Second Regular Session Seventy-third General Assembly STATE OF COLORADO

PREAMENDED

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

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

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A BILL FOR AN ACT

CONCERNING THE REGULATION OF KRATOM PROCESSORS.

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
19	SELLING, PREPARING, OR MAINTAINING A KRATOM PRODUCT.

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

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1	THE PROCESSOR OFFERS FOR SALE OR SELLS IN THIS STATE;
2	(b) FOR EACH KRATOM PRODUCT:
3	=
4	(I) THE NAME AND ADDRESS OF THE PERSON WHOSE NAME WILL
5	APPEAR ON THE PRODUCT LABEL, IF THE PERSON IS NOT THE PROCESSOR;
6	(II) WHETHER THE PRODUCT IS A POWDER, CAPSULE, PILL,
7	BEVERAGE, OR SOME OTHER EDIBLE FORM;
8	(III) THE RECOMMENDED USAGE AMOUNT AND CORRESPONDING
9	USAGE DIRECTIONS;
10	(IV) The weight or volume of the package of kratom
11	PRODUCT AND THE RECOMMENDED INDIVIDUAL SERVING SIZE OR AMOUNT;
12	AND
13	$\underline{(\mathrm{V})}$ A complete copy of the label that will appear on the
14	KRATOM PRODUCT OR THAT CAN BE VIEWED VIA A SCANNABLE BAR CODE
15	OR WEBSITE ADDRESS;
16	(c) A CERTIFICATE OF ANALYSIS, AT THE PROCESSOR'S OWN
17	EXPENSE, FOR THE KRATOM PRODUCT FROM AN ACCREDITED LABORATORY
18	THAT TESTS FOR THE PURITY OF PRODUCTS; AND
19	(d) If an additive or solvent is used in manufacturing the
20	KRATOM PRODUCT OR KRATOM EXTRACT, A WRITTEN ACKNOWLEDGMENT
21	THAT THE ADDITIVE OR SOLVENT COMPLIES WITH THE APPLICABLE
22	PRODUCT LIMITATIONS IN THE UNITED STATES PHARMACOPEIA.
23	(3) A KRATOM PROCESSOR IS NOT REQUIRED TO DISCLOSE ANY
24	INFORMATION THAT IS A TRADE SECRET, AS DEFINED IN SECTION 7-74-102
25	(4).
26	44-15-104. Kratom products - limitations - enforcement -
2.7	nenalties. (1) A KRATOM PROCESSOR SHALL NOT PREPARE. DISTRIBUTE.

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2	(a) A KRATOM PRODUCT THAT:
3	(I) IS MIXED OR PACKED WITH A NONKRATOM SUBSTANCE THAT
4	AFFECTS THE QUALITY OR STRENGTH OF THE KRATOM PRODUCT TO SUCH
5	A DEGREE AS TO RENDER THE KRATOM PRODUCT INJURIOUS TO A
6	CONSUMER;
7	(II) CONTAINS A POISONOUS OR OTHERWISE HARMFUL
8	NONKRATOM INGREDIENT, INCLUDING ANY SUBSTANCE LISTED IN PART 2
9	OF ARTICLE 18 OF TITLE 18;
10	(III) HAS A LEVEL OF 7-HYDROXYMITRAGYNINE IN THE ALKALOID
11	FRACTION THAT IS GREATER THAN TWO PERCENT OF THE OVERALL
12	ALKALOID COMPOSITION OF THE KRATOM PRODUCT;
13	(IV) HAS SYNTHETIC ALKALOIDS, INCLUDING SYNTHETIC
14	MITRAGYNINE, SYNTHETIC 7-HYDROXYMITRAGYNINE, OR ANY OTHER
15	SYNTHETICALLY DERIVED COMPOUNDS OF THE PLANT MITRAGYNA
16	SPECIOSA;
17	(V) Does not include a label with adequate directions
18	NECESSARY FOR SUGGESTED USE BY A CONSUMER, INCLUDING THE TOTAL
19	SUGGESTED SERVING SIZE OF THE KRATOM PRODUCT; AND
20	(VI) BEARS A LABEL THAT MAKES CLAIMS THAT THE KRATOM
21	PRODUCT IS INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT A
22	MEDICAL CONDITION OR DISEASE; OR
23	(b) A KRATOM EXTRACT WITH LEVELS OF RESIDUAL SOLVENTS
24	THAT ARE HIGHER THAN THE LEVELS ALLOWED BY THE UNITED STATES
25	PHARMACOPEIA.
26	(2) (a) A KRATOM PROCESSOR THAT VIOLATES THIS SECTION IS
27	SUBJECT TO A FINE OF FIVE HUNDRED DOLLARS FOR THE FIRST OFFENSE,

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SELL, OR OFFER FOR SALE:

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1	I WO I HOUSAND FIVE HUNDRED DOLLARS FOR THE SECOND OFFENSE, AND
2	FIVE THOUSAND DOLLARS FOR THE THIRD OR ANY SUBSEQUENT OFFENSE.
3	A KRATOM PROCESSOR SHALL DISCONTINUE SELLING OR OFFERING TO SELL
4	EACH KRATOM PRODUCT THAT FAILS TO MEET THE STANDARDS
5	ESTABLISHED IN THIS SECTION, AND THE KRATOM PROCESSOR SHALL NOT
6	RESUME THE SALE OF THE KRATOM PRODUCT UNLESS THE PRODUCT
7	COMPLIES WITH THE STANDARDS SPECIFIED IN THIS SECTION.
8	(b) The department may revoke the registration of a
9	KRATOM PROCESSOR, ORDER A KRATOM PRODUCT TO BE PERMANENTLY
10	REMOVED FROM SALE, OR PROHIBIT A PROCESSOR FROM REAPPLYING FOR
11	REGISTRATION AS A KRATOM PROCESSOR FOR A PERIOD OF UP TO THREE
12	YEARS IF:
13	(I) THE KRATOM PROCESSOR HAS MORE THAN THREE VIOLATIONS
14	WITHIN A FIVE-YEAR PERIOD; OR
15	$(II)\ The \ department \ determines\ that\ a\ Kratom\ Processor's$
16	VIOLATION OF THIS SECTION WAS WILLFUL.
17	(c) A RETAILER THAT VIOLATES SECTION 44-15-108 IS SUBJECT TO
18	A FINE IN AN AMOUNT DETERMINED BY THE DEPARTMENT BY RULE.
19	44-15-105. Kratom products - age limitations. A KRATOM
20	PROCESSOR MAY NOT DISTRIBUTE, SELL, OR OFFER FOR SALE A KRATOM
21	PRODUCT TO AN INDIVIDUAL UNDER <u>TWENTY-ONE</u> YEARS OF AGE.
22	44-15-106. Adverse events - mandatory reporting -
23	investigations. (1) A KRATOM PROCESSOR SHALL NOTIFY THE
24	DEPARTMENT WITHIN SEVEN DAYS AFTER BEING NOTIFIED THAT AN
25	ADVERSE EVENT HAS BEEN REPORTED TO THE FEDERAL FOOD AND DRUG
26	ADMINISTRATION FOR ONE OF THE PROCESSOR'S KRATOM PRODUCTS.
27	(2) When notified of an adverse event pursuant to

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1	SUBSECTION (1) OF THIS SECTION, THE DEPARTMENT MAY INVESTIGATE
2	WHETHER THE KRATOM PROCESSOR VIOLATED THIS ARTICLE 15.
3	(3) If the department opens an investigation into an
4	ADVERSE EVENT, THE KRATOM PROCESSOR, AT THE REQUEST OF THE
5	DEPARTMENT, SHALL PROVIDE THE DEPARTMENT WITH A CURRENT
6	CERTIFICATE OF ANALYSIS FOR THE KRATOM PRODUCT FOR WHICH THE
7	ADVERSE EVENT WAS FILED.
8	44-15-107. Rules. (1) The executive director shall
9	PROMULGATE RULES AS NECESSARY FOR THE ADMINISTRATION AND
10	ENFORCEMENT OF THIS <u>ARTICLE 15</u> , <u>INCLUDING RULES RELATING TO:</u>
11	(a) REQUIREMENTS TO PREVENT THE SALE OR DISTRIBUTION OF
12	KRATOM PRODUCTS AND KRATOM EXTRACTS TO PERSONS UNDER
13	TWENTY-ONE YEARS OF AGE;
14	(b) Prohibiting Kratom Processors from Specifically
15	DIRECTING ADVERTISING AND MARKETING OF KRATOM PRODUCTS AND
16	KRATOM EXTRACTS TO PERSONS UNDER TWENTY-ONE YEARS OF AGE;
17	(c) REQUIREMENTS FOR KRATOM PROCESSORS TO ANNUALLY
18	PROVIDE INFORMATION ON THE AGGREGATE MARKET SALES OF KRATOM
19	PRODUCTS AND KRATOM EXTRACTS TO THE DEPARTMENT;
20	(d) REQUIREMENTS FOR KRATOM PROCESSORS TO PACKAGE ANY
21	KRATOM PRODUCTS OR KRATOM EXTRACTS IN CHILD-RESISTANT
22	PACKAGING; AND
23	(e) REQUIREMENTS FOR THE SALE BY RETAILERS OF KRATOM
24	PRODUCTS AND KRATOM EXTRACTS MANUFACTURED BY KRATOM
25	PROCESSORS.
26	44-15-108. Local governments. Nothing in this article 15 or
27	THE RULES PROMULGATED BY THE EXECUTIVE DIRECTOR PURSUANT TO

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1	THIS ARTICLE 13 LIMITS A LOCAL GOVERNMENT FROM ENACTING OR
2	ENFORCING AN ORDINANCE, RESOLUTION, REGULATION, OR OTHER LAW
3	RELATING TO THE MANUFACTURE, SALE, OFFERING FOR SALE, TRANSFER.
4	POSSESSION, OR USE OF ANY KRATOM PRODUCT IN THE JURISDICTION OF
5	THE LOCAL GOVERNMENT, SO LONG AS THE ORDINANCE, RESOLUTION.
6	REGULATION, OR OTHER LAW ENACTED OR ENFORCED BY A LOCAL
7	GOVERNMENT IS NO LESS RESTRICTIVE THAN THE REQUIREMENTS OF THIS
8	ARTICLE 15.
9	44-15-109. Publishing of names and addresses of kratom
10	processors - reporting of sales of kratom products. (1) IN ORDER TO
11	ENFORCE LAWS RELATED TO THE REGULATION OF KRATOM PRODUCTS, THE
12	DEPARTMENT OF REVENUE SHALL MAINTAIN AND PUBLISH ON THE
13	DEPARTMENT'S WEBSITE THE BUSINESS NAMES AND ADDRESSES OF
14	KRATOM PROCESSORS AND MAY SHARE THE LIST WITH ANY STATE OR
15	LOCAL AGENCY RESPONSIBLE FOR THE ENFORCEMENT OF LAWS RELATING
16	TO THE MANUFACTURE, SALE, OFFERING FOR SALE, TRANSFER, POSSESSION.
17	OR USE OF KRATOM PRODUCTS.
18	(2) The department of revenue shall require kratom
19	PROCESSORS TO ANNUALLY REPORT THE AMOUNT OF SALES OF KRATOM
20	PRODUCTS TO THE DEPARTMENT. THE DEPARTMENT MAY PUBLISH ANY
21	AGGREGATE MARKET DATA COMPILED PURSUANT TO THIS SUBSECTION (2)
22	ON ITS WEBSITE.
23	44-15-110. Retailers. (1) A RETAILER SHALL NOT DISTRIBUTE.
24	SELL, OR OFFER FOR SALE A KRATOM PRODUCT:
25	(a) To an individual under twenty-one years of age; or
26	(b) Manufactured by a kratom processor that has not
2.7	COMPLIED WITH THE REQUIREMENTS OF SECTION 44-15-103.

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SECTION 2. Act subject to petition - effective date -
applicability. (1) This act takes effect at 12:01 a.m. on the day following
the expiration of the ninety-day period after final adjournment of the
general assembly; except that, if a referendum petition is filed pursuant
to section 1 (3) of article V of the state constitution against this act or an
item, section, or part of this act within such period, then the act, item,
section, or part will not take effect unless approved by the people at the
general election to be held in November 2022 and, in such case, will take
effect on the date of the official declaration of the vote thereon by the
governor.
(2) This act and is to an dust a coming an another the and is the

(2) This act applies to conduct occurring on or after the applicable effective date of this act.

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