Wisconsin Legislative Council AMENDMENT MEMO



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2023 Assembly Bill 393

Assembly Substitute Amendment 2

2023 ASSEMBLY BILL 393

2023 Assembly Bill 393 legalizes the sale of kratom in Wisconsin, subject to certain regulations applicable to processors and retailers, and removes two substances from Schedule I of Wisconsin's Uniform Controlled Substances Act that are contained in kratom: mitragynine and 7-hydroxymitragynine.

Under the bill, a kratom product is defined as: (1) any part of the leaf of the Mitragyna speciosa plant; and (2) any product intended for human or animal consumption, including food, drink, chewing gum, and food supplements, made from any part of the leaf of that plant.

The Department of Agriculture, Trade and Consumer Protection (DATCP) must maintain a publicly accessible registry that includes the kratom products that may be sold in Wisconsin, and may seize and destroy any kratom products offered for sale that are not registered in the registry.

A processor may not prepare, process, sell, offer for sale, or distribute a kratom product if the product is not included in the DATCP registry or if the processor is not licensed as a food processing plant. A person may not sell, offer for sale, or distribute a kratom product unless, for in-person sales, the person keeps or displays the product in a manner in which only store employees can access the product before sale, and, for online sales, the person verifies the buyer's identity, age, and location.

Additionally, a processor may not sell, offer for sale, or distribute a kratom product if any of the following apply:

- The product is mixed or packed with a substance other than kratom product that affects the product's quality or strength to such a degree that the product may cause injury.
- The product contains a poisonous or otherwise deleterious ingredient other than kratom, including any controlled substance or controlled substance analog.
- The product contains a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than one percent of the alkaloid composition of the product.
- The product contains any synthetic alkaloid, including synthetic mitragynine, synthetic 7hydroxymitragynine, or any other synthetically derived compound of the Mitragyna speciosa plant.
- The kratom product does not include a label on its packaging that states the amount of mitragynine and 7-hydroxymitragynine contained in the packaged kratom product.

A processor that violates this provision is guilty of a Class C misdemeanor,¹ but has a good faith defense if the processor shows by a preponderance of the evidence that the processor relied in good faith on the

 $^{^{\}rm 1}$ A Class C misdemean or is punishable by a fine of up to \$500 or imprisonment of up to 30 days or both.

representation of a manufacturer, a packer, a distributor, or another processor relating to a product represented to be a kratom product.

The bill also prohibits the sale, offer for sale, or distribution of a kratom product to any person under the age of 21. Any person who violates this provision is guilty of a Class C misdemeanor.

ASSEMBLY SUBSTITUTE AMENDMENT 2

Assembly Substitute Amendment 2 provides that all provisions of the bill are rendered void if the Controlled Substances Board (CSB) timely takes a specified action, among several other changes.

The amendment requires the CSB, before September 1, 2024, to meet and determine if published and peer-reviewed research provides clear and convincing evidence that mitragynine and 7-hydroxymitragynine in their natural state in the leaf of the Mitragyna speciosa plant meet the criteria established in the statutes for scheduling.² If the CSB determines that the two substances do not meet the criteria, it must notify the Legislative Reference Bureau (LRB) of its determination. If the LRB receives the notice before that date, the provisions in the bill are void. The provisions in the amendment take effect on September 1, 2024, unless they are voided under this process.

Unless voided, the amendment narrows the second prong of the definition of a kratom product so that is covers only a botanical supplement intended for human consumption made from any part of the leaf of the Mitragyna speciosa plant (rather than a product intended for human or animal consumption, including food, drink, chewing gum, and food supplements, made from that plant).

The amendment requires DATCP to maintain a publicly accessible registry of kratom products for which it has received a certificate of analysis (rather than a registry of products that may be sold in Wisconsin). A certificate of analysis is a written confirmation from an independent laboratory certifying that the laboratory has analyzed and tested a kratom product and that the kratom product meets requirements specified in the bill.

Under the amendment, a processor may only prepare, process, sell, offer for sale, or distribute a kratom product if the processor submits to DATCP a certificate of analysis for the product for inclusion in DATCP's registry. The producer must also pay a fee that DATCP may charge for maintaining the registry, if applicable, and follow guidelines set forth in federal regulations with regard to a botanical supplement.³

The amendment also requires that for in-person sales, a person may not sell, offer for sale, or distribute a kratom product unless the person has on the premises a certificate of analysis from the product's processor and keeps or displays the product in a manner in which only the person and employees can access it before sale or distribution. For online sales, the person must verify the buyer's identity, age, and location, and must post a certificate of analysis from the product's processor at the online location.

² Those criteria are the following: (1) the actual or relative potential for abuse; (2) the scientific evidence of its pharmacological effect, if known; (3) the state of current scientific knowledge regarding the substance; (4) the history and current pattern of abuse; (5) the scope, duration, and significance of abuse; (6) the risk to public health; (7) the potential of the substance to produce psychological or physical dependence liability; and (8) whether the substance is an immediate precursor of a substance already controlled under Wisconsin's Uniform Controlled Substances Act.

³ The federal regulations are titled "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements." [21 C.F.R. part 111.]

Additionally, a processor may not sell, offer for sale, or distribute a kratom product if any of the following applies:

- The product is mixed or packed with a substance other than kratom product that affects the product's quality or strength to such a degree that the product may cause injury.
- The product contains a poisonous or otherwise deleterious ingredient other than kratom, including any controlled substance or controlled substance analog.
- The product contains a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than two percent of the alkaloid composition of the product (instead of one percent, as under the bill) in the recommended service size as shown on the product's registered product label.
- The product contains any synthetic alkaloid, including synthetic mitragynine, synthetic 7hydroxymitragynine, or any other synthetically derived compound of the Mitragyna speciosa plant.
- The kratom product does not include a product label on its packaging that states the amount of mitragynine and 7-hydroxymitragynine contained in product's recommended serving size (rather than in the packaged kratom product, under the bill).

The amendment retains a penalty of up to 30 days of imprisonment and a fine of up to \$500 for violating this provision. As under the bill, a person who sells, offers for sale, or distributes a kratom product to a person under the age of 21 is guilty of a Class C misdemeanor under the amendment.

BILL HISTORY

Representative Murphy offered Assembly Substitute Amendment 2 on January 19, 2024. On January 24, 2024, the Assembly Committee on State Affairs recommended adoption of Assembly Substitute Amendment 2 on a vote of Ayes, 11; Noes, 2. The committee then recommended passage of the bill, as amended, on a vote of Ayes, 9; Noes, 4.

For a full history of the bill, visit the Legislature's <u>bill history page</u>.

TK:EL:ksm