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Bill Analysis

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Primary Sponsor: Sen. Blessing

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SUMMARY

- Requires food processing establishments and retail food establishments to register kratom products with the Director of Agriculture.
- Prohibits food processing and retail food establishments from processing, manufacturing, selling, or engaging in related activities involving a kratom product unless the product meets specified standards.
- Requires food processing and retail food establishments to disclose on a kratom product's label the basis on which it is representing a food as a kratom product.
- Prohibits food processing and retail food establishments from selling or distributing kratom products to individuals under 18.
- Requires the Director of Agriculture (and Director of Health with respect to retail food establishments) to adopt rules regarding kratom products.
- Exempts those rules from requirements governing the elimination of existing regulatory restrictions.
- Creates a civil cause of action for someone adversely affected by a violation of the requirements concerning kratom products.
- Names the bill the "Kratom Consumer Protection Act."

DETAILED ANALYSIS

Registration of kratom products

The bill requires kratom products to be registered with the state as a condition of being processed, manufactured, or sold by food processing and retail food establishments. For food processing establishments and retail food establishments, the products must be registered with the Director of Agriculture. "Kratom product," for purposes of the bill, is any food that contains

any part of a leaf of the plant *Mitragyna speciosa*. A food processing establishment is a premises or part of a premises where food is processed, packaged, manufactured, or otherwise held or handled for distribution to another location or for sale at wholesale (e.g. a food production factory). A retail food establishment is a premises or part of a premises where food is stored, processed, prepared, manufactured, or otherwise held or handled for retail sale (e.g a grocery store).¹

Kratom (*Mitragyna speciosa*) is a tropical tree native to Southeast Asia. Consumption of its leaves produces both stimulant effects (in low doses) and sedative effects (in high doses). Kratom is mostly used through oral ingestion in the form of a tablet, capsule, or extract. Kratom leaves may also be dried or powdered and ingested as tea, or they may be chewed.²

Activities requiring registration

Under the bill, a food processing establishment may not process, package, manufacture, hold or handle for distribution, distribute, or sell a kratom product without first registering the product.³ A retail food establishment license holder may not store, process, prepare, manufacture, hold or handle for retail sale, or sell a kratom without first registering the product.⁴

Standards for kratom products

The bill places several requirements on kratom products and on food processing and retail establishments that have registered their kratom products.

Product contents

A kratom product must satisfy all of the following standards regarding its content:

- The product cannot be mixed or packed with a nonkratom substance that affects the quality or strength of the kratom product and renders it injurious to a potential consumer;
- The product cannot contain a poisonous or otherwise deleterious nonkratom ingredient, including a controlled substance;
- The product cannot contain a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 1% of the alkaloid composition of the kratom product;

¹ R.C. 3715.01(A)(22) and 3717.01(T); R.C. 3715.021, not in the bill.

² U.S. Drug Enforcement Administration, *Drugs of Abuse: A DEA Resource Guide* (2017 edition), Chapter XI. Drugs of Concern: Kratom, available at: https://www.dea.gov/sites/default/files/drug_of_abuse.pdf.

³ R.C. 3715.026(A).

⁴ R.C. 3717.34(A).

- The product cannot contain a synthetic alkaloid, including synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compound of kratom;
- The product must include a product label that states the amount of mitragynine and 7-hydroxymitragynine contained in the product.⁵

A food processing establishment or retail food establishment license holder who recklessly violates the requirements regarding the content of a kratom product is guilty of a second degree misdemeanor.⁶ The bill specifies, however, that a food processing or retail food establishment does not violate the content requirements if the establishment demonstrates by a preponderance of the evidence that it relied in good faith on the representation of another food processing or retail food establishment that the kratom product meets all of the requirements.⁷

Labeling requirements

The bill further provides that a food processing or retail food establishment may not distribute or sell a kratom product without disclosing on the product's label the factual basis on which the establishment represents the food as a kratom product.⁸

Age restrictions

A food processing or retail food establishment may not sell or distribute a kratom product to an individual under 18.⁹ Under the bill, any person who recklessly sells or distributes a kratom product to an individual under 18 is guilty of a second degree misdemeanor.¹⁰

Rulemaking

The bill requires the adoption of rules regarding kratom products. In the case of food processors, the rules are to be adopted by the Director of Agriculture. In the case of retail food establishments, the rules are to be adopted by the Director of Agriculture and Director of Health.

Specifically, the Directors must adopt rules that establish the following:

- A procedure for registering kratom products, including associated application fees;
- Civil penalties for violations of the requirements for kratom product registration and specified labeling;

⁵ R.C. 3715.026(B)(1) and 3717.34(B)(1).

⁶ R.C. 3715.99(F) and 3717.99.

⁷ R.C. 3715.026(B)(2) and 3717.34(B)(2).

⁸ R.C. 3715.026(C) and 3717.34(C).

⁹ R.C. 3715.026(D) and 3717.34(D).

¹⁰ R.C. 3715.99(F) and 3717.99.

- Standards and procedures for appealing a decision to impose civil penalties;
- Procedures for seizing and destroying kratom products that do not meet product standards established by the bill;
- Standards and procedures for testing kratom products;
- Standards for labeling kratom products;
- Any other standards or procedures considered necessary to implement the bill.¹¹

In adopting the rules, the Directors must comply with the Administrative Procedure Act (R.C. Chapter 119).

Regulatory restriction reduction requirement exemption

The bill exempts the rules adopted by the Directors from continuing law requirements concerning reductions in regulatory restrictions. Currently, the Directors must take actions to reduce regulatory restrictions, including, by June 30, 2025, reducing the amount of regulatory restrictions contained in an inventory created in 2019 in accordance with a statutory schedule. A “regulatory restriction” is any part of an administrative rule that requires or prohibits an action.

Without that exemption, the Directors must do all of the following with respect to any regulatory restrictions contained in rules adopted under the bill:

- Until June 30, 2025, and for so long as the Directors fail to reach the reductions required under the statutory schedule, remove two or more existing regulatory restrictions for each new restriction adopted (referred to as the “two-for-one rule”);
- Refrain from adopting a regulatory restriction when doing so would negate a previous reduction;
- Beginning July 1, 2025, refrain from adopting a regulatory restriction when doing so would cause the total number of regulatory restrictions in effect to exceed a statewide cap calculated by the Joint Committee on Agency Rule Review.¹²

Civil action

The bill establishes a private cause of action for individuals who suffer damages as a result of a violation of the requirements regarding kratom products. An individual may bring a civil action if a food processing establishment or retail food establishment license holder (1) fails to register a kratom product, (2) processes, manufactures, sells, or engages in other specified activities involving a kratom product that does not meet the product requirements described above, (3) sells a kratom product without disclosing on the product’s label the factual

¹¹ R.C. 3715.026(E) and 3717.34(E).

¹² R.C. 3717.34(F), by reference to R.C. 121.95 to 121.953, not in the bill.

basis on which the food is represented as a kratom product, or (4) sells or distributes a kratom product to an individual under 18.¹³

Bill name

The bill is named the “Kratom Consumer Protection Act.”¹⁴

HISTORY

Action	Date
Introduced	04-05-23

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¹³ R.C. 3715.026(G) and 3717.34(G).

¹⁴ Section 3.