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OHIO LEGISLATIVE SERVICE COMMISSION

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Office

H.B. 236*
134th General Assembly

Occupational Regulation Report

[Click here for H.B. 236's Bill Analysis/Fiscal Note](#)

Primary Sponsors: Reps. Frazier and Lipps

Impacted Profession: Kratom processors

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LSC is required by law to issue a report for each introduced bill that substantially changes or enacts an occupational regulation. The report must: (1) explain the bill's regulatory framework in the context of Ohio's statutory policy of using the least restrictive regulation necessary to protect consumers, (2) compare the regulatory schemes governing the same occupation in other states, and (3) examine the bill's potential impact on employment, consumer choice, market competition, and cost to government.¹

LEAST RESTRICTIVE REGULATION COMPARISON

Ohio's general regulatory policy

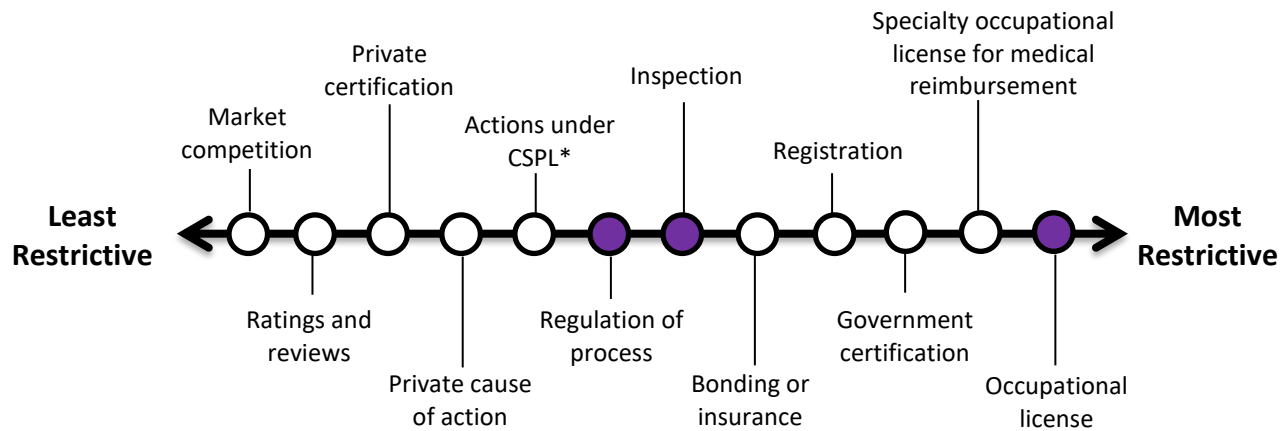
The general policy of the state is reliance on market competition and private remedies to protect the interests of consumers in commercial transactions involving the sale of goods or services. For circumstances in which the General Assembly determines that additional safeguards are necessary to protect consumers from "present, significant, and substantiated harms that threaten health, safety, or welfare," the state's expressed intent is to enact the "least restrictive regulation that will adequately protect consumers from such harms."²

The degree of "restrictiveness" of an occupational regulation is prescribed by statute. The following graphic identifies each type of occupational regulation expressly mentioned in the state's policy by least to most restrictive:

* This report addresses the "As Introduced" version of H.B. 236. It does not account for changes that may have been adopted after the bill's introduction.

¹ R.C. 103.26, not in the bill.

² R.C. 4798.01 and 4798.02, neither in the bill.



*CSPL – The Consumer Sales Practices Law

The bill requires licensure of kratom processors and authorizes the Department of Agriculture to inspect kratom processing and sales facilities. The bill also limits the level of 7-hydroxymitragynine contained in kratom products and prohibits the adulteration of such products with dangerous, nonkratom substances. Finally, it requires the Director of Agriculture to adopt rules pertaining to labeling, transportation, and disposal of kratom products.

Necessity of regulations

Representatives Scott Lipps and Mark Frazier, the sponsors of H.B. 236, testified that the legislation is necessary to protect the freedom of Ohioans to use kratom. The sponsors contend that, for some users, kratom is more effective or more acceptable than medicines approved by the United States Food and Drug Administration to manage pain or opioid withdrawal symptoms. The testimony asserts that, despite including ingredients that bind the brain's opioid receptors, kratom is not an opioid. The sponsors state that nearly all deaths reported in connection to kratom can be attributed to poly-drug use or adulterated kratom products.

In 2018, the Ohio Board of Pharmacy proposed a rule that would have banned kratom due to public safety concerns. The sponsors suggest that the bill's licensure requirement for kratom processors adequately addresses these concerns in a less restrictive manner. The bill is purportedly intended to curtail harmful adulteration of kratom products as opposed to prohibiting the substance, altogether.³

Restrictiveness of regulations

Licensing

Licensure is the most restrictive of all regulatory options identified within the state's general policy on occupational regulations. Accordingly, the policy prescribes a narrow range of situations in which it is appropriate. Specifically, when all of the following circumstances are

³ Representative Scott Lipps and Representative Mark Frazier, *H.B. 236 Sponsor Testimony*, House Health Committee, April 20, 2021.

present: (1) the occupation involves providing a service regulated by both state and federal law, (2) the licensing framework allows individuals licensed in other states and territories to practice in Ohio, and (3) the licensing requirement is based on uniform national laws, practices, and examinations that have been adopted by at least 50 U.S. states and territories.⁴

Kratom processing, sale, and use is neither regulated at the federal level nor subject to uniform national laws. In 2016, the United States Drug Enforcement Administration (DEA) announced a plan to ban kratom as a Schedule I substance but reversed course before finalizing the plan. Ohio is currently among the majority of states that do not have kratom-specific laws or regulations. Generally, the lack of kratom-related enactments means that the product remains legal and is unregulated.

According to the Legislative Analysis and Public Policy Association, only Arizona, Georgia, Nevada, and Utah have passed legislation that expressly deems kratom a legal product and regulates processing and sales. An additional three states, Illinois, Minnesota, and Tennessee, have adopted age restrictions for using kratom products but are silent on processing and sales. Six states, including Indiana, have banned kratom altogether.⁵ None of the four states that regulate kratom processing and sales require licensure of kratom processors. However, Utah does require processors to register as food establishments.⁶ The bill contains no reciprocity provision and thus does not allow persons authorized to process kratom in another state to do so in Ohio without a license.

Inspection

The state's policy provides that an inspection requirement is appropriate when the intention of the regulation is to "protect consumers against unsanitary facilities and general health, safety, or welfare concerns."⁷ The sponsors did not raise alarm over the cleanliness of kratom production and sales facilities, but the bill's inspection and testing provisions do appear to address general health, safety, and welfare concerns. The provisions provide a means for the Department to identify bad actors and prevent the proliferation of adulterated kratom products and kratom products with excessive levels of 7-hydroxymitragynine. The prospect of a government inspection might also serve as a deterrent to persons in the kratom industry who might otherwise violate the bill's rules and prohibitions.

Process regulations

The state's policy does not provide specific guidance as to when a regulation of process is the best means of protecting the health, safety, and welfare of consumers. However, the policy as a whole suggests that regulations of process are the most preferred method of regulation when market competition, ratings and reviews, private certifications, private causes of action, and actions under the state's Consumer Sales Practices Law do not provide sufficient protection.

⁴ R.C. 4798.02, not in the bill.

⁵ Legislative Analysis and Public Policy Association, [Regulation of Kratom in America](#).

⁶ Utah Code Ann. 4-45-104.

⁷ R.C. 4798.02(B)(2), not in the bill.

The restrictiveness of the bill's process regulations will largely depend on the rules adopted by the Director of Agriculture. As with the bill's licensing and inspection provisions, the sponsors' expressed intent for the process regulations is to mitigate the health risks associated with the proliferation of adulterated and unnaturally potent kratom products.

Overall

As a whole, the regulations proposed by the bill are less restrictive than an outright ban on kratom products, as previously contemplated by the DEA and the Ohio Board of Pharmacy. However, the regulations are more restrictive than current law and, arguably, would make Ohio among the most restrictive of the 44 states that allow processing and sale of kratom products. Despite the increase in restrictiveness, industry professionals would seemingly benefit from the security and stability afforded by the bill's express validation of kratom as a legal product. Furthermore, by prohibiting the Ohio Board of Pharmacy from regulating kratom as a controlled substance, the bill ensures that kratom cannot be banned by state administrative rule. Whether the need to protect Ohioans from adulterated and excessively potent kratom products outweighs the state's general preference for market competition and private remedies is a policy decision.

IMPACT STATEMENT

Opportunities for employment

By imposing state regulation on kratom processing, H.B. 236 could restrict opportunities for employment in this industry, by limiting employment with firms processing kratom to those firms at which a person is licensed by the Department of Agriculture. The degree of restrictiveness depends on implementation by the Department, including the setting of licensing fee amounts,⁸ and might not be onerous, however. Potentially in the longer term, the bill might enhance employment opportunities by increasing assurance among members of the public, the target market for these products, that kratom products offered for sale in Ohio are not mixed with harmful substances. No license is required to sell kratom products.

Consumer choice and cost

As noted above, the bill would provide greater assurance regarding the safety and quality of kratom products sold in this state. This would enhance consumer choice. Kratom processors would be required to pay fees to cover costs of regulation and could be expected to seek to recover the cost of those fees, thus tending to raise prices in the industry.

Market competition

The bill would tend to weed out industry participants that might otherwise produce substandard product. As noted above, the bill might tend to enhance demand for the product, perhaps thereby attracting additional companies to process kratom in the longer term, by providing greater assurance to consumers of the product regarding its quality and safety.

⁸ Such fees, including (1) an initial application fee to accompany license applications and (2) an annual licensing fee, are limited by the bill to the costs of administering and enforcing the provisions of law that the bill would enact and must be uniform for all applicants.

Cost to government

The costs to government are outlined in the [LBO fiscal note](#).

SUMMARY OF PROPOSED REGULATIONS

The bill requires the Director of Agriculture to adopt rules, standards, and processes to regulate kratom processing and sale of kratom products.⁹ At the same time, it prohibits the Ohio Board of Pharmacy from regulating kratom as a controlled substance and specifies that kratom and kratom products are not drugs for the purposes of the pharmaceuticals law and criminal drug offenses.¹⁰

Licensing

The bill requires a person who intends to process kratom into a kratom product to obtain a processing license from the Director of Agriculture. No license is required to possess, buy, or sell kratom or kratom products. Once issued, a kratom processing license is valid for three years, unless the Director suspends or revokes it. Other license procedures and requirements are to be established by rule of the Director – including forms, fees, reporting requirements, and grounds for denial, suspension, and revocation of licensure. The bill specifies that application and licensing fees must be uniform for all applicants and must not exceed the amount needed to cover the costs incurred by the Department of Agriculture in administering and enforcing kratom regulations.¹¹

Inspection

The bill authorizes the Director, at reasonable times, to enter into any public or private property where kratom is processed, distributed, or sold to determine compliance with kratom regulations. The Director must also adopt a procedure testing kratom products and for conducting annual inspections of, at minimum, a random sample of kratom processing license holders to verify that kratom plants are processed in compliance with kratom regulations. The Director may apply for, and any appropriate judge may issue, a search warrant if needed.

The Director may issue an emergency order requiring specific actions be taken to mitigate an emergency condition requiring immediate action to protect public health, safety, or the environment. The emergency order may be issued without prior notice or a hearing. Any person to whom the order is issued must immediately comply, but the person may apply to the Director for an adjudication hearing. The Director, the Attorney General, and a county prosecutor may apply to the court of common pleas in the county where a violation (including a violation of an emergency order) is happening for an injunction to restrain the person from continuing that violation.¹²

⁹ R.C. 930.02(A).

¹⁰ R.C. 4729.01(E) and 3719.41(D). See also, R.C. 2925.01, not in the bill.

¹¹ R.C. 930.02 and 930.03.

¹² R.C. 930.07.

Process regulations

The bill prohibits distributing, selling, or exposing for sale any of the following:

- A kratom product that is adulterated with a dangerous nonkratom substance. A kratom product is adulterated if it is mixed or packed with a nonkratom substance and that substance makes the kratom product injurious to a consumer;
- A kratom product that is contaminated with a dangerous nonkratom substance. A kratom product is contaminated with a dangerous nonkratom substance if it contains a poisonous or otherwise deleterious nonkratom ingredient, like a drug or a controlled substance (this could include an illegal drug, such as cocaine, or a prescription or over-the-counter drug);
- A kratom product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 2% of the overall alkaloid composition of the kratom product;
- A kratom product containing any synthetic alkaloids including synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compounds of the kratom plant;
- A kratom product that is not labeled in accordance with rules adopted by the Director; and
- A kratom product with a label containing claims that the kratom product is intended to diagnose, treat, cure, or prevent any medical condition or disease.¹³

In addition, the bill empowers the Director to adopt rules concerning labeling, transportation, and disposal of kratom products. A person who negligently violates any of these rules or prohibitions must abide by a corrective action plan issued by the Director. A person who recklessly, knowingly, or purposefully violates rules or prohibitions is subject to criminal penalties.¹⁴

¹³ R.C. 930.04(F).

¹⁴ R.C. 930.03 and 930.05.

COMPARISON TO OTHER STATES

Indiana classifies the active ingredient in kratom, 7-hydroxymitragynine, as a synthetic drug, the use, possession, or distribution of which is prohibited by law.¹⁵ Kratom remains legal in the other surrounding states and none of those states have enacted regulations concerning processing or sale of kratom products. The table below summarizes kratom regulations in Arizona, Georgia, Nevada, and Utah, the four states identified by the Legislative Analysis and Public Policy Association as those that have passed laws affirming the legality of kratom and regulating processing and sale of kratom products.

Kratom Regulations			
State	License/Registration Requirement	Sale, Use, and Processing Regulations	Label Requirements
Arizona ¹⁶	No kratom processing license required.	<p>Sale or transfer of kratom to persons aged below 18 years is prohibited.</p> <p>Adulteration of kratom with a nonkratom substance that affects its strength and makes the product injurious is prohibited.</p> <p>The level of 7-hydroxymitragynine must be 2% or less.</p> <p>Private cause of action available for persons injured by a kratom product.</p>	Product label must state the amount of mitragynine and 7-hydroxymitragynine contained in the product.
Georgia ¹⁷	No kratom processing license required.	<p>Sale or transfer of kratom to persons aged below 18 years is prohibited.</p> <p>Possession of kratom by persons aged below 18 years is also prohibited.</p>	<p>Product label must include the following:</p> <ul style="list-style-type: none"> ▪ The common or usual name of each ingredient used in the manufacture of the product;

¹⁵ Ind. Code Ann. 35-31.5-2-321(1)(LL).

¹⁶ Ariz. Rev. Stat. Ann. 36-795.02 and 36-795.03.

¹⁷ Ga. Code Ann. 16-13-121 and 16-13-122.

Kratom Regulations			
State	License/Registration Requirement	Sale, Use, and Processing Regulations	Label Requirements
			<ul style="list-style-type: none"> ▪ The amount of mitragynine and 7-hydroxymitragynine contained in the product; and ▪ Clear and adequate directions for the consumption and safe and effective use of the product.
Nevada ¹⁸	No kratom processing license required.	<p>Sale or transfer of kratom to persons aged below 18 years is prohibited.</p> <p>Adulteration of kratom with a nonkratom substance that affects its strength and makes the product injurious is prohibited.</p>	Product label must state ingredients and directions for safe and effective use of the product.
Utah ¹⁹	No kratom processing license but kratom product manufacturers must register as food establishments.	<p>Sale or transfer of kratom to persons aged below 18 years is prohibited.</p> <p>Alteration of kratom with a nonkratom substance that affects its strength and makes the product injurious is prohibited.</p> <p>The level of 7-hydroxymitragynine must be 2% or less.</p> <p>Private cause of action available for persons injured by a kratom product.</p>	Product label must state the amount of mitragynine and 7-hydroxymitragynine contained in the product.

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¹⁸ Nev. Rev. Stat. Ann. 597.998.

¹⁹ Utah Code Ann. 4-45-103 to 4-45-108.