS A PERSON THAT:
14	(I) SELLS, PREPARES, OR MAINTAINS A KRATOM PRODUCT; OR
15	(II) ADVERTISES, REPRESENTS, OR HOLDS ITSELF OUT AS SELLING,
16	PREPARING, OR MAINTAINING A KRATOM PRODUCT.
17	(b) "PROCESSOR" DOES NOT INCLUDE A RETAILER.
18	(7) "RETAILER" MEANS A PERSON THAT SELLS, OFFERS FOR SALE,
19	OR DISTRIBUTES A KRATOM PRODUCT TO INDIVIDUALS FOR PERSONAL
20	CONSUMPTION.
21	44-15-103. Prohibited acts - labeling requirements -
22	enforcement - penalties. (1) A PERSON SHALL NOT:
23	(a) Knowingly prepare, distribute, advertise, sell, or offer
24	TO SELL A KRATOM PRODUCT THAT IS ADULTERATED WITH FENTANYL OR
25	ANY OTHER CONTROLLED SUBSTANCE LISTED IN PART 2 OF ARTICLE 18 OF
26	TITLE 18;
27	(b) SELLAKDATOM DRODUCTTHAT DOES NOT HAVE A LABEL THAT

-3- SB23-147

1	CLEARLY SETS FORTH:
2	(I) THE IDENTITY AND ADDRESS OF THE MANUFACTURER; AND
3	(II) THE FULL LIST OF INGREDIENTS IN THE KRATOM PRODUCT;
4	(c) Knowingly prepare, distribute, advertise, sell, or offer
5	TO SELL A KRATOM PRODUCT TO A PERSON UNDER TWENTY-ONE YEARS OF
6	AGE; OR
7	(d) DISPLAY OR STORE KRATOM PRODUCTS IN A RETAIL LOCATION
8	IN A MANNER THAT WILL ALLOW THE PRODUCTS TO BE ACCESSED BY
9	INDIVIDUALS UNDER TWENTY-ONE YEARS OF AGE.
10	(2) A PROCESSOR SHALL NOT ADVERTISE, DISTRIBUTE, SELL, OR
11	OFFER FOR SALE:
12	(a) A KRATOM PRODUCT TO A PERSON UNDER TWENTY-ONE YEARS
13	OF AGE;
14	(b) A KRATOM PRODUCT THAT:
15	(I) IS MIXED OR PACKED WITH A NONKRATOM SUBSTANCE THAT
16	AFFECTS THE QUALITY OR STRENGTH OF THE KRATOM PRODUCT TO SUCH
17	A DEGREE AS TO RENDER THE KRATOM PRODUCT INJURIOUS TO A
18	CONSUMER;
19	(II) CONTAINS A POISONOUS OR OTHERWISE HARMFUL
20	NONKRATOM INGREDIENT, INCLUDING ANY SUBSTANCE LISTED IN PART 2
21	OF ARTICLE 18 OF TITLE 18;
22	(III) HAS A LEVEL OF 7-HYDROXYMITRAGYNINE IN THE ALKALOID
23	FRACTION THAT IS GREATER THAN ONE PERCENT OF THE OVERALL
24	ALKALOID COMPOSITION OF THE KRATOM PRODUCT; OR
25	(IV) HAS SYNTHETIC ALKALOIDS, INCLUDING SYNTHETIC
26	MITRAGYNINE, SYNTHETIC 7-HYDROXYMITRAGYNINE, OR ANY OTHER
77	SYNTHETICALLY DEDIVED COMPOLINDS OF THE DLANT MITPACYNA

-4- SB23-147

1	SPECIOSA; OR
2	(c) A KRATOM EXTRACT WITH LEVELS OF RESIDUAL SOLVENTS
3	THAT ARE HIGHER THAN ALLOWED BY CHAPTER 467 OF THE UNITED
4	STATES PHARMACOPEIA.
5	(3) (a) ANY KRATOM PRODUCT ADVERTISED, DISTRIBUTED, SOLD,
6	OR OFFERED FOR SALE IN THE STATE MUST INCLUDE A LABEL OR A QUICK
7	RESPONSE CODE OR A WEBSITE ADDRESS FOR A WEBSITE THAT:
8	(I) CONTAINS THE NAME AND ADDRESS OF THE KRATOM
9	PROCESSOR;
10	(II) INCLUDES ADEQUATE DIRECTIONS, INCLUDING THE TOTAL
11	RECOMMENDED SERVING SIZE OF THE KRATOM PRODUCT AND THE NUMBER
12	OF SERVINGS IN THE CONTAINER OR PACKAGE OF THE KRATOM PRODUCT;
13	(III) DESCRIBES THE FACTUAL BASIS UPON WHICH THE PROCESSOR
14	REPRESENTS THE KRATOM PRODUCT AS FOOD, INCLUDING:
15	(A) A PRODUCT FACT PANEL LISTING ALL INGREDIENTS THAT ARE
16	EXPRESSED BY NUMERICAL COUNT OR IN VOLUME OR WEIGHT; AND
17	(B) THE AMOUNT OF MITRAGYNINE AND 7-HYDROXYMITRAGYNINE
18	CONTAINED IN THE KRATOM PRODUCT OR PRODUCTS CONTAINED IN A
19	CONTAINER OR PACKAGE, SO LONG AS THE LEVEL OF
20	7-HYDROXYMITRAGYNINE IN THE ALKALOID FRACTION DOES NOT EXCEED
21	ONE PERCENT OF THE OVERALL ALKALOID COMPOSITION OF THE KRATOM
22	PRODUCT;
23	$(IV)\ IDENTIFIES A BATCH  NUMBER OR LOT NUMBER THAT MATCHES$
24	THE BATCH OR LOT NUMBER ON THE CERTIFICATE OF ANALYSIS SUBMITTED
25	FOR THE KRATOM PRODUCT PURSUANT TO SECTION 44-15-104 (1)(b);
26	(V) INCLUDES A DISCLAIMER THAT STATES: "THIS PRODUCT HAS
27	NOT BEEN EVALUATED BY THE UNITED STATES FOOD AND DRUG

-5- SB23-147

1	ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT,
2	CURE, OR PREVENT ANY DISEASE."; AND
3	(VI) DOES NOT INCLUDE ANY CLAIMS THAT THE KRATOM PRODUCT
4	IS INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY MEDICAL
5	CONDITION OR DISEASE.
6	(b) THE PROCESSOR SHALL PROVIDE THE INFORMATION DESCRIBED
7	IN SUBSECTION (3)(a) OF THIS SECTION IN ENGLISH. THE PROCESSOR MAY
8	ALSO PROVIDE THE INFORMATION IN ANOTHER LANGUAGE.
9	(4) A PROCESSOR THAT VIOLATES SUBSECTION $(2)$ OR $(3)$ OF THIS
10	SECTION OR FAILS TO COMPLY WITH SECTION 44-15-104(1) IS SUBJECT TO
11	A FINE OF NO MORE THAN FIVE HUNDRED DOLLARS FOR THE FIRST OFFENSE
12	AND NO MORE THAN ONE THOUSAND DOLLARS FOR THE SECOND OR ANY
13	SUBSEQUENT OFFENSES.
14	(5) THE EXECUTIVE DIRECTOR SHALL TRANSMIT ALL PENALTIES
15	COLLECTED UNDER THIS SECTION TO THE STATE TREASURER, WHO SHALL
16	CREDIT THEM TO THE FUND.
17	44-15-104. Registration of kratom products - certificate of
18	analysis - fees - rules. (1) PRIOR TO ADVERTISING, DISTRIBUTING,
19	SELLING, OR OFFERING TO SELL ANY KRATOM PRODUCT IN THE STATE,
20	EACH PROCESSOR SHALL:
21	(a) REGISTER AND MAINTAIN CURRENT REGISTRATION OF THE
22	KRATOM PRODUCT WITH THE DEPARTMENT;
23	(b) Provide to the department a certificate of analysis for
24	THE KRATOM PRODUCT AT THE PROCESSOR'S OWN EXPENSE; AND
25	(c) (I) PAY AN INITIAL REGISTRATION FEE AND, THEREAFTER, AN
26	ANNUAL RENEWAL FEE IN THE AMOUNT DETERMINED BY THE EXECUTIVE
27	DIRECTOR BY RULE.

-6- SB23-147

1	(II) THE AMOUNT OF THE FEES MUST REFLECT THE ACTUAL AND
2	DIRECT COSTS INCURRED BY THE DEPARTMENT IN IMPLEMENTING THIS
3	ARTICLE 15.
4	(2) (a) If the department receives credible notice that a
5	KRATOM PRODUCT VIOLATES SECTION 44-15-103 (2)(b) OR (2)(c), THE
6	EXECUTIVE DIRECTOR SHALL REQUIRE THE PROCESSOR OF THE KRATOM
7	PRODUCT TO SUBMIT TO THE DEPARTMENT A CURRENT CERTIFICATE OF
8	ANALYSIS, AT THE PROCESSOR'S OWN EXPENSE, FOR THE KRATOM PRODUCT
9	WITHIN A PERIOD DETERMINED BY THE EXECUTIVE DIRECTOR BY RULE.
10	(b) IF THE PROCESSOR DOES NOT SUBMIT A CURRENT CERTIFICATE
11	OF ANALYSIS TO THE DEPARTMENT WITHIN THE REQUIRED PERIOD, THE
12	DEPARTMENT MAY REVOKE THE PROCESSOR'S REGISTRATION FOR THE
13	APPLICABLE KRATOM PRODUCT.
14	(3) THE EXECUTIVE DIRECTOR SHALL TRANSMIT ALL FEES
15	COLLECTED UNDER THIS SECTION TO THE STATE TREASURER, WHO SHALL
16	CREDIT THEM TO THE FUND.
17	44-15-105. Adverse event reporting - third-party laboratory
18	testing - rules. (1) (a) If an adverse event report is submitted to
19	THE FEDERAL FOOD AND DRUG ADMINISTRATION FOR ANY OF A
20	PROCESSOR'S KRATOM PRODUCTS, THE PROCESSOR SHALL SUBMIT A COPY
21	OF THE ADVERSE EVENT REPORT TO THE DEPARTMENT WITHIN A PERIOD
22	DETERMINED BY THE EXECUTIVE DIRECTOR BY RULE.
23	(b) IF THE PROCESSOR FAILS TO SUBMIT A COPY OF AN ADVERSE
24	EVENT REPORT WITHIN THE REQUIRED PERIOD, THE DEPARTMENT MAY
25	REVOKE THE PROCESSOR'S REGISTRATION FOR THE KRATOM PRODUCT FOR
26	WHICH THE ADVERSE EVENT REPORT WAS FILED.
2.7	(2) (a) If the DEPARTMENT HAS A REASONABLE BASIS TO REQUIRE

-7- SB23-147

2	LABORATORY TO DETERMINE IF THE KRATOM PRODUCT VIOLATES SECTION
3	44-15-103 (2)(b) OR (2)(c), THE DEPARTMENT MAY:
4	(I) COORDINATE WITH A THIRD-PARTY LABORATORY OF THE
5	DEPARTMENT'S CHOICE TO CONDUCT THE TEST; AND
6	(II) REQUIRE THE PROCESSOR OF THE KRATOM PRODUCT TO PAY
7	THE COST OF THE TEST TO THE DEPARTMENT WITHIN A PERIOD
8	DETERMINED BY THE EXECUTIVE DIRECTOR BY RULE.
9	(b) IF THE PROCESSOR FAILS TO PROVIDE THE COST OF THE TEST TO
10	THE DEPARTMENT WITHIN THE REQUIRED PERIOD, THE DEPARTMENT MAY
11	REVOKE THE PROCESSOR'S REGISTRATION FOR THE APPLICABLE KRATOM
12	PRODUCT.
13	44-15-106. Rules. The executive director shall promulgate
14	RULES AS NECESSARY FOR THE ADMINISTRATION AND ENFORCEMENT OF
15	THIS ARTICLE 15.
16	44-15-107. Local governments. Nothing in this article 15 or
17	THE RULES PROMULGATED BY THE EXECUTIVE DIRECTOR PURSUANT TO
18	THIS ARTICLE 15 LIMITS A LOCAL GOVERNMENT FROM ENACTING OR
19	ENFORCING AN ORDINANCE, RESOLUTION, REGULATION, OR OTHER LAW
20	RELATING TO THE MANUFACTURE, SALE, OFFERING FOR SALE, TRANSFER,
21	POSSESSION, OR USE OF ANY KRATOM PRODUCT IN THE JURISDICTION OF
22	THE LOCAL GOVERNMENT, SO LONG AS THE ORDINANCE, RESOLUTION,
23	REGULATION, OR OTHER LAW ENACTED OR ENFORCED BY THE LOCAL
24	GOVERNMENT IS NO LESS RESTRICTIVE THAN THE REQUIREMENTS OF THIS
25	ARTICLE 15.
26	44-15-108. Kratom consumer protection cash fund. (1) THE
27	KRATOM CONSUMER PROTECTION CASH FUND IS CREATED IN THE STATE

1 A TEST OF A PROCESSOR'S KRATOM PRODUCT BY A THIRD-PARTY

-8- SB23-147

1	TREASURY. THE FUND CONSISTS OF:
2	(a) Money credited to the fund pursuant to section
3	44-15-104 (3);
4	(b) Any penalties collected pursuant to section 44-15-103
5	(5); AND
6	(c) Any money appropriated or transferred to the fund by
7	THE GENERAL ASSEMBLY.
8	(2) THE MONEY IN THE FUND, INCLUDING ANY UNEXPENDED AND
9	UNENCUMBERED MONEY REMAINING IN THE FUND AT THE END OF A STATE
10	FISCAL YEAR, SHALL NOT BE DEPOSITED IN, CREDITED TO, OR
11	TRANSFERRED TO THE GENERAL FUND OR ANY OTHER FUND. THE STATE
12	TREASURER SHALL CREDIT ALL INTEREST AND INCOME DERIVED FROM THE
13	DEPOSIT AND INVESTMENT OF MONEY IN THE FUND TO THE FUND.
14	(3) MONEY IN THE FUND IS CONTINUOUSLY APPROPRIATED TO THE
15	DEPARTMENT FOR COSTS RELATED TO ADMINISTERING AND ENFORCING
16	THIS ARTICLE 15.
17	SECTION 3. Act subject to petition - effective date -
18	applicability. (1) This act takes effect at 12:01 a.m. on the day following
19	the expiration of the ninety-day period after final adjournment of the
20	general assembly; except that, if a referendum petition is filed pursuant
21	to section 1 (3) of article V of the state constitution against this act or an
22	item, section, or part of this act within such period, then the act, item,
23	section, or part will not take effect unless approved by the people at the
24	general election to be held in November 2024 and, in such case, will take
25	effect on the date of the official declaration of the vote thereon by the
26	governor.
27	(2) This act applies to conduct occurring on or after July 1, 2024.

-9- SB23-147