Second Regular Session Seventy-third General Assembly STATE OF COLORADO

INTRODUCED

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

101

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 44 as follows: 3 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 (1) "FOOD" MEANS A FOOD, FOOD PRODUCT, FOOD INGREDIENT, 11 DIETARY INGREDIENT, DIETARY SUPPLEMENT, OR BEVERAGE FOR HUMAN 12 CONSUMPTION. (2) "KRATOM EXTRACT" MEANS A FOOD CONTAINING ANY PART OF 13 14 THE LEAF OF THE PLANT MITRAGYNA SPECIOSA THAT HAS BEEN 15 EXTRACTED AND CONCENTRATED IN ORDER TO PROVIDE MORE 16 STANDARDIZED DOSING. 17 (3) "Kratom Processor" or "Processor" means a person: 18 (a) THAT SELLS, PREPARES, OR MAINTAINS A KRATOM PRODUCT; OR 19 (b) THAT ADVERTISES, REPRESENTS, OR HOLDS ITSELF OUT AS

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1	SELLING, PREPARING, OR MAINTAINING A KRATOM PRODUCT.
2	(4) "Kratom product" or "product" means any part of the
3	LEAF OF THE PLANT MITRAGYNA SPECIOSA, OR A KRATOM EXTRACT,
4	MANUFACTURED AS A FOOD, POWDER, CAPSULE, PILL, BEVERAGE, OR SOME
5	OTHER EDIBLE PRODUCT.
6	44-15-103. Kratom processors - registration required -
7	disclosures required - rules. (1) Effective January 1, 2023, Prior to
8	SELLING OR OFFERING TO SELL ANY KRATOM PRODUCT IN THIS STATE,
9	EACH KRATOM PROCESSOR SHALL:
10	(a) REGISTER WITH THE DEPARTMENT IN THE FORM AND MANNER
11	DETERMINED BY THE EXECUTIVE DIRECTOR BY RULE; AND
12	(b) PAY AN INITIAL REGISTRATION FEE AND, THEREAFTER, AN
13	ANNUAL RENEWAL FEE IN THE AMOUNT DETERMINED BY THE EXECUTIVE
14	DIRECTOR BY RULE.
15	(2) EXCEPT AS PROVIDED IN SUBSECTION (3) OF THIS SECTION,
16	${\it EFFECTIVE JANUARY1,2023, PRIOR to SELLING or OFFERING to SELL any}$
17	KRATOM PRODUCT IN THIS STATE, EACH KRATOM PROCESSOR SHALL
18	PROVIDE THE DEPARTMENT WITH:
19	(a) A LIST OF EACH OF THE PROCESSOR'S KRATOM PRODUCTS THAT
20	THE PROCESSOR OFFERS FOR SALE OR SELLS IN THIS STATE;
21	(b) FOR EACH KRATOM PRODUCT:
22	(I) A CERTIFICATE OF ANALYSIS;
23	(II) THE NAME AND ADDRESS OF THE PERSON WHOSE NAME WILL
24	APPEAR ON THE PRODUCT LABEL, IF THE PERSON IS NOT THE PROCESSOR;
25	(III) WHETHER THE PRODUCT IS A FOOD, POWDER, CAPSULE, PILL,
26	BEVERAGE, OR SOME OTHER EDIBLE FORM;
27	(IV) THE RECOMMENDED USAGE AMOUNT AND CORRESPONDING

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1	USAGE DIRECTIONS;
2	(V) THE WEIGHT OR VOLUME OF THE PACKAGE OF KRATOM
3	PRODUCT AND THE RECOMMENDED INDIVIDUAL SERVING SIZE OR AMOUNT;
4	AND
5	(VI) A COMPLETE COPY OF THE LABEL THAT WILL APPEAR ON THE
6	KRATOM PRODUCT OR THAT CAN BE VIEWED VIA A SCANNABLE BAR CODE
7	OR WEBSITE ADDRESS;
8	(c) A CERTIFICATE OF ANALYSIS FOR THE KRATOM PRODUCT FROM
9	AN ACCREDITED LABORATORY THAT TESTS FOR THE PURITY OF FOOD
10	PRODUCTS; AND
11	(d) IF THE KRATOM PRODUCT THAT THE PROCESSOR IS OFFERING
12	FOR SALE OR SELLING IS A KRATOM EXTRACT, A WRITTEN
13	ACKNOWLEDGMENT THAT ALL FOOD-GRADE SOLVENTS USED IN
14	MANUFACTURING THE KRATOM EXTRACT COMPLY WITH THE APPLICABLE
15	PRODUCT LIMITATIONS IN THE UNITED STATES PHARMACOPEIA.
16	(3) A KRATOM PROCESSOR IS NOT REQUIRED TO DISCLOSE ANY
17	INFORMATION THAT IS A TRADE SECRET, AS DEFINED IN SECTION 7-74-102
18	(4).
19	44-15-104. Kratom products - limitations - enforcement -
20	penalties. (1) A KRATOM PROCESSOR SHALL NOT PREPARE, DISTRIBUTE,
21	SELL, OR OFFER FOR SALE:
22	(a) A KRATOM PRODUCT THAT:
23	(I) IS MIXED OR PACKED WITH A NONKRATOM SUBSTANCE THAT
24	AFFECTS THE QUALITY OR STRENGTH OF THE KRATOM PRODUCT TO SUCH
25	A DEGREE AS TO RENDER THE KRATOM PRODUCT INJURIOUS TO A
26	CONSUMER;
27	(II) CONTAINS A POISONOUS OR OTHERWISE HARMFUL

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1	Nonkratom ingredient, including any substance listed in part 2
2	of article 18 of title 18;
3	(III) HAS A LEVEL OF 7-HYDROXYMITRAGYNINE IN THE ALKALOID
4	FRACTION THAT IS GREATER THAN TWO PERCENT OF THE OVERALL
5	ALKALOID COMPOSITION OF THE KRATOM PRODUCT;
6	(IV) HAS SYNTHETIC ALKALOIDS, INCLUDING SYNTHETIC
7	MITRAGYNINE, SYNTHETIC 7-HYDROXYMITRAGYNINE, OR ANY OTHER
8	SYNTHETICALLY DERIVED COMPOUNDS OF THE PLANT MITRAGYNA
9	SPECIOSA;
10	(V) Does not include a label with adequate directions
11	NECESSARY FOR SAFE AND EFFECTIVE USE BY A CONSUMER, INCLUDING A
12	RECOMMENDED SERVING SIZE; AND
13	(VI) BEARS A LABEL THAT MAKES CLAIMS THAT THE KRATOM
14	PRODUCT IS INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT A
15	MEDICAL CONDITION OR DISEASE; OR
16	(b) A KRATOM EXTRACT WITH LEVELS OF RESIDUAL SOLVENTS
17	THAT ARE HIGHER THAN THE LEVELS ALLOWED BY THE UNITED STATES
18	PHARMACOPEIA.
19	(2) (a) A KRATOM PROCESSOR THAT VIOLATES THIS SECTION IS
20	SUBJECT TO A FINE OF FIVE HUNDRED DOLLARS FOR THE FIRST OFFENSE,
21	TWO THOUSAND FIVE HUNDRED DOLLARS FOR THE SECOND OFFENSE, AND
22	FIVE THOUSAND DOLLARS FOR THE THIRD OR ANY SUBSEQUENT OFFENSE.
23	A KRATOM PROCESSOR SHALL DISCONTINUE SELLING OR OFFERING TO SELL
24	EACH KRATOM PRODUCT THAT FAILS TO MEET THE STANDARDS
25	ESTABLISHED IN THIS SECTION, AND THE KRATOM PROCESSOR SHALL NOT
26	RESUME THE SALE OF THE KRATOM PRODUCT UNLESS THE PRODUCT
7	COMDITIES WITH THE STANDARDS SDECIFIED IN THIS SECTION

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1	(b) The department may revoke the registration of a
2	KRATOM PROCESSOR, ORDER A KRATOM PRODUCT TO BE PERMANENTLY
3	REMOVED FROM SALE, OR PROHIBIT A PROCESSOR FROM REAPPLYING FOR
4	REGISTRATION AS A KRATOM PROCESSOR FOR A PERIOD OF UP TO THREE
5	YEARS IF:
6	(I) THE KRATOM PROCESSOR HAS MORE THAN THREE VIOLATIONS
7	WITHIN A FIVE-YEAR PERIOD; OR
8	(II) THE DEPARTMENT DETERMINES THAT A KRATOM PROCESSOR'S
9	VIOLATION OF THIS SECTION WAS WILLFUL.
10	44-15-105. Kratom products - age limitations. A KRATOM
11	PROCESSOR MAY NOT DISTRIBUTE, SELL, OR OFFER FOR SALE A KRATOM
12	PRODUCT TO AN INDIVIDUAL UNDER EIGHTEEN YEARS OF AGE.
13	44-15-106. Adverse events - mandatory reporting -
14	investigations. (1) A KRATOM PROCESSOR SHALL NOTIFY THE
15	DEPARTMENT WITHIN SEVEN DAYS AFTER BEING NOTIFIED THAT AN
16	ADVERSE EVENT HAS BEEN REPORTED TO THE FEDERAL FOOD AND DRUG
17	ADMINISTRATION FOR ONE OF THE PROCESSOR'S KRATOM PRODUCTS.
18	(2) When notified of an adverse event pursuant to
19	SUBSECTION (1) OF THIS SECTION, THE DEPARTMENT MAY INVESTIGATE
20	WHETHER THE KRATOM PROCESSOR VIOLATED THIS ARTICLE 15.
21	(3) If the department opens an investigation into an
22	ADVERSE EVENT, THE KRATOM PROCESSOR, AT THE REQUEST OF THE
23	DEPARTMENT, SHALL PROVIDE THE DEPARTMENT WITH A CURRENT
24	CERTIFICATE OF ANALYSIS FOR THE KRATOM PRODUCT FOR WHICH THE
25	ADVERSE EVENT WAS FILED.
26	44-15-107. Rules. The executive director shall promulgate
27	RULES AS NECESSARY FOR THE ADMINISTRATION AND ENFORCEMENT OF

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THIS ARTICLE 1	15.
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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 applies to conduct occurring on or after the applicable effective date of this act.

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