HB3215

LRB10408737BDA18791b

104TH GENERAL ASSEMBLY

State of Illinois

2025 and 2026

HB3215

Introduced 2/18/2025, by Rep. Marcus C. Evans, Jr.

SYNOPSIS AS INTRODUCED:

New Act

Creates the Illinois Kratom Consumer Protection Act. Provides for procedures for kratom product registration, with certain requirements. Provides for labeling requirements for kratom products. Provides for enforcement and criminal and other penalties. Exempts a processor for any kratom products that has been reviewed and approved by the Department for safe consumption in combination with psychoactive compounds under clearly defined conditions of use. Exempts a retailer if it is shown by a preponderance of the evidence that the retailer relied in good faith upon the representations of certain entities. Requires the Department of Financial and Professional Regulation to adopt rules, with certain requirements. Conditions rulemaking upon federal promulgation of regulations in certain circumstances. Defines terms.

LRB104 08737 BDA 18791 b

A BILL FOR

AN ACT concerning kratom.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 1. Short title. This Act may be cited as the Illinois Kratom Consumer Protection Act.

Section 5. Definitions. As used in this Act:

"Attractive to children" means (i) in the shape of cartoons or animals or (ii) in a form that bears any reasonable resemblance to an existing candy product that is familiar to the public as a widely distributed, branded food product such that a product could be mistaken for the branded product, especially by children.

"Department" means the Department of Financial and Professional Regulation.

"Distributor" means a person that sells, prepares, distributes, or maintains kratom products, or advertises, represents, or holds itself out as selling, preparing, or maintaining kratom products.

"Independent testing laboratory" means a laboratory that is accredited by a third-party accrediting body as a competent testing laboratory pursuant to ISO/IEC 17025 of the International Organization for Standardization.

"Kratom" means the plant Mitragyna speciosa or any part of

that plant, including all components present in the natural plant.

"Kratom extract" means a substance or compound obtained by extraction of the Mitragyna speciosa leaf, intended for ingestion, containing more than trace amounts of Mitragyna speciosa and containing other alkaloids of the kratom plant, which does not contain any controlled substances or levels of residual solvents higher than is allowed in the U.S. Pharmacopeia 467.

"Kratom food service establishment" means any person who sells kratom as a beverage prepared on-site, or sells pre-packaged kratom beverages or finished kratom products, at a licensed food service establishment.

"Kratom product" means a food, food ingredient, dietary ingredient, dietary supplement, or beverage intended for human consumption which contains any part of the leaf of the plant Mitragyna speciosa or an extract of the Mitragyna speciosa leaf and is manufactured or served as a powder, capsule, pill, beverage, liquid, or other edible form.

"Registrant" means a person or processor that sells, prepares, manufactures, distributes, or maintains kratom products, or advertises, represents, or holds itself out as selling, preparing, or maintaining kratom products.

"Retailer" means any person that sells, distributes, advertises, represents, or holds itself out as selling kratom products.

"Synthesized material" means an alkaloid or alkaloid derivative that has been created by chemical synthesis or biosynthetic means, including, but not limited to, fermentation, recombinant techniques, yeast derived, or enzymatic techniques, rather than traditional food preparation techniques, such as heating or extracting that synthetically alters the composition of any kratom alkaloid or constituent.

Section 10. Kratom Product Limitations. No person shall prepare, distribute, sell, or expose for sale any of the following:

(1) A product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 2% of the alkaloid composition of the kratom product. Any product that contains a level of 7-hydroxymitragynine greater than the 2% limit as provided in this paragraph cannot be marketed, labeled, or contain any reference on its packaging, that it is a kratom product or that it is derived from the alkaloid mitragynine.

(2) A kratom product that is adulterated with a dangerous non-kratom substance. A kratom product is adulterated with a dangerous non-kratom substance if it contains a poisonous or otherwise deleterious non-kratom ingredient, including, but not limited to, the substances listed as a controlled substances under State or federal

law.

(3) A kratom product that contains dangerous psychoactive compounds, which include, but are not limited to, synthetic cannabinoids, synthetic cathinones, or any other compound that significantly alters the safety profile of the kratom product. A kratom product is mixed with another compound that is known to inhibit key cytochrome P450 enzymes, including CYP3A4 or CYP2D6 or a combination of CYP3A4 and CYP2D6, shall be deemed to be adulterated unless such specific product mixtures are scientifically validated as safe under the intended conditions of use and are specifically permitted by the Department.

(4) A kratom product in any form that is combustible, intended to be used for vaporization, or injectable.

(5) A product containing kratom that does not fall into the definition of "kratom product" as defined in Section 5 is prohibited.

(6) A kratom product that is manufactured in a manner that is attractive to children.

(7) A kratom product that contains any synthesized material as defined in Section 5 or that contains alkaloids or other plant constituents that have been isolated or manipulated to artificially increase their potency, other than using the approved extraction method provided herein, unless the manufacturer has safety data

to support the increased potency according to the conditions for use on the label in the populations the data supports.

(8) A substance or compound obtained by extraction of the Mitragyna speciosa leaf, intended for ingestion, containing more than trace amounts of Mitragyna speciosa, that contains levels of residual solvents higher than in the definition of "kratom extract" in Section 5.

Section 15. Kratom product registration.

(a) The party responsible for placing a kratom product into commerce in the State shall register annually to offer for sale kratom products manufactured in an approved kratom delivery form and pay a fee, adjusted annually, to cover all administrative costs for processing and administering such registrations, including the necessary staff and the publication and maintenance of a kratom registration webpage as provided in subsection (e) of this Section.

(b) Parties seeking to register a product listed under Section 10 shall be required to pay a fee based on the costs the Department incurs to retain the services of qualified experts to review the safety data provided by the registrant to allow the Department to conduct a review and make a final decision.

(c) The registration shall include the following sworn

certifications from the processor:

(1) The kratom product was manufactured, processed, or held in a facility that is in compliance with current good manufacturing practices that meet requirements of 21 CFR 111.

(2) A statement that the processor has a reasonable basis that the product is safe for consumption under the conditions of use set forth on the label. The registrant assumes responsibility and liability for any such products offered for sale.

(3) The submission of a certificate of analysis from a certified independent third-party laboratory showing compliance with the requirements of this Act for residual solvents, 7-hydroxymitragynine content, contaminants, and synthesized materials.

(d) A product that contains the same kratom ingredients in the same kratom delivery form, but a different container, package, or volume, shall be included in a single registration.

(e) The Department shall publish and maintain a kratom registration page on its official website listing all currently registered kratom products for sale by retailers that allows retailers to verify registered kratom products they are permitted to sell to consumers.

Section 20. Labeling.

A kratom product produced, manufactured, distributed, offered, sold, or offered for sale shall have a label that clearly and conspicuously provides all of the following information on each retail package:

(1) A statement against the use by individuals who are under 21 years of age, who are pregnant, or who are breastfeeding.

(2) A recommendation to consult a health care professional prior to use.

(3) A statement that kratom may be habit forming.

(4) The following statement: "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."

(5) The name and the address for the place of business of the registrant.

(6) Directions for use that include the following:

(A) A recommended amount of the kratom product per serving that is (i) clearly described on the label for product forms such as capsules, gummies, prepackaged single serving units, and similar product forms; or (ii) for beverages, liquids, or loose powders, a clear instruction or a mark on the package or container that clearly informs the consumer on the recommended serving size.

(B) A recommended number of servings that can be

safely consumed in a 24-hour period.

(C) A listing of the servings per container.

(D) A listing of kratom alkaloids and other ingredients in the product, including quantitative data not to exceed declarations of the amount per serving of each of the following: (i) Mitragynine and (ii) 7-hydroxymitragynine.

(E) A kratom food service establishment who sells kratom as a beverage prepared on-site shall provide an equivalent label in card form or prominently display the required language in a location next to the point-of-sale device to the customer at the time the beverage is purchased by the consumer.

(F) Any kratom product that contains psychoactive compounds otherwise permitted must be clearly labeled with a full disclosure of all active ingredients, the exact concentration of each compound, and adequate warning statements about the potential interactions and risks associated with the combined use of these substances.

Section 25. Enforcement.

(a) A registrant is prohibited from selling any kratom product that does not have a current registration with the Department, a distributor is prohibited from distributing any kratom product that does not have a current registration with

the Department, and a retailer is prohibited from selling any kratom product that does not have a current registration with the Department. Any kratom product not registered shall be seized and destroyed, and the costs associated with such enforcement shall be assessed to the party responsible for its availability for sale in the State.

(b) Kratom products that are intended for human ingestion may not be sold in this State to a person who is under 21 years of age. A person who knowingly and willfully violates this subsection commits a Class B misdemeanor. A person who knowingly and willfully commits a second or subsequent violation of this subsection within one year after the initial violation commits a Class A misdemeanor.

(c) A registrant that knowingly and willfully manufactures, delivers, holds, offers for sale, distributes or sells a kratom product that contains any controlled substance listed in State or federal law shall be guilty of a Class 4 felony.

(d) A registrant that knowingly and willfully manufactures, delivers, holds, offers for sale, distributes or sells a kratom product that contains synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compound of the plant Mitragyna speciosa commits a Class B misdemeanor. Any violation of this subsection shall result in the immediate seizure and destruction of the adulterated kratom products and may result in civil or

criminal penalties as provided in State law. Repeat offenders shall be subject to enhanced penalties, including permanent revocation of licenses to sell or distribute kratom products.

(e) Upon receipt of a violation report on any kratom product offered for sale, the Department shall require the registrant to produce an updated and current certificate of analysis in a reasonable time frame from a certified independent third-party laboratory showing compliance with the requirements of this Act for safe kratom products. If the registrant does not provide the certificate of analysis in the specified time frame, the registration for that product shall be revoked and a stop sales order will be issued for products covered by this registration.

(f) If the Department has a reasonable basis to require an independent third-party test of a registered kratom product by a laboratory of the Department's choice, the registrant shall be required to submit payment for the test within a reasonable time frame. If the registrant does not tender payment to the Department within 30 days of receipt of the invoice for the testing, the Department shall revoke the registration for that product and a stop sales order will be issued for products covered by this registration.

(g) A processor does not violate this Section for any kratom product that has been reviewed and approved by the Department for safe consumption in combination with psychoactive compounds under clearly defined conditions of

use.

(h) A retailer does not violate this Section if it is shown by a preponderance of the evidence that the retailer relied in good faith upon the representations of a manufacturer, processor, packer, or distributor of food represented to be a kratom product.

Section 30. Rules.

(a) The Department shall adopt rules to implement this Act. The rules must provide for:

(1) The process for a registration of a kratom product by a processor, distributor, or a retailer.

(2) The requirements for enforcing the restriction on the sale of any kratom product to a person under the age of 21.

(3) Proof of appropriate quality testing from an ISO 17025 laboratory in the form of a Certificate of Analysis representing the product does not contain levels of residual solvents, biological contaminants or heavy metal contaminants that meet the standard for dietary supplement products.

(b) If at any time on or after the effective date of this Act, the federal government or any department or agency thereof, including but not limited to the federal Drug Enforcement Agency or Food and Drug Administration, regulates 7-hydroxymitragynine, 7-hydroxymitragynine extracts,

7-hydroxymitragynine products, any other derivative of the plant Mitragyna speciosa, 7-hydroxymitragynine processors, or 7-hydroxymitragynine retailers, including the acceptance by the Food and Drug Administration of a new dietary ingredient notification, the Department of Financial and Professional Regulation may adopt rules not inconsistent with such federal regulations.

Section 35. Federal preemption. If at any time on or after the effective date of this Act, the federal government or any department or agency thereof, including but not limited to the federal Drug Enforcement Agency or Food and Drug Administration, regulates 7-hydroxymitragynine, 7-hydroxymitragynine extracts, 7-hydroxymitragynine products, any other derivative of the plant Mitragyna speciosa, 7-hydroxymitragynine processors, or 7-hydroxymitragynine retailers, including the acceptance by the Food and Drug Administration of a new dietary ingredient notification, those federal regulations shall supersede and take precedence over any provision of this Act and any rule adopted thereunder to the contrary that is addressed by the federal action.