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Bill Analysis

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Version: As Introduced

Primary Sponsors: Reps. Odioso and Lorenz

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SUMMARY

- Requires food processing establishments and retail food establishments to register kratom products with the Director of Agriculture (ODA Director).
- 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 ODA Director (and Director of Health with respect to retail food establishments) to adopt rules regarding kratom products.
- Creates a civil cause of action for someone adversely affected by a violation of the requirements concerning kratom products.

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 these establishments, the products must be registered with the Director of Agriculture (ODA Director). "Kratom product," for purposes of the bill, is a finished article that contains either (1) any part of a leaf of the plant *Mitragyna speciosa* (kratom) in fresh, dehydrated, or dried

form; or (2) a kratom extract that is manufactured using U.S. Food and Drug Administration-approved (U.S. FDA) food grade solvents.¹ A food processing establishment is all 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). It includes all or part of any premises where kratom is processed, packaged, manufactured, or otherwise held or handled for distribution to another location or for sale at wholesale.² A retail food establishment is all 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).³

Kratom 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.⁴

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.⁵ 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.⁶ Both types of establishments must apply to the ODA Director for registration in a manner prescribed by the Director.

Standards for kratom products

The bill places several requirements on kratom products and on food processing and retail food 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 contain a controlled substance or a residual solvent higher than is allowed in the U.S. Pharmacopeia General Chapter 467 (an independent standard recognized by the U.S. FDA);
- The product cannot contain:

¹ R.C. 3715.01(A)(22) and (23) and 3717.01(T).

² R.C. 3715.026(A)(1); also see R.C. 3715.021, not in the bill.

³ R.C. 3717.01(C).

⁴ U.S. Drug Enforcement Administration, *Drugs of Abuse: A DEA Resource Guide* (2024 edition), “Drugs of Concern: Kratom”, which may be accessed on the DEA’s website, www.dea.gov by searching “Drugs of Abuse 2024.”

⁵ R.C. 3715.026(B).

⁶ R.C. 3717.34(B).

- A level of naturally occurring 7-hydroxymitragynine in the alkaloid fraction that is greater than 2% of the alkaloid composition of the kratom product; and
- A level of 7-hydroxymitragynine that is greater than one milligram per serving in its final product form, as documented by a certificate of analysis on the finished product prior to distribution.
- The product cannot contain a synthetic kratom-like compound or semi-synthetic alkaloid (see below) where mitragynine is not the majority of the alkaloid in the product;
- The product must include a product label that states the amount of mitragynine and 7-hydroxymitragynine contained in the product.⁷

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.⁸ 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.⁹

The bill defines the following additional terms governing kratom products:¹⁰

Term	Definition
“Synthetic kratom-like compound”	A synthesized material that is not found naturally in the <i>Mitragyna speciosa</i> plant and is created entirely through laboratory synthesis to mimic the pharmacological effects of kratom alkaloids or constituent.
“Synthesized material”	An alkaloid, metabolite of an alkaloid, or alkaloid derivative that has been created by chemical synthesis or biosynthetic means, including fermentation, recombinant techniques, yeast derived, enzymatic techniques, and oxidation. “Synthesized material” does not include an alkaloid, metabolite of an alkaloid, or alkaloid derivative created by traditional food preparation techniques.

⁷ R.C. 3715.026(C)(1) and 3717.34(C)(1).

⁸ R.C. 3715.99(F) and 3717.99.

⁹ R.C. 3715.026(C)(2) and 3717.34(C)(2).

¹⁰ R.C. 3715.26(A) and 3717.34(A).

Term	Definition
“Semi-synthetic alkaloid”	A substance derived from an alkaloid naturally occurring in kratom that has been chemically altered through chemical reactions, including oxidation, reduction, acetylation, or other processes to change the structure or pharmacological activity of the naturally occurring kratom alkaloid. “Semi-synthetic alkaloid” includes the synthesis of 7-hydroxymitragynine when produced by chemical alteration of mitragynine.

Labeling requirements

The bill further provides that a food processing or retail food establishment may not distribute or sell a kratom product without disclosing to the ODA Director at the time the product is registered the factual basis on which the establishment represents the food as a kratom product.¹¹

Age restrictions

A food processing or retail food establishment may not sell or distribute a kratom product to an individual under 18.¹² 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.¹³

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 ODA Director. In the case of retail food establishments, the rules are to be adopted by the ODA Director and Director of Health.

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

- A procedure for registering kratom products, including associated registration fees. The registration fee must be based on the square footage of the food processing establishment or retail food establishment, as applicable. The fee cannot exceed the registration fee for a food processing establishment established in existing rules adopted by the ODA Director. That fee is between \$50 and \$300, depending on the establishment’s square footage.

¹¹ R.C. 3715.026(D) and 3717.34(D).

¹² R.C. 3715.026(E) and 3717.34(E).

¹³ R.C. 3715.99(F) and 3717.99.

- Civil penalties for violations of the requirements for kratom product registration and specified labeling;
- 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.¹⁴

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

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 basis on which the food is represented as a kratom product, or (4) sells or distributes a kratom product to an individual under 18.¹⁵

HISTORY

Action	Date
Introduced	11-12-25

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¹⁴ R.C. 3715.026(F) and 3717.34(F).

¹⁵ R.C. 3715.026(H) and 3717.34(H).