Second Regular Session Seventy-third General Assembly STATE OF COLORADO

ENGROSSED

This Version Includes All Amendments Adopted on Second Reading in the House of Introduction

LLS NO. 22-0128.01 Sarah Lozano x3858

SENATE BILL 22-120

SENATE SPONSORSHIP

Ginal and Coram,

HOUSE SPONSORSHIP

Sullivan,

Senate Committees

House Committees

Finance Appropriations

A BILL FOR AN ACT

101 CONCERNING THE REGULATION OF KRATOM <u>PROCESSORS, AND, IN</u>
102 CONNECTION THEREWITH, MAKING AN APPROPRIATION.

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.)

Effective January 1, 2023, the bill requires that, prior to selling or offering for sale any kratom product, each kratom processor must register with the department of revenue (department) and disclose certain information regarding each of the kratom processor's kratom products.

The bill also:

• Establishes the minimum requirements for kratom

products;

- Prohibits the sale of kratom products to individuals under 18 years of age;
- Requires a kratom processor to notify the department within 7 days after being notified that an adverse effect report was made with the federal food and drug administration regarding any of the kratom processor's kratom products; and
- Authorizes the department to investigate adverse effect reports to determine whether a kratom processor has violated any of the standards specified in the bill.

The executive director of the department is required to adopt rules to administer and enforce the bill.

1 Be it enacted by the General Assembly of the State of Colorado: 2 **SECTION 1.** In Colorado Revised Statutes, add article 15 to title 3 44 as follows: 4 **ARTICLE 15** 5 Colorado Kratom Consumer Protection Act 6 **44-15-101. Short title.** THE SHORT TITLE OF THIS ARTICLE 15 IS 7 THE "COLORADO KRATOM CONSUMER PROTECTION ACT". 8 **44-15-102. Definitions.** AS USED IN THIS ARTICLE 15, UNLESS THE 9 CONTEXT OTHERWISE REQUIRES: 10 11 (1) "Kratom extract" means a <u>Product</u> containing any 12 PART OF THE LEAF OF THE PLANT MITRAGYNA SPECIOSA THAT HAS BEEN 13 EXTRACTED AND CONCENTRATED IN ORDER TO PROVIDE MORE 14 STANDARDIZED DOSING. 15 16 (2) (a) "KRATOM PROCESSOR" OR "PROCESSOR" MEANS A PERSON: 17 (I) THAT SELLS, PREPARES, OR MAINTAINS A KRATOM PRODUCT; OR 18 (II) THAT ADVERTISES, REPRESENTS, OR HOLDS ITSELF OUT AS

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1	SELLING, PREPARING, OR MAINTAINING A KRATOM PRODUCT.
2	(b) "Kratom processor" or "processor" does not include a
3	RETAILER.
4	(3) "Kratom product" or "product" means any part of the
5	LEAF OF THE PLANT MITRAGYNA SPECIOSA, OR A KRATOM EXTRACT,
6	MANUFACTURED AS A POWDER, CAPSULE, PILL, BEVERAGE, OR SOME
7	OTHER EDIBLE PRODUCT.
8	(4) "LOCAL GOVERNMENT" MEANS A HOME RULE OR STATUTORY
9	COUNTY, MUNICIPALITY, OR CITY AND COUNTY.
10	(5) "RETAILER" MEANS A PERSON THAT SELLS, OFFERS FOR SALE,
11	OR DISTRIBUTES A KRATOM PRODUCT TO INDIVIDUALS FOR PERSONAL
12	CONSUMPTION.
13	44-15-103. Kratom processors - registration required -
14	disclosures required - rules. (1) Effective <u>July 1, 2023,</u> Prior to
15	SELLING OR OFFERING TO SELL ANY KRATOM PRODUCT IN THIS STATE,
16	EACH KRATOM PROCESSOR SHALL:
17	(a) REGISTER WITH THE DEPARTMENT IN THE FORM AND MANNER
18	DETERMINED BY THE EXECUTIVE DIRECTOR BY RULE; AND
19	(b) PAY AN INITIAL REGISTRATION FEE AND, THEREAFTER, AN
20	ANNUAL RENEWAL FEE IN THE AMOUNT DETERMINED BY THE EXECUTIVE
21	DIRECTOR BY RULE. THE AMOUNT OF THE FEE MUST REFLECT THE ACTUAL
22	DIRECT COSTS INCURRED BY THE DEPARTMENT IN IMPLEMENTING THIS
23	ARTICLE 15.
24	(2) EXCEPT AS PROVIDED IN SUBSECTION (3) OF THIS SECTION,
25	EFFECTIVE <u>July 1, 2023,</u> Prior to selling or offering to sell any
26	KRATOM PRODUCT IN THIS STATE, EACH KRATOM PROCESSOR SHALL
27	PROVIDE THE DEPARTMENT WITH:

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1	(a) A LIST OF EACH OF THE PROCESSOR'S KRATOM PRODUCTS THAT
2	THE PROCESSOR OFFERS FOR SALE OR SELLS IN THIS STATE;
3	(b) FOR EACH KRATOM PRODUCT:
4	_
5	(I) THE NAME AND ADDRESS OF THE PERSON WHOSE NAME WILL
6	APPEAR ON THE PRODUCT LABEL, IF THE PERSON IS NOT THE PROCESSOR;
7	(II) WHETHER THE PRODUCT IS A POWDER, CAPSULE, PILL,
8	BEVERAGE, OR SOME OTHER EDIBLE FORM;
9	(III) THE RECOMMENDED USAGE AMOUNT AND CORRESPONDING
10	USAGE DIRECTIONS;
11	(IV) The weight or volume of the package of kratom
12	PRODUCT AND THE RECOMMENDED INDIVIDUAL SERVING SIZE OR AMOUNT;
13	AND
14	$\underline{(V)}$ A complete copy of the label that will appear on the
15	KRATOM PRODUCT OR THAT CAN BE VIEWED VIA A SCANNABLE BAR CODE
16	OR WEBSITE ADDRESS;
17	(c) A CERTIFICATE OF ANALYSIS, AT THE PROCESSOR'S OWN
18	EXPENSE, FOR THE KRATOM PRODUCT FROM AN ACCREDITED LABORATORY
19	THAT TESTS FOR THE PURITY OF PRODUCTS; AND
20	(d) If an additive or solvent is used in manufacturing the
21	KRATOM PRODUCT OR KRATOM EXTRACT, A WRITTEN ACKNOWLEDGMENT
22	THAT THE ADDITIVE OR SOLVENT COMPLIES WITH THE APPLICABLE
23	PRODUCT LIMITATIONS IN THE UNITED STATES PHARMACOPEIA.
24	(3) A KRATOM PROCESSOR IS NOT REQUIRED TO DISCLOSE ANY
25	INFORMATION THAT IS A TRADE SECRET, AS DEFINED IN SECTION 7-74-102
26	(4).
27	(4) THE EXECUTIVE DIDECTOR SHALL TRANSMIT ALL FEES

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1	COLLECTED UNDER THIS SECTION TO THE STATE TREASURER, WHO SHALL
2	CREDIT THEM TO THE KRATOM CONSUMER PROTECTION CASH FUND,
3	CREATED IN SECTION 44-15-111.
4	44-15-104. Kratom products - limitations - enforcement -
5	penalties. (1) A KRATOM PROCESSOR SHALL NOT PREPARE, DISTRIBUTE,
6	SELL, OR OFFER FOR SALE:
7	(a) A KRATOM PRODUCT THAT:
8	(I) IS MIXED OR PACKED WITH A NONKRATOM SUBSTANCE THAT
9	AFFECTS THE QUALITY OR STRENGTH OF THE KRATOM PRODUCT TO SUCH
10	A DEGREE AS TO RENDER THE KRATOM PRODUCT INJURIOUS TO A
11	CONSUMER;
12	(II) CONTAINS A POISONOUS OR OTHERWISE HARMFUL
13	NONKRATOM INGREDIENT, INCLUDING ANY SUBSTANCE LISTED IN PART 2
14	OF ARTICLE 18 OF TITLE 18;
15	(III) HAS A LEVEL OF 7-HYDROXYMITRAGYNINE IN THE ALKALOID
16	FRACTION THAT IS GREATER THAN TWO PERCENT OF THE OVERALL
17	ALKALOID COMPOSITION OF THE KRATOM PRODUCT;
18	(IV) HAS SYNTHETIC ALKALOIDS, INCLUDING SYNTHETIC
19	MITRAGYNINE, SYNTHETIC 7-HYDROXYMITRAGYNINE, OR ANY OTHER
20	SYNTHETICALLY DERIVED COMPOUNDS OF THE PLANT MITRAGYNA
21	SPECIOSA;
22	(V) Does not include a label with adequate directions
23	NECESSARY FOR SUGGESTED USE BY A CONSUMER, INCLUDING THE TOTAL
24	SUGGESTED SERVING SIZE OF THE KRATOM PRODUCT; AND
25	(VI) BEARS A LABEL THAT MAKES CLAIMS THAT THE KRATOM
26	PRODUCT IS INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT A
27	MEDICAL CONDITION OR DISEASE; OR

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1	(b) A KRATOM EXTRACT WITH LEVELS OF RESIDUAL SOLVENTS
2	THAT ARE HIGHER THAN THE LEVELS ALLOWED BY THE UNITED STATES
3	PHARMACOPEIA.
4	(2) (a) A KRATOM PROCESSOR THAT VIOLATES THIS SECTION IS
5	SUBJECT TO A FINE OF FIVE HUNDRED DOLLARS FOR THE FIRST OFFENSE,
6	TWO THOUSAND FIVE HUNDRED DOLLARS FOR THE SECOND OFFENSE, AND
7	FIVE THOUSAND DOLLARS FOR THE THIRD OR ANY SUBSEQUENT OFFENSE.
8	A KRATOM PROCESSOR SHALL DISCONTINUE SELLING OR OFFERING TO SELL
9	EACH KRATOM PRODUCT THAT FAILS TO MEET THE STANDARDS
10	ESTABLISHED IN THIS SECTION, AND THE KRATOM PROCESSOR SHALL NOT
11	RESUME THE SALE OF THE KRATOM PRODUCT UNLESS THE PRODUCT
12	COMPLIES WITH THE STANDARDS SPECIFIED IN THIS SECTION.
13	(b) The department may revoke the registration of a
14	KRATOM PROCESSOR, ORDER A KRATOM PRODUCT TO BE PERMANENTLY
15	REMOVED FROM SALE, OR PROHIBIT A PROCESSOR FROM REAPPLYING FOR
16	REGISTRATION AS A KRATOM PROCESSOR FOR A PERIOD OF UP TO THREE
17	YEARS IF:
18	(I) THE KRATOM PROCESSOR HAS MORE THAN THREE VIOLATIONS
19	WITHIN A FIVE-YEAR PERIOD; OR
20	(II) THE DEPARTMENT DETERMINES THAT A KRATOM PROCESSOR'S
21	VIOLATION OF THIS SECTION WAS WILLFUL.
22	(c) A RETAILER THAT VIOLATES SECTION 44-15-110 IS SUBJECT TO
23	A FINE IN AN AMOUNT DETERMINED BY THE DEPARTMENT BY RULE.
24	44-15-105. Kratom products - age limitations. A KRATOM
25	PROCESSOR MAY NOT DISTRIBUTE, SELL, OR OFFER FOR SALE A KRATOM
26	PRODUCT TO AN INDIVIDUAL UNDER <u>TWENTY-ONE</u> YEARS OF AGE.
27	44-15-106. Adverse events - mandatory reporting -

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1	investigations. (1) A KRATOM PROCESSOR SHALL NOTIFY THE
2	DEPARTMENT WITHIN SEVEN DAYS AFTER BEING NOTIFIED THAT AN
3	ADVERSE EVENT HAS BEEN REPORTED TO THE FEDERAL FOOD AND DRUG
4	ADMINISTRATION FOR ONE OF THE PROCESSOR'S KRATOM PRODUCTS.
5	(2) When notified of an adverse event pursuant to
6	SUBSECTION (1) OF THIS SECTION, THE DEPARTMENT MAY INVESTIGATE
7	WHETHER THE KRATOM PROCESSOR VIOLATED THIS ARTICLE 15.
8	(3) If the department opens an investigation into an
9	ADVERSE EVENT, THE KRATOM PROCESSOR, AT THE REQUEST OF THE
10	DEPARTMENT, SHALL PROVIDE THE DEPARTMENT WITH A CURRENT
11	CERTIFICATE OF ANALYSIS FOR THE KRATOM PRODUCT FOR WHICH THE
12	ADVERSE EVENT WAS FILED.
13	44-15-107. Rules. (1) The executive director shall
14	PROMULGATE RULES AS NECESSARY FOR THE ADMINISTRATION AND
15	ENFORCEMENT OF THIS <u>ARTICLE 15</u> , <u>INCLUDING RULES RELATING TO:</u>
16	(a) REQUIREMENTS TO PREVENT THE SALE OR DISTRIBUTION OF
17	KRATOM PRODUCTS AND KRATOM EXTRACTS TO PERSONS UNDER
18	TWENTY-ONE YEARS OF AGE;
19	(b) PROHIBITING KRATOM PROCESSORS FROM SPECIFICALLY
20	DIRECTING ADVERTISING AND MARKETING OF KRATOM PRODUCTS AND
21	KRATOM EXTRACTS TO PERSONS UNDER TWENTY-ONE YEARS OF AGE;
22	(c) REQUIREMENTS FOR KRATOM PROCESSORS TO ANNUALLY
23	PROVIDE INFORMATION ON THE AGGREGATE MARKET SALES OF KRATOM
24	PRODUCTS AND KRATOM EXTRACTS TO THE DEPARTMENT;
25	(d) REQUIREMENTS FOR KRATOM PROCESSORS TO PACKAGE ANY
26	KRATOM PRODUCTS OR KRATOM EXTRACTS IN CHILD-RESISTANT
27	PACKAGING; AND

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1	(e) REQUIREMENTS FOR THE SALE BY RETAILERS OF KRATOM
2	PRODUCTS AND KRATOM EXTRACTS MANUFACTURED BY KRATOM
3	PROCESSORS.
4	44-15-108. Local governments. Nothing in this article 15 or
5	THE RULES PROMULGATED BY THE EXECUTIVE DIRECTOR PURSUANT TO
6	THIS ARTICLE 15 LIMITS A LOCAL GOVERNMENT FROM ENACTING OR
7	ENFORCING AN ORDINANCE, RESOLUTION, REGULATION, OR OTHER LAW
8	RELATING TO THE MANUFACTURE, SALE, OFFERING FOR SALE, TRANSFER,
9	POSSESSION, OR USE OF ANY KRATOM PRODUCT IN THE JURISDICTION OF
10	THE LOCAL GOVERNMENT, SO LONG AS THE ORDINANCE, RESOLUTION,
11	REGULATION, OR OTHER LAW ENACTED OR ENFORCED BY A LOCAL
12	GOVERNMENT IS NO LESS RESTRICTIVE THAN THE REQUIREMENTS OF THIS
13	ARTICLE 15.
14	44-15-109. Publishing of names and addresses of kratom
15	processors - reporting of sales of kratom products. (1) IN ORDER TO
16	ENFORCE LAWS RELATED TO THE REGULATION OF KRATOM PRODUCTS, THE
17	DEPARTMENT SHALL MAINTAIN AND PUBLISH ON THE DEPARTMENT'S
18	WEBSITE THE BUSINESS NAMES AND ADDRESSES OF KRATOM PROCESSORS
19	AND MAY SHARE THE LIST WITH ANY STATE OR LOCAL AGENCY
20	RESPONSIBLE FOR THE ENFORCEMENT OF LAWS RELATING TO THE
21	MANUFACTURE, SALE, OFFERING FOR SALE, TRANSFER, POSSESSION, OR USE
22	OF KRATOM PRODUCTS.
23	(2) THE DEPARTMENT SHALL REQUIRE KRATOM PROCESSORS TO
24	ANNUALLY REPORT THE AMOUNT OF SALES OF KRATOM PRODUCTS TO THE
25	DEPARTMENT. THE DEPARTMENT MAY PUBLISH ANY AGGREGATE MARKET
26	DATA COMPILED PURSUANT TO THIS SUBSECTION (2) ON ITS WEBSITE.
2.7	44-15-110. Retailers. (1) A RETAILER SHALL NOT DISTRIBUTE.

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1	SELL, OR OFFER FOR SALE A KRATOM PRODUCT:
2	(a) TO AN INDIVIDUAL UNDER TWENTY-ONE YEARS OF AGE; OR
3	(b) Manufactured by a kratom processor that has not
4	COMPLIED WITH THE REQUIREMENTS OF SECTION 44-15-103.
5	44-15-111. Kratom consumer protection cash fund. (1) THE
6	KRATOM CONSUMER PROTECTION CASH FUND, REFERRED TO IN THIS
7	SECTION AS THE "FUND", IS HEREBY CREATED IN THE STATE TREASURY.
8	THE FUND CONSISTS OF:
9	(a) Money credited to the fund pursuant to section
10	<u>44-15-103 (4);</u>
11	(b) Any fines collected pursuant to section 44-15-104; and
12	(c) Money appropriated to or transferred to the fund by
13	THE GENERAL ASSEMBLY.
14	(2) The money in the fund shall not be deposited in or
15	TRANSFERRED TO THE GENERAL FUND OR ANY OTHER FUND. THE STATE
16	TREASURER SHALL CREDIT ALL INTEREST AND INCOME DERIVED FROM THE
17	DEPOSIT AND INVESTMENT OF MONEY IN THE FUND TO THE FUND. ANY
18	UNEXPENDED AND UNENCUMBERED MONEY IN THE FUND SHALL REMAIN
19	IN THE FUND AND SHALL NOT BE CREDITED OR TRANSFERRED TO THE
20	GENERAL FUND OR ANY OTHER FUND.
21	(3) Money in the fund is continuously appropriated to the
22	DEPARTMENT FOR COSTS RELATED TO ADMINISTERING AND ENFORCING
23	THIS ARTICLE 15.
24	SECTION 2. Appropriation. (1) For the 2022-23 state fiscal
25	year, \$241,341 is appropriated to the department of revenue. This
26	appropriation is from the general fund. To implement this act, the
27	department may use this appropriation as follows:

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1	(a) \$152,628 for kratom enforcement, which amount is based on
2	an assumption that the department will require an additional 2.0 FTE; and
3	(b) \$88,713 for the purchase of legal services.
4	(2) For the 2022-23 state fiscal year, \$88,713 is appropriated to
5	the department of law. This appropriation is from reappropriated funds
6	received from the department of revenue under subsection (1)(b) of this
7	section and is based on an assumption that the department of law will
8	require an additional 0.5 FTE. To implement this act, the department of
9	law may use this appropriation to provide legal services for the
10	department of revenue.
11	SECTION 3. Act subject to petition - effective date -
12	applicability. (1) This act takes effect at 12:01 a.m. on the day following
13	the expiration of the ninety-day period after final adjournment of the
14	general assembly; except that, if a referendum petition is filed pursuant
15	to section 1 (3) of article V of the state constitution against this act or an
16	item, section, or part of this act within such period, then the act, item,
17	section, or part will not take effect unless approved by the people at the
18	general election to be held in November 2022 and, in such case, will take
19	effect on the date of the official declaration of the vote thereon by the
20	governor.
21	(2) This act applies to conduct occurring on or after the applicable
22	effective date of this act.

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