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Kratom Compliance in an Evolving Regulatory Landscape

Kratom is an herbal substance derived from the leaves of the *Mitragyna speciosa* tree, a tropical evergreen tree in the Rubiaceae (coffee) family. The tree is indigenous to many countries throughout Southeast Asia, including Cambodia, Thailand, Indonesia, and Malaysia, and has been used in traditional medicine there for hundreds of years.

Kratom is typically ingested orally by either chewing fresh leaves or grounding dried leaves into a fine powder, which is then swallowed dry or mixed with liquids. Kratom is also processed into concentrates, extracts, beverages, edible products, and even vape products. While kratom contains numerous alkaloids, the primary active alkaloids are mitragynine and 7-hydroxymitragynine. These alkaloids act as partial agonists at certain opioid receptors, and at appropriate therapeutic doses may provide positive effects including pain relief, alertness, and improved mood. At higher doses, there is increased risk of negative side effects.

Worldwide, kratom is treated as a controlled substance in several countries. In the United States, kratom is legal and largely unregulated at the federal level, but several states and localities have banned kratom or regulate it as a controlled substance. While legal in most states, approximately half and the District of Columbia have implemented regulations such as minimum age requirements and manufacturing and testing standards.

As kratom continues to gain popularity across the United States for its potential benefits in pain management, anxiety relief, and opioid withdrawal support, manufacturers and retailers face mounting regulatory challenges. With a patchwork of state laws and the looming possibility of federal oversight, staying compliant is no longer optional, it is essential for survival in the kratom industry.

Inconsistent and Complicated Kratom Regulatory Environment

While kratom remains largely uncontrolled at the federal level, federal agencies continue to police it through import actions and misbranding and advertising enforcement. Kratom is unregulated in many states, but approximately half, and the District of Columbia, have regulatory requirements. Six states and several cities, counties, and localities ban it outright. That means your compliance program must harmonize federal risk with state-by-state requirements and local ordinances—an ever-moving target.

In 2016, the U.S. Drug Enforcement Agency attempted to designate mitragynine and 7-hydroxymitragynine (commonly referred to as “7-OH”) as Schedule I controlled substances but dropped those efforts after overwhelming public comments in opposition. More recently, in February of this year, the U.S. Food & Drug Administration published Import Alert 5415, which authorizes detention without physical examination (DWPE) of dietary supplements and bulk ingredients that are or contain kratom.

This DWPE alert reflects FDA’s position that kratom is a new dietary ingredient lacking adequate evidence of safety, meaning that under FDA rules, such products are considered adulterated if marketed as dietary supplements. Taking things even further, in July of this year, FDA began pushing for 7-OH to be scheduled as a Schedule I controlled substance. 7-OH is found in small quantities in raw kratom leaf, but some processors have begun manufacturing concentrates and synthetics of 7-OH. If the DEA follows through, products containing synthetic or concentrated 7-OH could be banned nationwide, even as natural kratom leaf products remain legal. This shift would dramatically impact manufacturers producing enhanced kratom extracts, gummies, and vape products.

Navigating the patchwork of differing state and local rules

Six states—Alabama, Arkansas, Indiana, Rhode Island, Vermont, and Wisconsin—have banned kratom entirely. In some of those states, even simple possession of kratom carries the risk of significant criminal penalties, including jail time. Approximately half the states and the District of Columbia have enacted consumer protection laws that regulate labeling, age restrictions, and product testing,

with severe penalties for noncompliance. In yet others, like California and Mississippi, kratom is legal at the state level, with varying degrees of regulatory oversight, while it is banned in certain counties, cities, and localities within those states. Within the states that regulate kratom, you should expect variation in fundamental requirements, including age limits, labeling content, testing standards, retail display, product registration, and alkaloid concentration limits. Some examples of state-level regulatory requirements include:

- Age restrictions are universal among regulated states, although some states set that at 18 and others at 21.
- Colorado, through the Daniel Bregger Act, added modern controls that became effective in 2024, including minimum labeling elements, minimum age limit of 21, and authority to require third-party testing and to review certificates of analysis (COAs).
- Florida enacted a statewide 21+ restriction in 2023 through passage of the Florida Kratom Consumer Protection Act.
- Georgia updated its Kratom Consumer Protection Act earlier this year by raising the age restriction to 21+, adding restrictions on vaporized products, requiring retail displays to be secured, and establishing alkaloid content limitations for kratom products.
- Mississippi illustrates local divergence. While at the state level, kratom is legal under a recent regulatory scheme that prohibits sales to individuals under 21 and sets limitations on alkaloid concentrations, amongst other regulatory requirements, Mississippi allowed pre-existing municipal and county bans to remain in place.
- Tennessee prohibits sales to consumers under 21, requires kratom to be in “natural form” (i.e., leaf and powdered leaf), and requires that product labels contain specific warnings and manufacturer information.
- Utah, which was one of the first states to regulate kratom through a consumer protection act, requires facility and product registration with the Department of Agriculture &

Food. Manufacturers must register as manufactured food establishments and each kratom formulation must be registered with the state Kratom Program.

Create a jurisdictional matrix

This inconsistent patchwork of state regulatory schemes makes compliance extremely challenging for kratom manufacturers and retailers. We recommend working with counsel experienced with kratom regulation to create a jurisdictional matrix for all states where you currently manufacture or sell or intend to manufacture or sell kratom products. The matrix should reflect specific requirements like age limitations, labeling and testing, COA submission, registration, retailer display, potency limits, and any local bans in effect within each state. That matrix should be updated regularly and no less frequently than monthly because the regulatory landscape is changing constantly.

Creating an Efficient and Reliable Compliance Program

While at the federal level, kratom cannot be marketed as a dietary supplement under FDA's current position, aligning your quality control system and compliance program to follow recognized FDA Current Good Manufacturing Practices (CGMPs) will materially lower risk and make broad state compliance more efficient. Two specific CGMPs, those related to dietary supplements (Part 111) and human foods (Part 117), should be followed to the fullest extent possible.

The dietary supplement CGMPs provide for things like maintaining master manufacturing records, batch production records, quality control release, investigations, lab controls, and compliant handling. Even if a product is not being marketed as a dietary supplement, these controls are industry standard for botanicals. The human food CGMPs, which are tied to the Food Safety Modernization Act, cover things like hazard analysis, preventive controls, recall plans, foreign supplier verification, sanitary transport, and traceability.

By mapping your manufacturing to Parts 111 and 117, you reduce risk by ensuring your compliance program contemplates supplier qualification and audits, botanical identity verification, sanitation and environmental monitoring; allergen control in co-processing arrangements, sampling plans, lab testing protocols for alkaloid concentrations, heavy metals, and adulterants, and adequate recall procedures.

Accredited lab testing

Every lot or batch should be tested using ISO/IEC accredited labs. Your compliance program should include a specific and finished-product release testing panel aligned to state requirements and known risks, including the following:

- Identity and assay of mitragynine and 7-hydroxymitragynine with acceptance criteria consistent with the jurisdiction.
- Microbiological pathogens, at minimum *Salmonella* and *coli*, given prior outbreaks.
- Heavy metals like lead, arsenic, cadmium, mercury due to FDA findings of heavy metals in kratom samples.
- Residual solvents (for extracts) and pesticides (as appropriate for agricultural inputs).
- Adulterants screens for controlled substances like fentanyl.

Labeling and advertising discipline

In addition to complying with various state labeling and advertising requirements, it is important that all labeling and advertising is compliant with Federal Trade Commission laws regarding false and misleading statements.

- Know what the states where you do business require. Some examples of requirements in many states include manufacturer identity and address, ingredient lists, alkaloid disclosures and concentrations, and required warnings statements.

- Avoid claims that kratom products treat any disease or medical condition or assist with addiction and withdrawal from opioid medications or opiate-derived drugs. FDA and FTC have jointly warned kratom manufacturers and retailers that such claims render products unapproved drugs and violate advertising laws. You should train your marketing and sales teams accordingly and carefully review websites, social media posts, and packaging.
- Maintain COAs and lot traceability at the retail level. Several states can request COAs or require registration of products and facilities.

Monitor and Prepare for Potential Future Federal Regulation

Even without federal scheduling, two federal pathways can materially impact your compliance burden: FDA FSMA requirements and the potential for renewed or additional action by DEA, FDA, or Congress. Business disruptions can be minimized by planning for both.

- Operate like the FSMA will be enforced against kratom.
 - Register facilities as required; maintain a written safety plan, conduct hazard analysis, implement preventive controls, and monitor, verify, and maintain records.
 - Develop a comprehensive recall plan.
 - Create an adverse event log and escalation protocol. Even where not required by federal law, some states require processors to notify authorities when FDA receives an adverse event report for their products.
- Expect import scrutiny to intensify.
 - If you import raw kratom leaf or extracts, build a foreign supplier verification program including on-site audits, validated testing steps (if any), method harmonization, contaminant controls, and pre-shipment COAs that anticipate FDA sampling. The DWPE framework under

Import Alert 5415 means shipments can be stopped purely based on the product category.

- Plan for possible content limits and definitions that could subject kratom imports to greater risk of seizure.
- Monitor the developing debate over “7-OH” and “synthetic” alkaloids. Some states are setting limits on 7OH and defining “synthetic” vs. “natural” alkaloids, and future federal rulemaking could normalize such limits. You should ensure formulation flexibility to adjust to developing limitations.
- Monitor scheduling risk signals, including reviewing World Health Organization Expert Committee on Drug Dependence updates, DEA petitions, and FDA rulemaking proposals.

Staying Compliant and Reducing Risk

The most defensible kratom operations behave like highly compliant food and supplement manufacturing facilities, meet or exceed the strictest state framework in their operational footprints, and document everything, from supplier controls to retail age gating. That approach minimizes risk today and positions your business to pivot quickly if federal oversight or even greater state scrutiny arrives tomorrow. Develop your jurisdictional matrix and update it regularly.

Operating a compliant and ethical kratom business also helps support the entire industry by minimizing risk and reputational harm. Some kratom advocacy groups, including the American Kratom Association and the Kratom Consumer Advisory Council, have published their own recommended GMPs that track with FDA’s CGMPs for foods and supplements. While these may provide a good starting point, you should have experienced regulatory counsel conduct an audit of your compliance program and manufacturing processes to ensure that best practices are being followed.

In an industry facing increasing scrutiny, compliance is more than a legal obligation, it is a strategic asset. Manufacturers and retailers who invest in GMP certification, third-party testing, and jurisdiction-specific operations will not only avoid regulatory pitfalls but also build consumer trust and brand loyalty. As federal

oversight looms and state laws evolve, proactive compliance will separate responsible businesses from those at risk of enforcement. By embracing transparency, safety, and adaptability, kratom vendors can thrive in a complex and changing regulatory landscape.

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