



# Kratom Regulation: Federal Status and State Approaches

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Kratom, or *Mitragyna speciosa*, is a tree related to the coffee plant and is native to parts of Southeast Asia. Peoples indigenous to the tree's range have traditionally consumed the leaves of the tree for medicinal and other purposes. Users report both stimulant and sedative effects, believed to be caused by two compounds in the leaves, mitragynine and 7-hydroxymitragynine. Some commentators have raised safety concerns over kratom use, while others have suggested various beneficial uses. Additionally, some kratom products intended for sale in the United States have been found to contain dangerous contaminants, such as salmonella and heavy metals.

Kratom use in the United States has reportedly become more widespread in the past decade, and its regulatory status has been a matter of recent debate. This Sidebar begins by reviewing federal administrative actions relating to kratom before summarizing kratom-focused bills introduced in the current Congress. The Sidebar then describes the various approaches taken by 22 states that have regulated or banned kratom, which may be instructive as Congress considers action on kratom.

## **Executive Branch Actions**

The Controlled Substances Act (CSA) creates the federal framework for regulating drugs and other substances deemed to pose a risk of abuse and dependence. The CSA divides controlled substances into five numbered lists, known as Schedules I-V, with Schedule I status imposing the most stringent restrictions. Congress may modify these schedules through legislation. Congress has also delegated authority to the Drug Enforcement Administration (DEA) to schedule, reschedule, or deschedule substances under the CSA through regulation.

In 2016, DEA published notice of its intent to place mitragynine and 7-hydroxymitragynine in Schedule I on an emergency basis, which would have criminalized possession of kratom and made distribution a felony. However, after receiving numerous comments from some Members of Congress, advocacy groups, and others, DEA withdrew that notice. DEA has listed kratom as a Drug and Chemical of Concern but to date has not exercised its authority to schedule kratom or its active compounds under the CSA.

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, the Food and Drug Administration (FDA) may regulate drugs and dietary supplements sold in the United States. FDA has

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https://crsreports.congress.gov LSB11082 approved no drug products containing kratom, mitragynine, or 7-hydroxymitragynine. FDA has also taken the position that kratom is an unapproved new dietary ingredient and therefore may not be marketed in the United States as either a nutritional supplement or a food additive. FDA has issued a series of import alerts, most recently in July 2023, authorizing FDA personnel to seize imported kratom products from specified firms without physical inspection. FDA has also seized kratom products manufactured in the United States, including an April 2023 seizure of kratom products worth approximately \$3 million from an Oklahoma company.

### **Congressional Proposals**

In October 2023, Members introduced essentially identical bills in both the House and the Senate to "protect access to kratom." Members introduced similar bills in the House and the Senate in the 117<sup>th</sup> Congress. These bills would neither ban kratom nor impose new regulations on kratom. Instead, the bills would direct the Secretary of Health and Human Services (the Secretary) to gather information about kratom and would limit the Secretary's authority to impose regulations on kratom.

The bills would require the Secretary to hold at least one public hearing to discuss the safety of kratom products. That hearing would have to cover several specified topics, including any potential benefits of kratom usage and any adverse health impacts of a kratom ban. The bills would also require the Secretary to establish a task force to coordinate and report on federally funded kratom-related research. Before promulgating any new rule regulating kratom, the Secretary would have to follow procedures for formal rulemaking and to have public, in-person hearings.

The bills would prohibit the Secretary from:

- imposing requirements on kratom that are more restrictive than those for foods, dietary supplements, or dietary ingredients under the FD&C Act;
- requiring kratom to follow the notification requirements for new dietary ingredients;
- using certain specified grounds to treat kratom as an adulterated dietary supplement; or
- enforcing any import alert for kratom products absent evidence that the particular product is adulterated.

Each bill contains a nonpreemption provision, which would leave existing state laws—whether banning kratom or regulating it—in place.

### State Regulation of Kratom

As Congress considers these bills or other action on kratom products, the experience of the states may be pertinent. States that have addressed the topic have taken two approaches: an outright ban on kratom or regulation of kratom sales or possession.

#### **Kratom Bans**

Alabama, Arkansas, Indiana, Rhode Island, Vermont, and Wisconsin currently ban mitragynine and hydroxymitragynine or 7-hydroxymitragynine (kratom's active alkaloids) under state-law analogues of the CSA. Legislators in Indiana, Rhode Island, Wisconsin, and Vermont have introduced bills to replace existing bans with regulations that would permit the sale of kratom products.

Tennessee enacted a ban on mitragynine and hydroxymitragynine in 2013. An opinion of the state's Office of the Attorney General, however, indicated that this ban extended only to synthetic versions of

those alkaloids, not to the kratom plant itself. Tennessee law, as amended, now regulates the sale of the kratom plant in its natural form but continues to ban synthetic kratom alkaloids.

Some local governments in other states have also adopted bans.

### **Kratom Regulations**

As of the date of this Sidebar, sixteen states regulate the sale of kratom products in some fashion. Some states have adopted versions of a model law proposed by kratom advocacy groups, but these state laws are not uniform. Their differences arise in their handling of particular issues relating to kratom products, as described below.

Age restriction: Arizona, Georgia, Illinois, Minnesota, Nevada, Oklahoma, Texas, and Utah ban sales to persons under 18 years of age. Colorado, Florida, Louisiana, Oregon, South Dakota, Tennessee, Virginia, and West Virginia ban sales to persons under 21. Georgia, Illinois, Minnesota, South Dakota, Tennessee, and West Virginia also ban possession by underage persons. West Virginia imposes a separate requirement that websites and remote sellers employ an age-verification mechanism.

**Marketing to children:** Utah prohibits flavoring or packaging that appeals to children and requires childsafe packaging. West Virginia's recently adopted law requires the commissioner of agriculture to develop similar standards.

Adulteration and contamination: Arizona prohibits sale of a kratom product adulterated with a "nonkratom substance" that affects the quality or strength of the product "to such a degree as to render the kratom product injurious to a consumer." Nevada, Oklahoma, Texas, and Utah have similar prohibitions. Effective July 1, 2024, Colorado will prohibit sale of kratom products "adulterated with fentanyl" or other substances controlled under state law. Arizona, Oklahoma, Texas, and Utah separately prohibit sale of kratom products contaminated with dangerous or deleterious non-kratom substances.

**Strength:** Arizona, Oklahoma, Texas, and Utah prohibit sale of products in which 7-hydroxymitragynine is greater than 2% of the total alkaloid content.

**Labeling:** Nine of the sixteen states with laws regulating kratom sales require labels on kratom products, but the content required varies by state:

- **Directions for safe use:** Texas, Nevada, Georgia, and Oklahoma require that kratom products include labels with directions for safe or suggested use. Texas also requires a recommended serving size.
- Warnings: Utah and Virginia require that labels bear a warning that the product may be harmful; has not been evaluated by the FDA; and is not intended to diagnose, treat, cure, or prevent any disease. West Virginia requires the commissioner of agriculture to develop labeling standards, which must include warnings to keep the product out of reach of children and to consult a physician before use if pregnant or taking medication. Georgia and Oklahoma require a statement that sale or transfer to a person under 18 is prohibited, along with "[a]ny precautionary statements as to the safety and effectiveness" of the kratom product.
- Manufacturer or distributor information: Colorado (effective July 1, 2024), Georgia, and Oklahoma require that labels state the identity and address of the product's manufacturer or distributor.
- Alkaloid content: Arizona, Georgia, Oklahoma, and Utah require that labels state the amount of mitragynine and 7- hydroxymitragynine in the product.

- **Ingredients:** Colorado (effective July 1, 2024), Nevada, and Virginia require labels listing all ingredients. Georgia and Oklahoma require a list of ingredients that includes common names.
- Factual basis: Arizona and Utah require that labels indicate the "factual basis" underlying any representation that the product is a "kratom product," defined as a food or dietary ingredient containing part of the leaf of *Mitragyna speciosa*.

**Testing and sampling:** Oklahoma law requires kratom vendors to provide, upon request of the State Department of Health, test results from a "United States-based testing facility" confirming the items on the label. Oregon requires third-party testing for microbiological contaminants, pesticides, solvents, heavy metals, and mycotoxins. Utah requires a certificate of analysis from a certified third-party laboratory indicating the results of testing for alkaloid content and levels of pathogens and specified heavy metals. The state periodically tests kratom products to confirm those certificates of analysis and may test for pesticides, fentanyl derivatives, cannabinoids, cocaine, and benzodiazepines. West Virginia requires sampling and testing of kratom "to determine purity levels."

**Registration and permitting:** Oregon and Utah require kratom sellers to register with state agencies. West Virginia requires kratom sellers to obtain state permits.

**Synthetic alkaloids:** Colorado, Florida, Illinois, Louisiana, Minnesota, Nevada, and South Dakota apply their laws regulating kratom sales to both natural and synthetic products. Arizona, Texas, Oklahoma, and Utah use definitions of "*kratom*" that do not include synthetic kratom alkaloids, but each state prohibits the sale of any kratom product adulterated with synthetic compounds. Tennessee prohibits the sale of kratom except "in its natural form." Virginia's kratom law applies to "extracts" of *Mitragyna speciosa*.

**Local authority:** Colorado and Louisiana explicitly allow localities to adopt stricter controls on kratom or to ban kratom completely but do not allow localities to permit sales to persons under 21 years of age. Florida's kratom law does not address localities, but at least one county bans the sale of kratom as a "designer drug."

**Private right of action:** Oklahoma and Utah permit individuals harmed by violations of their kratom laws to bring private civil actions for damages.

**Tax:** West Virginia law provides for a tax on kratom, the proceeds of which are split among an agricultural fees fund, an alcohol beverage control enforcement fund, and a substance abuse fund.

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