SENATE FLOOR VERSION
April 11, 2024

ENGROSSED HOUSE
BILL NO. 3574 By: Pae of the House

and

Prieto of the Senate

An Act relating to public health and safety; amending 63 O.S. 2021, Sections 1-1432.2 and 1-1432.4, which relate to the Oklahoma Kratom Consumer Protection Act; adding and modifying definitions; providing restrictions on the preparation, distribution, or sale of certain kratom products; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. AMENDATORY 63 O.S. 2021, Section 1-1432.2, is amended to read as follows:

Section 1-1432.2 As used in this act:

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

2. "Kratom leaf" means the leaf of the kratom plant, Mitragyna speciosa, in fresh or dehydrated or dried form that undergoes no post-harvest processing other than drying or size reduction by cutting, milling, or similar procedure, and may be cleaned or sterilized using standard treatments applied to food ingredients, such as heat, steam, pressurization, or irradiation or other

standard treatments applied to food ingredients. The total alkaloid content of kratom leaf material used in the kratom product shall not exceed three and one-half percent (3.5%) measured on a dried weight-to-weight basis;

3. "Kratom leaf extract" means the material obtained by extracting kratom using a solvent consisting of:

a. water, ethanol, or food-grade carbon dioxide (CO_2), or

b. any other solvent allowed by federal or state regulation for use in manufacturing a food ingredient.

The extracted material shall contain mitragynine as the most abundant alkaloid, measured on a weight-to-weight basis, and at a level that is equal to or exceeds twice that of any other alkaloid present. The ratio of mitragynine to other alkaloids in the extract shall be equal to or greater than the ratio found in the starting material;

4. "Kratom product" means a food ~~product~~ or ~~ingredient containing any part of the~~ dietary supplement that consists of or contains kratom leaf ~~of the plant *Mitragyna speciosa*~~ or kratom leaf extract that does not contain any synthesized kratom alkaloids, other kratom constituents, or synthesized metabolites of any kratom constituent in which the level of 7-hydroxymitragynine, on a percent weight basis, is not greater than one percent (1%) of the amount of total kratom alkaloids, as confirmed with a high-performance liquid chromatography testing method. For purposes of this paragraph,

"synthesized" refers to substances produced using directed synthetic or biosynthetic chemistry, as opposed to traditional food preparation techniques such as heating or extracting; ~~and~~

~~3.~~ 5. "Total kratom alkaloids" means the sum of mitragynine, speciociliatine, speciogynine, paynantheine, and 7-hydroxymitragynine; and

6. "Vendor" means a person that sells, prepares or maintains kratom products or that advertises, represents or holds itself out as selling, preparing or maintaining kratom products and includes a manufacturer, wholesaler, store, restaurant, hotel, catering facility, camp, bakery, delicatessen, supermarket, grocery store, convenience store, nursing home or food or drink company.

SECTION 2. AMENDATORY 63 O.S. 2021, Section 1-1432.4, is amended to read as follows:

Section 1-1432.4 A. A vendor shall not prepare, distribute, sell or expose for sale any of the following:

1. A kratom product that ~~is adulterated with a nonkratom substance. A~~ does not meet the definition for a kratom product ~~is adulterated with a nonkratom substance if the kratom product is mixed or packed with a nonkratom substance and that substance affects the quality or strength of the kratom product to such a degree as to render the kratom product injurious to a consumer~~ pursuant to Section 1-1432.2 of this title;

2. A kratom product that is contaminated with a dangerous nonkratom substance. A kratom product is contaminated with a dangerous nonkratom substance if the kratom product contains a substance that is not safe for human consumption;

3. A kratom product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than ~~two~~ one percent ~~(2%)~~ (1%) of the alkaloid composition of the product;

4. A kratom product containing any ~~synthetic~~ synthesized alkaloid including ~~synthetic~~ synthesized mitragynine, ~~synthetic~~ synthesized 7-hydroxymitragynine or any other ~~synthetically derived~~ synthesized compounds of the kratom plant; ~~or~~

5. A kratom product containing any controlled substance listed in the Uniform Controlled Dangerous Substances Act, unless the product is compounded by a licensed pharmacist with the controlled substance dispensed in accordance with a valid prescription; or

6. A kratom product containing a level of any residual solvent that was used in the manufacturing of the extract that exceeds the residual level specified for pharmaceutical products in the document "Q3C - Tables and List, Guidance for Industry, [June 2017] ICH Revision 3" issued by the United States Department of Health and Human Services, Food and Drug Administration.

B. Kratom products shall be accompanied by a label~~, or a quick response (QR) code on the product label linked to a website,~~ bearing the following information prior to its sale in this state:

1. A list of the ingredients, which shall include the common or usual name of each ingredient used in the manufacture of the product, listed in descending order of predominance;

2. That the sale or transfer of kratom to a person under eighteen (18) years of age is prohibited;

3. The amount of total kratom alkaloids, mitragynine, and 7-hydroxymitragynine contained in the product;

4. The amount of total kratom alkaloids, mitragynine, and 7-hydroxymitragynine contained in packaging for the product;

5. The name and the principal street address of the vendor or the person responsible for distributing the product;

6. ~~The suggested~~ Any federal food allergen labeling requirements, if applicable, and clear and adequate directions for the consumption and safe and effective use of ~~the~~ such product, including the recommended serving size, the number of servings in the container, and the number of servings that can be safely consumed in a day. Provided, liquid kratom products shall be packaged in a retail container that has clear serving size markings and be subject to the following requirements:

a. products of less than eight (8) fluid ounces which contain more than three servings shall be accompanied by a calibrated measuring device, and

b. if such a product contains more than the eight (8) fluid ounces, the requirements specified in subparagraph a of this paragraph do not apply.

Provided further, packaging for powdered kratom products not in capsule form shall have a calibrated measuring device included in the container; ~~and~~

7. Any precautionary statements as to the safety and effectiveness of the product, including a warning that a consumer should consult a health care professional on questions about the use of kratom, that the product may be habit-forming, and a statement that the kratom product is not intended to "diagnose, treat, cure, or prevent any disease"; and

8. A statement that a kratom product label is prohibited from making any therapeutic claims unless approved by the United States Food and Drug Administration.

C. A vendor may not distribute, sell or expose for sale a kratom product to an individual under eighteen (18) years of age.

D. Upon request by the State Department of Health, the vendor shall provide test results from a United States-based testing facility to confirm the items listed on the product label.

SECTION 3. This act shall become effective November 1, 2024.

COMMITTEE REPORT BY: COMMITTEE ON HEALTH AND HUMAN SERVICES
April 11, 2024 - DO PASS