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.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. In Colorado Revised Statutes, add article 15 to title 44 as follows:

ARTICLE 15
Colorado Kratom Consumer Protection Act

44-15-101. Short title. The short title of this article 15 is the "Colorado Kratom Consumer Protection Act".

44-15-102. Definitions. As used in this article 15, unless the context otherwise requires:

(1) "Food" means a food, food product, food ingredient, dietary ingredient, dietary supplement, or beverage for human consumption.

(2) "Kratom extract" means a food containing any part of the leaf of the plant Mitragyna speciosa that has been extracted and concentrated in order to provide more standardized dosing.

(3) "Kratom processor" or "processor" means a person:

(a) That sells, prepares, or maintains a kratom product; or

(b) That advertises, represents, or holds itself out as
SELLING, PREPARING, OR MAINTAINING A KRATOM PRODUCT.

(4) "KRATOM PRODUCT" OR "PRODUCT" MEANS ANY PART OF THE LEAF OF THE PLANT MITRAGYNA SPECIOSA, OR A KRATOM EXTRACT, MANUFACTURED AS A FOOD, POWDER, CAPSULE, PILL, BEVERAGE, OR SOME OTHER EDIBLE PRODUCT.

44-15-103. Kratom processors - registration required - disclosures required - rules. (1) Effective January 1, 2023, prior to selling or offering to sell any Kratom product in this state, each Kratom processor shall:

(a) Register with the department in the form and manner determined by the executive director by rule; and

(b) Pay an initial registration fee and, thereafter, an annual renewal fee in the amount determined by the executive director by rule.

(2) Except as provided in subsection (3) of this section, effective January 1, 2023, prior to selling or offering to sell any Kratom product in this state, each Kratom processor shall provide the department with:

(a) A list of each of the processor's Kratom products that the processor offers for sale or sells in this state;

(b) For each Kratom product:

(I) A certificate of analysis;

(II) The name and address of the person whose name will appear on the product label, if the person is not the processor;

(III) Whether the product is a food, powder, capsule, pill, beverage, or some other edible form;

(IV) The recommended usage amount and corresponding
USAGE DIRECTIONS;

(V) THE WEIGHT OR VOLUME OF THE PACKAGE OF KRATOM PRODUCT AND THE RECOMMENDED INDIVIDUAL SERVING SIZE OR AMOUNT; AND

(VI) A COMPLETE COPY OF THE LABEL THAT WILL APPEAR ON THE KRATOM PRODUCT OR THAT CAN BE VIEWED VIA A SCANNABLE BAR CODE OR WEBSITE ADDRESS;

(c) A CERTIFICATE OF ANALYSIS FOR THE KRATOM PRODUCT FROM AN ACCREDITED LABORATORY THAT TESTS FOR THE PURITY OF FOOD PRODUCTS; AND

(d) IF THE KRATOM PRODUCT THAT THE PROCESSOR IS OFFERING FOR SALE OR SELLING IS A KRATOM EXTRACT, A WRITTEN ACKNOWLEDGMENT THAT ALL FOOD-GRADE SOLVENTS USED IN MANUFACTURING THE KRATOM EXTRACT COMPLY WITH THE APPLICABLE PRODUCT LIMITATIONS IN THE UNITED STATES PHARMACOPEIA.

(3) A KRATOM PROCESSOR IS NOT REQUIRED TO DISCLOSE ANY INFORMATION THAT IS A TRADE SECRET, AS DEFINED IN SECTION 7-74-102.

44-15-104. Kratom products - limitations - enforcement - penalties. (1) A KRATOM PROCESSOR SHALL NOT PREPARE, DISTRIBUTE, SELL, OR OFFER FOR SALE:

(a) A KRATOM PRODUCT THAT:

(I) IS MIXED OR PACKED WITH A NONKRATOM SUBSTANCE THAT AFFECTS THE QUALITY OR STRENGTH OF THE KRATOM PRODUCT TO SUCH A DEGREE AS TO RENDER THE KRATOM PRODUCT INJURIOUS TO A CONSUMER;

(II) CONTAINS A POISONOUS OR OTHERWISE HARMFUL
NONKRATOM INGREDIENT, INCLUDING ANY SUBSTANCE LISTED IN PART 2
OF ARTICLE 18 OF TITLE 18;

(III) HAS A LEVEL OF 7-HYDROXYMITRAGYNINE IN THE ALKALOID
FRACTION THAT IS GREATER THAN TWO PERCENT OF THE OVERALL
ALKALOID COMPOSITION OF THE KRATOM PRODUCT;

(IV) HAS SYNTHETIC ALKALOIDS, INCLUDING SYNTHETIC
MITRAGYNINE, SYNTHETIC 7-HYDROXYMITRAGYNINE, OR ANY OTHER
SYNTETICALLY DERIVED COMPOUNDS OF THE PLANT MITRAGYNA
SPECIOSA;

(V) DOES NOT INCLUDE A LABEL WITH ADEQUATE DIRECTIONS
NECESSARY FOR SAFE AND EFFECTIVE USE BY A CONSUMER, INCLUDING A
RECOMMENDED SERVING SIZE; AND

(VI) BEARS A LABEL THAT MAKES CLAIMS THAT THE KRATOM
PRODUCT IS INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT A
MEDICAL CONDITION OR DISEASE; OR

(b) A KRATOM EXTRACT WITH LEVELS OF RESIDUAL SOLVENTS
THAT ARE HIGHER THAN THE LEVELS ALLOWED BY THE UNITED STATES
PHARMACOPEIA.

(2) (a) A KRATOM PROCESSOR THAT VIOLATES THIS SECTION IS
SUBJECT TO A FINE OF FIVE HUNDRED DOLLARS FOR THE FIRST OFFENSE,
TWO THOUSAND FIVE HUNDRED DOLLARS FOR THE SECOND OFFENSE, AND
FIVE THOUSAND DOLLARS FOR THE THIRD OR ANY SUBSEQUENT OFFENSE.
A KRATOM PROCESSOR SHALL DISCONTINUE SELLING OR OFFERING TO SELL
EACH KRATOM PRODUCT THAT FAILS TO MEET THE STANDARDS
ESTABLISHED IN THIS SECTION, AND THE KRATOM PROCESSOR SHALL NOT
RESUME THE SALE OF THE KRATOM PRODUCT UNLESS THE PRODUCT
COMPLIES WITH THE STANDARDS SPECIFIED IN THIS SECTION.
(b) The department may revoke the registration of a kratom processor, order a kratom product to be permanently removed from sale, or prohibit a processor from reapplying for registration as a kratom processor for a period of up to three years if:

(I) the kratom processor has more than three violations within a five-year period; or

(II) the department determines that a kratom processor's violation of this section was willful.

44-15-105. Kratom products - age limitations. A kratom processor may not distribute, sell, or offer for sale a kratom product to an individual under eighteen years of age.

44-15-106. Adverse events - mandatory reporting - investigations. (1) A kratom processor shall notify the department within seven days after being notified that an adverse event has been reported to the federal food and drug administration for one of the processor's kratom products.

(2) When notified of an adverse event pursuant to subsection (1) of this section, the department may investigate whether the kratom processor violated this article 15.

(3) If the department opens an investigation into an adverse event, the kratom processor, at the request of the department, shall provide the department with a current certificate of analysis for the kratom product for which the adverse event was filed.

44-15-107. Rules. The executive director shall promulgate rules as necessary for the administration and enforcement of
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.