Kratom Product Regulation and Accountability Act

Summary: This model bill creates a state regulatory framework for the production and sales of products containing kratom or kratom alkaloids. It specifies the types of kratom products permissible for sale, prescribes manufacturing and testing standards for allowable kratom products, imposes labeling requirements, restricts the sale of kratom products to persons below the age of 21, and imposes civil and criminal penalties on manufacturers or retailers of kratom products who fail to comply with the standards set forth in this bill.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF _____:

Section 1. Short Title.

This Act shall be known and may be cited as the "Kratom Product Regulation and Accountability Act."

Section 2. Purpose.

The purpose of this Act is to:

(a) protect consumers from mislabeled or adulterated kratom products by imposing accountability on the manufacturers of these products; and

(b) prevent the marketing or sales of kratom products to children.

Section 3. Definitions.

For the purposes of this Act:

(a) "**Attractive to children**" means a product packaged with labeling that includes a cartoon character, an animal, or other image that the department, by rule, determines is intended to illicit the interest of children or which is packaged in a form that resembles any existing candy or cereal product.

(b) "**Department**" means the department of health and social services.

(c) **"Minimally processed kratom product"** means a finished kratom product consisting of dried kratom leaf, powder, capsule, tablet, or beverage that has not undergone chemical

extraction, concentration, alkaloid enrichment, or the addition of isolated or synthesized kratom alkaloids.

(d) "**Finished kratom product**" means a kratom product that is ready for sale to the end user. For purposes of registration, a finished kratom product is differentiated by its ingredients, not by its weight, volume or size.

(e) "**Food service establishment**" means any establishment providing or serving food directly to consumers that is regulated by the department or local public health agencies.

(f) "**Kratom"** means the plant or any part of the plant *Mitragyna speciosa* in any form.

(g) **"Kratom beverage"** means a prepackaged liquid kratom product in the form of a tea, a seltzer or tonic water, or a tincture.

(h) **"Kratom product"** means a food product, food ingredient, dietary ingredient, dietary supplement, or beverage intended for human consumption that contains any part of the leaf of the plant *Mitragyna speciosa* and is manufactured as a powder, capsule, pill, beverage, or other consumable form.

(i) **"Enhanced kratom product"** means a finished kratom product that has undergone chemical extraction, concentration, or alkaloid enrichment, or to which isolated or synthetized kratom alkaloids have been added.

(j) **"Processor"** is an entity that:

1. Refines kratom into input ingredients for the purpose of manufacturing a finished kratom product;

2. Manufactures finished kratom products; or

3. Packages finished kratom products for resale.

Section 4. Retail sales of kratom products.

(a) General retail access. Minimally processed kratom products may be sold in any retail establishment authorized to sell age-restricted products, including convenience stores, gas stations and pharmacies, provided that:

(1) The establishment verifies that the purchaser is twenty-one years of age or older; and

(2) The products comply with the testing, labeling, and packaging requirements of this Act.

(b) Enhanced kratom products shall be sold only in establishments that restrict entry to persons who are twenty-one years of age or older and require age verification.

(c) Kratom products shall not be served in a form that combines or mixes finished kratom products with psychoactive substances that impact the central nervous system including, but not limited to, alcohol, caffeine, kava, cannabinoids, and nicotine.

(d) All kratom products held in inventory at a retail establishment, a convenience store, or a kava or kratom bar in this state must be secured in an enclosed, locked space.

Section 5. Packaging of kratom products.

Finished kratom products sold to consumers at a retail establishment, a convenience store, or a kava or kratom bar in this state:

(a) Shall be in one of the following delivery forms:

(1) Dried leaf;

(2) Kratom beverage;

(3) Powder;

(4) Pill;

(5) Liquid dietary supplement;

(6) Gummy or food that is not attractive to children; or

(7) Capsule;

(b) Shall possess a certificate of analysis that has been submitted to the department as required under Section 6(e);

(c) Shall be registered with the department;

(d) Shall include directions for consumption of the kratom product on the product's label including, but not limited to:

(1) Maximum dosage of one hundred milligrams of kratom alkaloids per serving;

(2) Number of servings per package;

(3) Milligrams of 7-hydroxymitragynine and mitragynine per serving;

(4) A warning advising consumers of the number of servings that may be safely consumed in a twenty-four-hour period;

(5) A warning prohibiting use by individuals who are under twenty-one years of age;

(6) A warning advising against use by individuals who are pregnant or breast- feeding;

(7) A warning advising against use by individuals who also consume known contraindicated drugs, including, but not limited to: opioids, benzodiazepines, sleep aids, muscle relaxants, selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, antihistamines that cause drowsiness, or alcohol.

(8) A warning advising the consumer to consult a health care professional before use, that the product may be habit-forming, and that it may cause adverse health effects;

(9) A warning stating the following: "These statements have not been evaluated by the United States Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.";

(10) The expiration date; and

(11) The name and place of business of the registrant;

(e) Shall comply with the packaging and labeling requirements set forth in this chapter and the rules adopted thereunder;

(f) Shall not be attractive to children;

(g) Shall be in a container that:

(1) Is suitable to contain products for human consumption;

(2) Is compliant with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. Section 1471 et seq.; and

(c) Contains a graduated measuring device, if applicable.

Section 6. Kratom product manufacturing.

(a) Kratom products shall be manufactured or distributed in this state only by a processor who is subject to and in compliance with all state laws and regulations applicable to food processors.

(b) A processor that manufactures, processes, packs, or offers for sale kratom, kratom products, or finished kratom products shall be properly registered with the United States Food and Drug Administration.

(c) A processor shall comply with Current Good Manufacturing Practices contained in 21 CFR Part 210.

(d) A processor shall maintain product liability insurance with an occurrence limit of three million dollars.

(e) For each batch of a registered finished kratom product, the processor shall retain and submit, upon request, a certificate of analysis to the department from an accredited laboratory. The laboratory shall be accredited under the International Organization for Standardization

(ISO)/International Electrotechnical Commission (IEC) 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories standard by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement or a subsequent arrangement. The processor shall not have any direct or indirect financial or economic interest in the laboratory or accrediting body. The processor shall maintain the certificates of analysis for a minimum of one year after the finished kratom product's expiration date. The certificate of analysis shall demonstrate that the finished kratom product is in compliance with the statutory and rule concentration limits for:

(1) Alkaloid and alkaloid metabolites;

(2) Residual solvents;

(3) Heavy metals including, but not limited to, cadmium, arsenic, mercury, and lead;

(4) microbes; and

(5) Pesticides and any substance limited by rule of the department.

(f) A finished kratom product served by a kratom food service establishment shall be registered with the department and comply with the requirements of this Act, except that a separate registration under this Act is not required when a kratom beverage is combined with another food or beverage by the kratom food service establishment for consumption on premises. It is unlawful to serve kratom beverages combined with alcohol, drugs, or other kratom products.

(g) Section 5 shall not apply to finished kratom products processed or manufactured in this state and subsequently shipped or transported out of this state for sale or use outside of this state.

(h) Finished kratom products produced in this state and subsequently shipped or transported out of this state for sale or use outside of this state:

(1) Shall not be sold, shipped, or transported to a consumer in this state, to a retail establishment in this state, or to a person who sells or intends to sell such products to a consumer in this state;

(2) Shall be in a package marked "NOT FOR USE OR RETAIL SALE IN [THIS STATE]" in a bold font size of at least thirty-six points; and

(3) Shall be physically separated from finished kratom products that are, or are intended to be, sold or used in this state.

Section 7. Adulterants and adverse events.

(a) A processor shall not offer for sale any finished kratom product that that processor has reasonable cause to suspect is adulterated, either as a result of the certificate of analysis or for any other cause. Impermissible adulterants include, but are not limited to, metals, pesticides, or pathogens in excess of the limits established by this Act or department rule.

(b) If a processor or the department receives notice of any adverse health event suspected to be related to the processor's kratom product, the processor or the department shall submit an adverse event report as set out in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 379aa-1(b)(1), to the United States Food and Drug Administration.

(c) If probable cause exists that a kratom product may be adulterated, the department may require an independent third-party test of the kratom product by a laboratory of the department's choice, and the processor shall pay the cost of the test. If the processor does not make such payment to the department within thirty days after receiving the invoice for the testing fee, the department shall revoke the registration for that product.

Section 8. Importation of kratom and kratom-derived products

(a) A wholesaler, distributor, or retailer may import kratom and kratom-derived products manufactured outside the boundaries of this state with the intent to sell those products in-state if the out-of-state manufacturer or processor has:

(1) Registered with the Department on a form prescribed by the Department;

(2) Paid an annual registration fee of $200 per product, not to exceed $5,000 annually per manufacturer;

(3) Provided documentation demonstrating that the out-of-state manufacturer holds a valid permit or license to produce kratom products in its home-state, if such state regulates kratom products; and

(4) Provided documentation demonstrating that the home-state regulations of kratom product manufacturing or processing are compliant with Section 6 of this act.

(b) In lieu of the documentation required under subsection (3) and (4) of this Section, an out-of-state manufacturer from a state that does not regulate kratom manufacturing or processing may certify compliance with this Act by:

(1) Submitting to the Department a certificate of analysis from an ISO-IEC 17025-accredited laboratory for each batch, demonstrating compliance with subsection (e) of Section 6; and

(2) Attesting under penalty of perjury that the product was manufactured, tested, and packaged in full compliance with Sections 5, 6, and 7 of this Act.

(c) The Department shall maintain a publicly available list of out-of-state manufacturers registered under this section. The Department may revoke or suspend a registration for cause, including failure to comply with any provision of this Act.

(d) Products imported under this section shall bear labeling that identifies the out-of-state manufacturer by name, address, and registration number issued by the Department.

(e) An out-of-state manufacturer that sells, ships, or causes to be shipped kratom products into this state in violation of this Act is subject to:

(1) A civil penalty of not less than $1,000 or more than $10,000 per violation; and

(2) Embargo and destruction of noncompliant products at the manufacturer's expense; and

(3) Injunctive relief.

Section 9. Penalties.

(a) A violation of Section 6 is a class B misdemeanor.

(b) A processor that manufactures, delivers, offers for sale, distributes, or sells a finished kratom product that violates subdivision (b) or (c) of Section 5 shall be guilty of a class B misdemeanor.

(c) Kratom products possessed, manufactured, delivered, offered for sale, distributed, or sold in violation of this Act by an entity regulated under this Act may be detained or embargoed by the department, and the entity in violation is subject to all penalties and remedies established by the department by rule, including an administrative fine not to exceed $10,000 for the first instance. The department shall not grant permission to remove or use, except for disposal, detained or embargoed finished kratom products that are attractive to children until the finished kratom products comply with all provisions of this Act.

(d) If a processor fails to provide the department with a certificate of analysis within seven days after receiving a request from the department or fails to immediately report an adverse health event to the department as required by Section 7, the department may revoke the processor's finished kratom product registration.

(e) A processor that manufactures, delivers, offers for sale, distributes, or sells a kratom product that contains any controlled substance or adulterants is in violation of sections this Act.

(f) A laboratory that fails to ensure the accuracy of its certificates of analysis issued in compliance with this Act is subject to an administrative fine in an amount determined by the department by rule.

Section 10. Rulemaking.

The department shall promulgate all necessary rules and regulations for the administration of this Act.